Periodic Safety Statement of SUSARs

Drug Substance	Durvalumab (MEDI4736)
Date	04 December 2025

Periodic Safety Statement of Suspected Unexpected Serious Adverse Reactions (SUSARs) of IMFINZI™ (durvalumab/MEDI4736)

Period covered: 01 May 2025 to 31 October 2025

IMFINZI™ is a trademark of AstraZeneca group of companies

This document contains trade secrets and confidential commercial information, disclosure of which is prohibited without providing advance notice to AstraZeneca and opportunity to object.

LIST OF APPENDICES

Appendix A Periodic SUSAR Line Listings

This safety statement includes all new reports of Suspected Unexpected Serious Adverse Reactions (SUSARs) as well as previously reported SUSARs with significant new or changed information received and processed from 01 May 2025 to 31 October 2025 for AstraZeneca Investigational Medicinal Product (IMP) IMFINZI™ (durvalumab/MEDI4736). The Line Listing attached to this safety statement includes SUSAR reports from all treatment arms of AstraZeneca sponsored clinical studies of IMFINZI, including SUSAR reports related to placebo, non-drug comparators (eg, surgery), study procedures, and other AstraZeneca sponsored studies involving the IMP (as a comparator, combination product or additional investigational product).

A review of the SUSAR line listings does not change the overall benefit-risk profile for IMFINZI. During the reporting period, no new safety concerns were identified for IMFINZI. The safety profile is consistent with that in the Investigator's Brochure and prescribing information. The benefit-risk for IMFINZI remains unchanged.

Periodic Safety Statement of SUSARs Appendix A

Drug Substance	Durvalumab (MEDI4736)
Date	04 December 2025

Appendix A

Periodic SUSAR Line Listings

Period covered: 01 May 2025 to 31 October 2025

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID:

Study ID: 20240178

EudraCT No:

Study Design: Not Blinded

Study Description: #A Phase 3, Open Label, Multicenter, Randomized Study of First Line Tarlatamab in combination with D

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Infections and infestations									
202510GLO012086TR	TURKEY 67 Years Male	**Infection (Infection)***	Not Recovered	10-Oct-2025 nk	DURVALUMAB	Infusion	1500 milligram IV bolus	15-SEP-2025 to	

Concomitant Medication(s): Tarlatamab (S) | | Etoposide (S) | Carboplatin (S) | Xgeva (C) | Neulastim (C) | Exforge (C) | NaCl (C) | Decort (C) | Avil (C) | Granexa (C) | Panocer (C) | Dexamethasone (C) | Kytril (C) | Parol (C) | Fraven (C) | Primsel (C) | Tazilix (C) | Tramosel (C) | Progas (C) | Ebafit (C) | Duphalac (C) | Potassium chloride (C) | Kalinor (C) | Todavit (C) | Lamelat (C) | Neoset (C) | Sodium chloride (C) | Belogent (C) | Gadexon (C)

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D4191

Study ID: D4191C00137

EudraCT No: 2021-003031-29

Study Design: Not Blinded

Study Description: D4191C00137 ROSY-D (Roll-over study for Durvalumab) - ROSY-D: Roll Over StudY for Patients Who Have Completed a Previous Oncology Study with Durvalumab and Are Judged by the Investigator to Clinically Benefit From Continued Treatment

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Infections and infestations									
202507GLO021236KR	KOREA, REPUBLIC OF 65 Years Male	**Parapharyngeal space infection (Parapharyngeal abscess)***	Recovered	21-Jul-2025 1 year 11 months	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	22-AUG-2023 to 15-JUL-2025 1 year 10 months 24 days	

Concomitant Medication(s):

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933A

Study ID: D4191C00140

EudraCT No: 2022-002527-35

Study Design: Not Blinded

Study Description: D4191C00140 TOURMALINE (Topaz Phase 3b) - A Phase IIIb, Single Arm, Open-label, Multicentre Study of Durvalumab in Combination with Chemotherapy for the First Line Treatment for Patients with Advanced Biliary Tract Cancers (TOURMALINE)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
202410GLO009015JP	JAPAN 81 Years Female	**Thrombocytopenia (Thrombocytopenia)***	Recovered	07-Oct-2024 6 months 19 days	DURVALUMAB	Infusion	1500 milligram Intravenous use	27-AUG-2024 to 14-FEB-2025 5 months 19 days	
						Infusion	1500 milligram qd Intravenous use	19-MAR-2024 to 19-JUL-2024 4 months 1 day	
					GIMERACIL, OTERACIL POTASSIUM, TEGAFUR	Capsule	50 milligram Intravenous use	26-APR-2024 to 12-JUL-2024 2 months 17 days	
						Capsule	60 milligram Intravenous use	19-MAR-2024 to 11-APR-2024 24 days	

Concomitant Medication(s): | GEMCITABINE (S) | CISPLATIN (S) | GIMERACIL, OTERACIL POTASSIUM, TEGAFUR (S) | Ursodeoxycholic acid (C) | Vonoprazan fumarate (C) | Acofide (C) | Tulobuterol (C) | Tramadol hydrochloride (C) | Magnesium oxide (C) | Hyalein (C) | Lac b (C) | Irbesartan (C) | Amlodipine besilate (C) | Rosuvastatin (C)

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933A

Study ID: D4191C00140

EudraCT No: 2022-002527-35

Study Design: Not Blinded

Study Description: D4191C00140 TOURMALINE (Topaz Phase 3b) - A Phase IIIb, Single Arm, Open-label, Multicentre Study of Durvalumab in Combination with Chemotherapy for the First Line Treatment for Patients with Advanced Biliary Tract Cancers (TOURMALINE)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Cardiac disorders									
2024A012059	JAPAN 82 Years Male	**Myocarditis (Myocarditis)***	Not Recovered	10-Jan-2024 1 month 25 days 11 hrs 53 min	DURVALUMAB	Infusion	1500 milligram Intravenous use	15-NOV-2023 12:07 to 15-NOV-2023 13:08 1 hr 1 min	Periodic Report Comment. Investigator: myocarditis related to Durvalumab, enterocolitis unrelated to Durvalumab. Company: myocarditis and enterocolitis unrelated to Durvalumab.
						Infusion	1500 milligram single Intravenous use	06-DEC-2023 13:28 to 06-DEC-2023 14:03 35 min	
						Infusion	1500 milligram single Intravenous use	27-DEC-2023 13:24 to 27-DEC-2023 13:57 33 min	
Concomitant Medication(s): | Gemcitabine (S) | Carvedilol (C) | Rivaroxaban (C) | Azilsartan (C) | Nifedipine (C) | Vonoprazan fumarate (C) | Ketoprofen (C) | Chlorpromazine hydrochloride (C) | Acetaminophen (C) | Bilastine (C)									
SOC:Endocrine disorders									
2024A212246	JAPAN 65 Years Female	**Secondary adrenocortical insufficiency (Secondary adrenal insufficiency)***	Recovering	25-Sep-2024 5 months 12 days 13 hrs 46 min	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	12-APR-2024 10:14 to 09-AUG-2024 11:18 17 weeks 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933A

Study ID: D4191C00140

EudraCT No: 2022-002527-35

Study Design: Not Blinded

Study Description: D4191C00140 TOURMALINE (Topaz Phase 3b) - A Phase IIIb, Single Arm, Open-label, Multicentre Study of Durvalumab in Combination with Chemotherapy for the First Line Treatment for Patients with Advanced Biliary Tract Cancers (TOURMALINE)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | Tegafur (C) | Cisplatin (C) | Gemcitabine (C) | Acelio (C) | Albumin (C) | Cortef (C) | Sennoside (C) | LInzess (C) | Ensure h (C) | Heparinoid (C) | Vonoprazan fumarate (C) | Cortril (C)									
SOC:Gastrointestinal disorders									
2023A268887	JAPAN 47 Years Male	**Enteritis (Enteritis)***	Recovered	16-Nov-2023 2 weeks 1 day	GIMERACIL , OTERACIL POTASSIUM , TEGAFUR	Capsule	40 milligram bid Oral use	12-DEC-2023 to 17-DEC-2023 6 days	Periodic Report Comments. The investigator did not consider that there was a reasonable possibility of a causal relationship between the study therapy Durvalumab, Gemcitabine and the following event(s): enteritis. The investigator considered that there was a reasonable possibility of a causal relationship between the study therapy Gimeracil, Oteracil Potassium, Tegafur and the following event(s): enteritis. The company physician did not consider that there was a reasonable possibility of a causal relationship between the study therapy and the event (s).
						Capsule	40 milligram bid Oral use	26-DEC-2023 to 31-DEC-2023 6 days	
						Capsule	40 milligram qd Oral use	01-JAN-2024 to 01-JAN-2024 1 day	
						Capsule	40 milligram qd Oral use	11-DEC-2023 to 11-DEC-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933A

Study ID: D4191C00140

EudraCT No: 2022-002527-35

Study Design: Not Blinded

Study Description: D4191C00140 TOURMALINE (Topaz Phase 3b) - A Phase IIIb, Single Arm, Open-label, Multicentre Study of Durvalumab in Combination with Chemotherapy for the First Line Treatment for Patients with Advanced Biliary Tract Cancers (TOURMALINE)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Capsule	40 milligram qd Oral use	18-DEC-2023 to 18-DEC-2023 1 day	
						Capsule	40 milligram qd Oral use	25-DEC-2023 to 25-DEC-2023 1 day	
						Capsule	50 milligram bid Oral use	02-NOV-2023 to 03-NOV-2023 2 days	
						Capsule	50 milligram bid Oral use	08-NOV-2023 to 14-NOV-2023 1 week	
						Capsule	50 milligram qd Oral use	01-NOV-2023 to 01-NOV-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933A

Study ID: D4191C00140

EudraCT No: 2022-002527-35

Study Design: Not Blinded

Study Description: D4191C00140 TOURMALINE (Topaz Phase 3b) - A Phase IIIb, Single Arm, Open-label, Multicentre Study of Durvalumab in Combination with Chemotherapy for the First Line Treatment for Patients with Advanced Biliary Tract Cancers (TOURMALINE)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Capsule	50 milligram qd Oral use	04-NOV-2023 to 04-NOV-2023 1 day	
						Capsule	50 milligram qd Oral use	07-NOV-2023 to 07-NOV-2023 1 day	
						Capsule	50 milligram qd Oral use	15-NOV-2023 to 15-NOV-2023 1 day	

Concomitant Medication(s): DURVALUMAB (S) | | GEMCITABINE (S) | Gemcitabine (C) | Nanoparticle albumin-bound paclitaxel (C) | Tegafur (C) | Nifedipine (C) | Olmesartan medoxomil (C) | Arotinolol hydrochloride (C) | Ursodeoxycholic acid (C) | Loxoprofen sodium hydrate (C) | Rebamipide (C) | Toaraset (C) | Vonoprazan fumarate (C) | Ferrous sulfate (C) | Hydromorphone hydrochloride (C) | Naldemedine tosilate (C) | Antibiotics-resistant lactic acid bacteriae (C) | Sennoside a+b calcium (C) | Sodium picosulfate monohydrate (C) | Sodium bicarbonate (C) | Posterisan forte (C) | Sulbactam sodium (C) | Ulinastatin (C) | Diphenhydramine (C) | Fexofenadine hydrochloride (C) | Betamethasone butyrate propionate (C) | Cefmetazole sodium (C) | Carbazochrome sodium sulfonate (C) | Menatetrenone (C) | Tranexamic acid (C) | Dexamethasone sodium phosphate (C) | Butylscopolamine bromide (C) | Pentazocine (C) | Midazolam (C) | Glucagon (C)

SOC:Hepatobiliary disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933A

Study ID: D4191C00140

EudraCT No: 2022-002527-35

Study Design: Not Blinded

Study Description: D4191C00140 TOURMALINE (Topaz Phase 3b) - A Phase IIIb, Single Arm, Open-label, Multicentre Study of Durvalumab in Combination with Chemotherapy for the First Line Treatment for Patients with Advanced Biliary Tract Cancers (TOURMALINE)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202412GLO010801JP	JAPAN 81 Years Female	**Hepatic function abnormal (Hepatic function disorder)***	Recovered	12-Sep-2024 5 months 25 days	CISPLATIN	Infusion	27 milligram Intravenous use	05-APR-2024 to 05-JUL-2024 3 months 1 day	
						Infusion	31 milligram Intravenous use	19-MAR-2024 to 19-MAR-2024 1 day	
					DURVALUMAB	Infusion	1500 milligram Intravenous use	15-JAN-2025 to 14-FEB-2025 1 month	
						Infusion	1500 milligram Intravenous use	19-JUL-2024 to 19-JUL-2024 1 day	
						Infusion	1500 milligram Intravenous use	19-MAR-2024 to 19-MAR-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933A

Study ID: D4191C00140

EudraCT No: 2022-002527-35

Study Design: Not Blinded

Study Description: D4191C00140 TOURMALINE (Topaz Phase 3b) - A Phase IIIb, Single Arm, Open-label, Multicentre Study of Durvalumab in Combination with Chemotherapy for the First Line Treatment for Patients with Advanced Biliary Tract Cancers (TOURMALINE)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram Intravenous use	21-JUN-2024 to 21-JUN-2024 1 day	
						Infusion	1500 milligram Intravenous use	22-OCT-2024 to 22-OCT-2024 1 day	
						Infusion	1500 milligram Intravenous use	26-APR-2024 to 26-APR-2024 1 day	
						Infusion	1500 milligram Intravenous use	26-MAY-2024 to 26-MAY-2024 1 day	
						Infusion	1500 milligram Intravenous use	26-NOV-2024 to 26-NOV-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933A

Study ID: D4191C00140

EudraCT No: 2022-002527-35

Study Design: Not Blinded

Study Description: D4191C00140 TOURMALINE (Topaz Phase 3b) - A Phase IIIb, Single Arm, Open-label, Multicentre Study of Durvalumab in Combination with Chemotherapy for the First Line Treatment for Patients with Advanced Biliary Tract Cancers (TOURMALINE)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
					GEMCITABINE	Infusion	1400 milligram Intravenous use	26-APR-2024 to 05-JUL-2024 2 months 10 days	
						Infusion	1560 milligram Intravenous use	19-MAR-2024 to 05-APR-2024 18 days	
					TEGAFUR, GIMERACIL, OTERACIL	Capsule	50 milligram Intravenous use	26-APR-2024 to 12-JUL-2024 2 months 17 days	
						Capsule	60 milligram Intravenous use	19-MAR-2024 to 11-APR-2024 24 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933A

Study ID: D4191C00140

EudraCT No: 2022-002527-35

Study Design: Not Blinded

Study Description: D4191C00140 TOURMALINE (Topaz Phase 3b) - A Phase IIIb, Single Arm, Open-label, Multicentre Study of Durvalumab in Combination with Chemotherapy for the First Line Treatment for Patients with Advanced Biliary Tract Cancers (TOURMALINE)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): DURVALUMAB (S) | GEMCITABINE (S) | | TEGAFUR, GIMERACIL, OTERACIL (S) | Ursodeoxycholic acid (C) | Vonoprazan fumarate (C) | Acofide (C) | Tulobuterol (C) | Tramadol hydrochloride (C) | Magnesium oxide (C) | Sennoside (C) | Palonosetron hydrochloride (C) | Fosnetupitant (C) | Dexamethasone sodium phosphate (C) | Hyalin (C) | Red blood cells (C) | Irbesartan (C) | Amlodipine besilate (C) | Rosuvastatin (C) | Juvela (C) | Ethyl icosapentate (C) | Loxoprofen (C) | Pydoxal (C) | Dexamethasone (C) | Metoclopramide (C) | Napageln (C) | Artificial tear (C) | Sodium gualenate hydrate (C) | Etizolam (C) | Belsomra (C) | Levofloxacin (C) | Celecoxib (C) | Filgrastim (C) | Cefepime dihydrochloride (C) | Neutrogin (C) | Lidocaine (C)									
SOC:Metabolism and nutrition disorders									
202505GLO025256FR	FRANCE 73 Years Female	**Hyponatraemia (Hyponatremia)***	Fatal	20-May-2025 2 months 8 days 20 hrs 40 min	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	01-APR-2025 15:10 to 01-APR-2025 15:40 30 min	The patient experienced HYPONATREMIA. Investigator: Related. Company: Not related to Durvalumab, not applicable for Oxaliplatin.
						Infusion	1500 milligram q3w Intravenous use	11-MAR-2025 13:20 to 11-MAR-2025 14:20 1 hr	
						Infusion	1500 milligram q3w Intravenous use	22-APR-2025 to 22-APR-2025 1 day	
Concomitant Medication(s): | Oxaliplatin (S) | Gemcitabine (S) | Carboplatin (S) | Cisplatin (S) | Paclitaxel (S) | Gimeracil (S)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933A

Study ID: D4191C00140

EudraCT No: 2022-002527-35

Study Design: Not Blinded

Study Description: D4191C00140 TOURMALINE (Topaz Phase 3b) - A Phase IIIb, Single Arm, Open-label, Multicentre Study of Durvalumab in Combination with Chemotherapy for the First Line Treatment for Patients with Advanced Biliary Tract Cancers (TOURMALINE)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO012730JP	JAPAN 69 Years Male	**Decreased appetite (Decreased appetite)***	Recovered	07-Jul-2025 1 year 3 months 19 days	GIMERACIL, OTERACIL POTASSIUM, TEGAFUR	Capsule	60 milligram Intravenous use	19-MAR-2024 to 05-JUL-2024 3 months 17 days	

Concomitant Medication(s): DURVALUMAB (S) | GEMCITABINE (S) | CISPLATIN (S) | | Silodosin (C) | Dutasteride (C) | Heparinoid (C) | Amlodipine besilate (C) | Palonosetron hydrochloride (C) | Fexofenadine hydrochloride (C) | Apixaban (C) | Suvorexant (C) | Fluorometholone (C)

SOC:Renal and urinary disorders

202505GLO019796US	UNITED STATES 58 Years Female	**Acute kidney injury (Acute kidney injury)***	Not Recovered	19-May-2025 4 months 20 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	30-DEC-2024 to 26-MAR-2025 2 months 25 days	Periodic Report Comments. The patient experienced Acute kidney injury. Investigator: related to durvalumab. Company: not related;Periodic Report Comments. Patient experienced event Acute kidney injury. Action taken with Durvalumab, Gemcitabine, Oxaliplatin, Cisplatin, Carboplatin and Paclitaxel was Not applicable. Investigator Causality: Related, CC: Related for Durvalumab

Concomitant Medication(s): | Gemcitabine (S) | Oxaliplatin (S) | Cisplatin (S) | Carboplatin (S) | Paclitaxel (S) | Tylenol (C) | Ondansetron (C) | Pegfilgrastim (C) | Amlodipine (C) | Vitamin d3 (C) | Pantoprazole (C) | Carvedilol (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419A

Study ID: D419AC00003

EudraCT No: 2015-002197-21

Study Design: Not Blinded

Study Description: D419AC00003 (NEPTUNE) Ph3 PDL1 + Treme v Soc N=800 OS Study - A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 in Combination with Tremelimumab Therapy Versus Standard of Care Platinum-Based Chemotherapy in First-Line Treatment of Patients with Advanced or Metastatic Non-Small-Cell Lung Cancer (NSCLC) (NEPTUNE).

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Hepatobiliary disorders									
202507GLO024354PT	PORTUGAL 58 Years Female	**Drug-induced liver injury (Hy's law case)***	Not Recovered	29-Dec-2016 1 month 26 days	DURVALUMAB	Infusion	20 milligram/kilogram q4w Intravenous use	04-NOV-2016 to 04-NOV-2016 1 day	
						Infusion	20 milligram/kilogram q4w Intravenous use	30-NOV-2016 to 30-NOV-2016 1 day	
					TREMELIMUMAB	Infusion	Intravenous use	04-NOV-2016 to 04-NOV-2016 1 day	
						Infusion	Intravenous use	30-NOV-2016 to 30-NOV-2016 1 day	

Concomitant Medication(s): | TREMELIMUMAB (S) | Venlafaxine (S) | Methylprednisolone (C) | Fentanyl (C) | Morphine sulfate (C) | Bisacodyl (C) | Amitriptilin (C) | Clobazam (C) | Pantoprazole (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419C

Study ID: D419CL00025

EudraCT No:

Study Design: Not Blinded

Study Description: An Open-label, Multi-center Phase II Study of Durvalumab and Tremelimumab with Lenvatinib as First-line Treatment in Patients with Unresectable Hepatocellular Carcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
202509GLO027205CN	CHINA Unknown	**Thrombocytopenia (Thrombocytopenia)***	Unknown	25-Sep-2025 nk	DURVALUMAB	Infusion	1500 milligram q4w Unknown	to	
					TREMELIMUMAB	Infusion	300 milligram Unknown	to	
Concomitant Medication(s): | TREMELIMUMAB (S)									
SOC:Gastrointestinal disorders									
202510GLO009339CN	CHINA Male	**Abdominal distension (Abdominal distension)***	Not Recovered	03-Oct-2025 nk	DURVALUMAB	Infusion	1500 microgram Intravenous use	to	
					TREMELIMUMAB	Infusion	300 microgram Intravenous use	to	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419C

Study ID: D419CL00025

EudraCT No:

Study Design: Not Blinded

Study Description: An Open-label, Multi-center Phase II Study of Durvalumab and Tremelimumab with Lenvatinib as First-line Treatment in Patients with Unresectable Hepatocellular Carcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | TREMELIMUMAB (S)									
SOC:Hepatobiliary disorders									
202510GLO005562CN	CHINA 60 Years Male	**Suspected drug-induced liver injury (Suspected drug-induced liver injury)***	Not Recovered	06-Oct-2025 1 month 16 days	DURVALUMAB	Infusion	Unknown	21-AUG-2025 to 18-SEP-2025 29 days	
					TREMELIMUMAB	Infusion	Unknown	21-AUG-2025 to 21-AUG-2025 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S)									
202510GLO009371CN	CHINA 46 Years Male	**Suspected drug-induced liver injury (Suspected drug-induced liver injury)***	Not Recovered	10-Oct-2025 nk	LENVATINIB	Capsule	Oral use	to	
					DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	19-SEP-2025 to 19-SEP-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419C

Study ID: D419CL00025

EudraCT No:

Study Design: Not Blinded

Study Description: An Open-label, Multi-center Phase II Study of Durvalumab and Tremelimumab with Lenvatinib as First-line Treatment in Patients with Unresectable Hepatocellular Carcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					TREMELIMUMAB	Infusion	300 milligram single Intravenous use	19-SEP-2025 to 19-SEP-2025 1 day	

Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | | Methylprednisolone sodium succinate (S)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419C

EudraCT No:

Study Design: Not Blinded

Study ID: D419CR00026

Study Description: An Single Arm, Open-label, Multi-center Phase IIIb Study of Durvalumab and Tremelimumab as First-line Treatment in Patients with Unresectable Hepatocellular Carcinoma. - An Single Arm, Open-label, Multi-center Phase IIIb Study of Durvalumab and Tremelimumab as First-line Treatment in Patients with Unresectable Hepatocellular Carcinoma.

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Gastrointestinal disorders									
2024A008986	CHINA 66 Years Female	**Upper gastrointestinal haemorrhage (Upper gastrointestinal hemorrhage)***	Not Recovered	30-Dec-2023 14 weeks 1 day	TREMELIMUMAB	Infusion	300 milligram single Intravenous use	22-SEP-2023 to 22-SEP-2023 1 day	Periodic Report Comment. the patient experienced grade three upper gastrointestinal hemorrhage, related to Durvalumab, Tremelimumab (Durvalumab/tremelimumab combo therapy) and Durvalumab (Durvalumab/tremelimumab combo therapy). Company causality not related.
					DURVALUMAB	Infusion	1500 milligram single Intravenous use	21-DEC-2023 to 21-DEC-2023 1 day	
						Infusion	1500 milligram single Intravenous use	23-NOV-2023 12:27 to 23-NOV-2023 13:28 1 hr 1 min	
						Infusion	1500 milligram single Intravenous use	24-OCT-2023 11:05 to 24-OCT-2023 12:05 1 hr	

Concomitant Medication(s): DURVALUMAB (S) | | Gansulin r (C) | Chang xiu lin (C) | Diformin (C) | Loratadine (C) | Rifaximin (C) | Ursodeoxycholic acid (C) | Oxycodone (C) | Potassium chloride (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419C

Study ID: D419CR00026

EudraCT No:

Study Design: Not Blinded

Study Description: An Single Arm, Open-label, Multi-center Phase IIIb Study of Durvalumab and Tremelimumab as First-line Treatment in Patients with Unresectable Hepatocellular Carcinoma. - An Single Arm, Open-label, Multi-center Phase IIIb Study of Durvalumab and Tremelimumab as First-line Treatment in Patients with Unresectable Hepatocellular Carcinoma.

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:General disorders and administration site conditions									
202509GLO001394CN	CHINA 50 Years Male	**Death (Unknown cause of death)***	Fatal	29-Aug-2025 1 month 20 days	DURVALUMAB	Infusion	1500 milligram Intravenous use	10-JUL-2025 to 07-AUG-2025 29 days	
					TREMELIMUMAB	Infusion	Intravenous use	10-JUL-2025 to 10-JUL-2025 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S)									
SOC:Hepatobiliary disorders									
2023A205662	CHINA 64 Years Male	**Drug-induced liver injury (Drug-induced liver injury)***	Recovered	06-Sep-2023 2 months 23 days	DURVALUMAB	Infusion	1500 milligram Intravenous use	10-AUG-2023 to 10-AUG-2023 1 day	Periodic Report Comment. Patient experienced: Drug-induced liver injury, Serious, Related.
						Infusion	1500 milligram Intravenous use	13-JUL-2023 to 13-JUL-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419C

Study ID: D419CR00026

EudraCT No:

Study Design: Not Blinded

Study Description: An Single Arm, Open-label, Multi-center Phase IIIb Study of Durvalumab and Tremelimumab as First-line Treatment in Patients with Unresectable Hepatocellular Carcinoma. - An Single Arm, Open-label, Multi-center Phase IIIb Study of Durvalumab and Tremelimumab as First-line Treatment in Patients with Unresectable Hepatocellular Carcinoma.

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram Intravenous use	15-JUN-2023 to 15-JUN-2023 1 day	
					TREMELIMUMAB	Infusion	300 milligram Intravenous use	15-JUN-2023 to 15-JUN-2023 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S) | ENTECAVIR (C)									
2024A121525	CHINA 61 Years Male	**Hepatic function abnormal (Hypohepatia)***	Fatal	22-May-2024 48 weeks 6 days	DURVALUMAB	Infusion	1500 milligram Intravenous use	15-JUN-2023 to 25-APR-2024 45 weeks 1 day	Patient experienced HYPOHEPATIA Inv causality: RELATED with Durvalumab NOT RELATED with Tremelimumab CCC: NOT RELATED
Concomitant Medication(s): | TREMELIMUMAB (S) | ENTECAVIR (C) | Polyene phosphatidylcholine (C) | URSOFALK (C) | Cetirizine hydrochloride (C) | Compound Mentholatum (C) | Halometasone (C) | EUTHYROX (C)									
202505GLO024977CN	CHINA 57 Years Male	**Hepatic function abnormal (Hepatic function abnormal)***	Recovering	27-May-2025 1 year 6 months 6 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	22-AUG-2023 to 14-MAR-2025 1 year 6 months 21 days	PRC. Patient experienced CTC 3 liver function impairment. Investigator: related with Durvalumab and not related with Tremelimumab. company physician: Not related
Concomitant Medication(s): | TREMELIMUMAB (S) | Entecavir (C) | Tenofovir alafenamide fumarate (C) | Polyene phosphatidylcholine (C) | Bicyclol (C) | Esomeprazole magnesium (C) | Omeprazole magnesium (C)									

SOC:Infections and infestations

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419C

Study ID: D419CR00026

EudraCT No:

Study Design: Not Blinded

Study Description: An Single Arm, Open-label, Multi-center Phase IIIb Study of Durvalumab and Tremelimumab as First-line Treatment in Patients with Unresectable Hepatocellular Carcinoma. - An Single Arm, Open-label, Multi-center Phase IIIb Study of Durvalumab and Tremelimumab as First-line Treatment in Patients with Unresectable Hepatocellular Carcinoma.

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202510GLO014476CN	CHINA 67 Years Male	**Pneumonia fungal (Pulmonary mycosis)***	Recovering	06-Oct-2025 2 months 29 days	DURVALUMAB	Infusion	1500 milligram Intravenous use	08-JUL-2025 to 17-SEP-2025 2 months 10 days	Periodic Report Comments. Patient experience serious event pulmonary fungal infection, Inv causality - related, CCA - not related
					TREMELIMUMAB	Infusion	300 milligram Intravenous use	08-JUL-2025 to 08-JUL-2025 1 day	

Concomitant Medication(s): | TREMELIMUMAB (S)

SOC:Investigations

202504GLO016004CN	CHINA 67 Years Male	**Aspartate aminotransferase increased (AST increased)***	Recovered	09-Apr-2025 15 days	TREMELIMUMAB	Infusion	300 milligram q3w Intravenous use	26-MAR-2025 to 26-MAR-2025 1 day	

Concomitant Medication(s): DURVALUMAB (S) | | Nitrendipine (C) | Silibinin (C) | Insulin aspart (C) | Caffeic acid (C)

SOC:Respiratory, thoracic and mediastinal disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419C

Study ID: D419CR00026

EudraCT No:

Study Design: Not Blinded

Study Description: An Single Arm, Open-label, Multi-center Phase IIIb Study of Durvalumab and Tremelimumab as First-line Treatment in Patients with Unresectable Hepatocellular Carcinoma. - An Single Arm, Open-label, Multi-center Phase IIIb Study of Durvalumab and Tremelimumab as First-line Treatment in Patients with Unresectable Hepatocellular Carcinoma.

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A195014	CHINA 55 Years Female	**Acute respiratory failure (Acute respiratory failure)*** Pneumonia (Lung infection)*	Fatal	25-Aug-2023 1 week	DURVALUMAB	Infusion	1500 milligram Intravenous use	18-AUG-2023 to 18-AUG-2023 1 day	Periodic Report Comment. PT had ACUTE RESPIRATORY FAILURE and LUNG INFECTION, related to study therapy.
					TREMELIMUMAB	Infusion	Intravenous use	18-AUG-2023 to 18-AUG-2023 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S) | ENTECAVIR (C)									
202411GLO025858CN	CHINA 57 Years Male	**Immune-mediated lung disease (Immune-mediated pneumonitis)***	Recovered	15-Nov-2024 1 year 2 months 25 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	22-AUG-2023 to 14-MAR-2025 1 year 6 months 21 days	
Concomitant Medication(s): | TREMELIMUMAB (S) | Entecavir (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419C

Study ID: D419CR00030

EudraCT No: 2022-502012-37-00

Study Design: Not Blinded

Study Description: D419CR00030 SIERRA HIMALAYA Ph3b (Child Pugh-B) - A Phase IIIb Single Arm, Open-label, Multicentre Study of Durvalumab and Tremelimumab as First Line Treatment in Participants with Advanced Hepatocellular Carcinoma (SIERRA)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Hepatobiliary disorders									
2024A086227	ITALY 73 Years Male	**Drug-induced liver injury (Drug-induced liver injury)***	Recovered	04-Apr-2024 3 weeks 6 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	08-MAR-2024 12:30 to 08-MAR-2024 13:30 1 hr	Periodic Report Comment. Patient experienced Hy's law, investigator: event related to study therapy. comp: related.;PRC. The patient experienced drug induced liver injury. Investigator: related to durvalumab and tremelimumab company physician: related to study therapy.;Periodic Report Comment. The patient experienced drug induced liver injury. Investigator: related to durvalumab and tremelimumab company physician: not related to study therapy.
						Infusion	1500 milligram q4w Intravenous use	17-JUN-2024 09:30 to 09-OCT-2025 15:00 1 year 3 months 22 days 5 hrs 30 min	
					TREMELIMUMAB	Infusion	Intravenous use	08-MAR-2024 10:00 to 08-MAR-2024 11:00 1 hr	

Concomitant Medication(s): | TREMELIMUMAB (S) | Deltacortene (C) | Clexane (C) | Lamivudina (C) | Adefor (C) | Pioglitazone (C) | Propafenone (C) | Sitagliptin (C) | Clobetasolo isdin (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419J

Study ID: D419JC00001

EudraCT No: 2023-505341-23-00

Study Design: Not Blinded

Study Description: D419JC00001 (POTOMAC) Durvalumab and BCG in Non-Muscle Invasive Bladder Cancer - A Phase III Randomized, Open-Label, Multi-Center, Global Study of Durvalumab and Bacillus Calmette-Guerin (BCG) Administered as Combination Therapy Versus BCG Alone in High-Risk, BCG Naïve Non Muscle Invasive Bladder Cancer Patients (POTOMAC)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Injury, poisoning and procedural complications									
2021A691025	FRANCE 59 Years Male	**Immunisation reaction (Immunisation reaction)***	Recovered	18-Aug-2021 49 weeks 1 day	BCG	Powder for intravesical suspension	Intravesical use	01-DEC-2020 14:00 to 01-DEC-2020 14:45 45 min	Periodic Report Comment. patient experienced fever related to bcg. Inv. not related to study therapy.
						Powder for intravesical suspension	Intravesical use	02-MAR-2021 14:00 to 02-MAR-2021 14:45 45 min	
						Powder for intravesical suspension	Intravesical use	06-OCT-2020 14:00 to 06-OCT-2020 14:45 45 min	
						Powder for intravesical suspension	Intravesical use	08-DEC-2020 14:00 to 08-DEC-2020 14:45 45 min	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419J

Study ID: D419JC00001

EudraCT No: 2023-505341-23-00

Study Design: Not Blinded

Study Description: D419JC00001 (POTOMAC) Durvalumab and BCG in Non-Muscle Invasive Bladder Cancer - A Phase III Randomized, Open-Label, Multi-Center, Global Study of Durvalumab and Bacillus Calmette-Guerin (BCG) Administered as Combination Therapy Versus BCG Alone in High-Risk, BCG Naïve Non Muscle Invasive Bladder Cancer Patients (POTOMAC)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for intravesical suspension	Intravesical use	08-SEP-2020 15:00 to 08-SEP-2020 15:45 45 min	
						Powder for intravesical suspension	Intravesical use	11-AUG-2021 15:15 to 11-AUG-2021 16:00 45 min	
						Powder for intravesical suspension	Intravesical use	13-OCT-2020 14:30 to 13-OCT-2020 15:12 42 min	
						Powder for intravesical suspension	Intravesical use	15-DEC-2020 14:00 to 15-DEC-2020 14:45 45 min	
						Powder for intravesical suspension	Intravesical use	15-SEP-2020 11:30 to 15-SEP-2020 12:15 45 min	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419J

Study ID: D419JC00001

EudraCT No: 2023-505341-23-00

Study Design: Not Blinded

Study Description: D419JC00001 (POTOMAC) Durvalumab and BCG in Non-Muscle Invasive Bladder Cancer - A Phase III Randomized, Open-Label, Multi-Center, Global Study of Durvalumab and Bacillus Calmette-Guerin (BCG) Administered as Combination Therapy Versus BCG Alone in High-Risk, BCG Naïve Non Muscle Invasive Bladder Cancer Patients (POTOMAC)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for intravesical suspension	Intravesical use	17-MAR-2021 14:00 to 17-MAR-2021 14:45 45 min	
						Powder for intravesical suspension	Intravesical use	18-AUG-2021 15:30 to 18-AUG-2021 16:15 45 min	
						Powder for intravesical suspension	Intravesical use	21-OCT-2020 11:00 to 21-OCT-2020 11:45 45 min	
						Powder for intravesical suspension	Intravesical use	23-FEB-2021 14:45 to 23-FEB-2021 15:30 45 min	
						Powder for intravesical suspension	Intravesical use	25-AUG-2021 14:30 to 25-AUG-2021 15:15 45 min	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419J

Study ID: D419JC00001

EudraCT No: 2023-505341-23-00

Study Design: Not Blinded

Study Description: D419JC00001 (POTOMAC) Durvalumab and BCG in Non-Muscle Invasive Bladder Cancer - A Phase III Randomized, Open-Label, Multi-Center, Global Study of Durvalumab and Bacillus Calmette-Guerin (BCG) Administered as Combination Therapy Versus BCG Alone in High-Risk, BCG Naïve Non Muscle Invasive Bladder Cancer Patients (POTOMAC)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for intravesical suspension	Intravesical use	29-SEP-2020 14:45 to 29-SEP-2020 15:30 45 min	

Concomitant Medication(s): | SECTRAL (C) | ASPIRINE (C) | AMLOR (C) | CRESTOR (C) | EFFEXOR (C) | TRANXENE (C) | XATRAL (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419J

Study ID: D419JC00002

EudraCT No:

Study Design: Not Blinded

Study Description: D419JC00002 PATAPSCO - A Phase IIIb Open-Label, Single-Arm, Multi-Center, US Study of Bacillus Calmette-Guerin (BCG) Administered in Combination with Durvalumab in Adult BCG-naïve, High-risk Non−Muscle Invasive Bladder Cancer Participants (PATAPSCO)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Gastrointestinal disorders									
202507GLO009234US	UNITED STATES 53 Years Male	**Pancreatitis acute (Acute pancreatitis)***	Not Recovered	08-Jul-2025 1 year 2 months 27 days 9 hrs 36 min	DURVALUMAB	Infusion	1500 milligram Intravenous use	10-APR-2024 14:24 to 15-APR-2024 16:04 5 days 1 hr 40 min	
						Infusion	1500 milligram q4w Intravenous use	06-NOV-2024 to 23-APR-2025 5 months 18 days	
Concomitant Medication(s): | BACILLUS CALMETTE-GUERIN (S) | Silodosin (C) | Amlodipine besylate (C) | Ibuprofen (C) | Phenazopyridine (C) | Acetaminophen (C) | Diphenhydramine (C) | Levothyroxine (C) | Famotidine (C) | Magnesium glycinate (C) | Oxybutynin chloride er (C)									
SOC:Metabolism and nutrition disorders									
2024A089259	UNITED STATES 70 Years Male	**Diabetic ketoacidosis (Diabetic ketoacidosis)*** Hyperkalaemia (Hyperkalemia)*	Recovered	11-Apr-2024 4 weeks 3 days	DURVALUMAB	Infusion	1500 milligram Intravenous use	11-MAR-2024 14:42 to 09-APR-2024 15:40 4 weeks	Periodic Report Comment. Male patient experienced Diabetic ketoacidosis and Hyperkalemia, Inv: Related to DURVALUMAB, CCA: Not related
Concomitant Medication(s): | BCG (S) | Allopurinol (C) | Atorvastatin (C) | Carvedilol (C) | Gabapentin (C) | Lisinopril (C) | Tadalafil (C) | Metformin (C) | Vitamin D2 (C) | Insulin (C) | Levothyroxine (C) | Trazodone (C) | Ceftriaxone (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419J

Study ID: D419JC00002

EudraCT No:

Study Design: Not Blinded

Study Description: D419JC00002 PATAPSCO - A Phase IIIb Open-Label, Single-Arm, Multi-Center, US Study of Bacillus Calmette-Guerin (BCG) Administered in Combination with Durvalumab in Adult BCG-naïve, High-risk Non−Muscle Invasive Bladder Cancer Participants (PATAPSCO)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO021222US	UNITED STATES 74 Years Male	**Hyponatraemia (Hyponatremia)*** Adrenal insufficiency (Adrenal insufficiency)	Not Recovered	01-Jul-2025 6 months 15 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	10-FEB-2025 to 06-MAY-2025 2 months 27 days	
						Infusion	1500 milligram q4w Intravenous use	13-JAN-2025 to 13-JAN-2025 1 day	
						Infusion	1500 milligram q4w Intravenous use	17-DEC-2024 to 17-DEC-2024 1 day	

Concomitant Medication(s): | BACILLUS CALMETTE-GUERIN (S) | Hydroxyzine (C) | Omeprazole (C) | Claritin (C) | Fluticasone propionate (C) | Rivaroxaban (C) | Losartan (C) | Metoprolol succinate (C)

SOC:Renal and urinary disorders

2024A074304	UNITED STATES 55 Years Male	**Autoimmune nephritis (Autoimmune nephritis)***	Recovered	13-Mar-2024 5 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	08-MAR-2024 to 08-MAR-2024 1 day	Periodic Report Comment. patient exp grade three autoimmune nephritis. inv causality yes with durvalumab.

Concomitant Medication(s): | BCG (S) | AMLODIPINE (C) | DULOXETINE (C) | FINASTERIDE (C) | HYDROXYZINE (C) | MELOXICAM (C) | OMEPRAZOLE (C) | SIMVASTATIN (C) | TADALAFIL (C) | Ciprofloxacin (C) | Ampicillin (C) | Aspirin (C) | Atorvastatin (C) | Insuline glargine (C) | Insulin lispro (C) | Lidocaine (C) | Amlodipine/benazepril (C) | Prednisone (C) | Saxagliptin (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419J

Study ID: D419JC00002

EudraCT No:

Study Design: Not Blinded

Study Description: D419JC00002 PATAPSCO - A Phase IIIb Open-Label, Single-Arm, Multi-Center, US Study of Bacillus Calmette-Guerin (BCG) Administered in Combination with Durvalumab in Adult BCG-naïve, High-risk Non−Muscle Invasive Bladder Cancer Participants (PATAPSCO)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Respiratory, thoracic and mediastinal disorders									
2024A087146	UNITED STATES 75 Years Male	**Acute respiratory failure (Acute hypoxic respiratory failure)*** Pulmonary embolism (Pulmonary artery embolism)*	Recovered	04-Apr-2024 1 month 2 days 12 hrs	DURVALUMAB	Infusion	1500 milligram single Intravenous use	01-MAR-2024 12:00 to 01-MAR-2024 12:50 50 min	Periodic Report Comment. The patient experienced acute hypoxic respiratory failure and elevated troponin .Inv: related to durvalumab , not related -BCG study therapy. CCA: Not related to study therapy
Concomitant Medication(s): | BCG (S) | Lisinopril/hctz (C) | Aspirin (C) | Terazosin (C) | Finasteride (C) | Metformin (C) | Atorvastatin (C) | Proair HFA (C) | Fluticasone propionate (C) | Fiber (C) | Multivitamin (C) | Diclofenac (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419M

EudraCT No:

Study Design: Not Blinded

Study ID: D419ML00003

Study Description: D419ML00003 TRITON - A Phase IIIb, Randomized, Multicenter, Open-label Study to assess the Efficacy of Durvalumab plus Tremelimumab versus Pembrolizumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Metastatic Non-Small Cell Lung Cancer Patients with Non-squamous histology who have Mutations and/or Co-mutations in STK11, KEAP1, or KRAS (TRITON)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
202508GLO011163US	UNITED STATES 61 Years Female	**Pancytopenia (Pancytopenia)***	Recovered	11-Aug-2025 2 months 20 days	CARBOPLATIN	Infusion	332 Intravenous use	23-MAY-2025 to 28-JUL-2025 2 months 6 days	
Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | PEMETREXED (S) | | Oxycodone (C) | Dexamethasone (C) | Metoprolol tartrate (C)									
SOC:Gastrointestinal disorders									
202509GLO008463US	UNITED STATES 81 Years Female	**Nausea (Nausea)*** Diarrhoea (Diarrhea) Vomiting (Vomiting)*	Not Recovered	30-Aug-2025 4 months 30 days	DURVALUMAB	Infusion	1500 milligram Intravenous use	01-APR-2025 to 22-SEP-2025 5 months 22 days	
Concomitant Medication(s): | TREMELIMUMAB (S) | Pemetrexed (S) | Carboplatin (S) | Hydroxyzine (C)									
202509GLO028112US	UNITED STATES 60 Years Female	**Colitis (Colitis)*** Diarrhoea (Diarrhea)	Not Recovered	13-Oct-2025 nk	CARBOPLATIN	Infusion	Intravenous use	to	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419M

Study ID: D419ML00003

EudraCT No:

Study Design: Not Blinded

Study Description: D419ML00003 TRITON - A Phase IIIb, Randomized, Multicenter, Open-label Study to assess the Efficacy of Durvalumab plus Tremelimumab versus Pembrolizumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Metastatic Non-Small Cell Lung Cancer Patients with Non-squamous histology who have Mutations and/or Co-mutations in STK11, KEAP1, or KRAS (TRITON)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	20-AUG-2025 13:24 to 10-SEP-2025 14:02 21 days 38 min	
Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | PEMETREXED (S) | | Folic acid (C) | Cholecalciferol (C) | Fluoxetine (C) | Rosuvastatin (C) | Montelukast (C) | Centrum (C) | Magnesium oxide (C) | Vitamin b-12 (C) | Paxlovid (C) | Imodium (C) | Zofran (C) | Protonix (C) | Vitamin d3 (C) | Calcium carbonate (C) | Solumedrol (C) | Benadryl (C) | Prevalite (C) | Questran (C) | Bactroban (C) | Potassium chloride (C) | Sodium chloride (C) | Duoneb (C) | Magnesium sulfate (C) | Zosyn (C) | Lactated ringer's (C) | K-lyte (C) | Ofirmev (C) | Bentyl (C) | Morphine (C) | Rocephin (C) | Bactrim ds (C) | Deltasone (C) | Heparin (C) | Lomotil (C) | Tylenol (C) | Dilaudid (C)									
202510GLO017493US	UNITED STATES 60 Female	**Colitis (Colitis)***	Fatal	13-Oct-2025 1 month 24 days	CARBOPLATIN	Infusion	5	10-SEP-2025 to 10-SEP-2025 1 day	
						Infusion	5	20-AUG-2025 to 20-AUG-2025 1 day	
					DURVALUMAB	Infusion	1500 milligram	10-SEP-2025 to 10-SEP-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419M

Study ID: D419ML00003

EudraCT No:

Study Design: Not Blinded

Study Description: D419ML00003 TRITON - A Phase IIIb, Randomized, Multicenter, Open-label Study to assess the Efficacy of Durvalumab plus Tremelimumab versus Pembrolizumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Metastatic Non-Small Cell Lung Cancer Patients with Non-squamous histology who have Mutations and/or Co-mutations in STK11, KEAP1, or KRAS (TRITON)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram	20-AUG-2025 to 20-AUG-2025 1 day	
					PEMETREXED	Infusion	500 milligram/sq. meter	10-SEP-2025 to 10-SEP-2025 1 day	
						Infusion	500 milligram/sq. meter	20-AUG-2025 to 20-AUG-2025 1 day	
					TREMELIMUMAB	Infusion	75 milligram	10-SEP-2025 to 10-SEP-2025 1 day	
						Infusion	75 milligram	20-AUG-2025 to 20-AUG-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419M

Study ID: D419ML00003

EudraCT No:

Study Design: Not Blinded

Study Description: D419ML00003 TRITON - A Phase IIIb, Randomized, Multicenter, Open-label Study to assess the Efficacy of Durvalumab plus Tremelimumab versus Pembrolizumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Metastatic Non-Small Cell Lung Cancer Patients with Non-squamous histology who have Mutations and/or Co-mutations in STK11, KEAP1, or KRAS (TRITON)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | | PEMETREXED (S) | Folic acid (C) | Cholecalciferol (C) | Fluoxetine (C) | Rosuvastatin (C) | Montelukast (C) | Magnesium oxide (C) | Cyanocobalamin (C) | Paxlovid (C) | Imodium (C) | Zofran (C) | Pantoprazole (C) | Cholecalciferol (C) | Calcium carbonate (C) | Diphenhydramine (C) | Methylprednisolone sodium succinate (C) | Magnesium sulfate (C) | Magnesium sulfate (C) | Potassium bicarbonate (C) | Potassium chloride (C) | ACETAMINOPHEN (C) | Dicyclomine (C) | Ondansetron (C) | Morphine (C) | Ceftriaxone (C) | PREDNISONE (C) | Hydromorphone (C)									
SOC:General disorders and administration site conditions									
202505GLO027977US	UNITED STATES 81 Years Female	**Pyrexia (Fever)***	Recovered with Sequelae	22-May-2025 1 month 22 days	TREMELIMUMAB	Infusion	75 milligram q3w Intravenous use	01-APR-2025 to 29-JUL-2025 3 months 29 days	Periodic Report Comments. Patient has event fever. Action taken with study therapy was No change. Investigator Causality: Related, CC: Not Related
Concomitant Medication(s): DURVALUMAB (S) | | CARBOPLATIN (S) | PEMETREXED (S) | Fluconazole (C) | Candesartan (C) | Clotrimazole (C) | Imodium (C) | Tramadol (C) | Amlodipine (C) | Calcium carbonate (C) | Atacand (C) | Cholecalciferol (C) | Folvite (C) | Lorazepam (C) | Rosuvastatin (C) | Ondansetron (C) | Cyanocobalamin (C) | Triamcinolone (C)									
SOC:Immune system disorders									
202509GLO014444US	UNITED STATES 47 Years	**Cytokine release syndrome (Cytokine release syndrome)*** Rash maculo-papular (Rash maculo-papular)* Wheezing (Wheezing)* Anaphylactic reaction (Anaphylaxis)*	Recovered	09-Sep-2025 nk	CARBOPLATIN	Infusion	Intravenous use	to	
Concomitant Medication(s): TREMELIMUMAB (S) | DURVALUMAB (S) | PEMETREXED (S) | | CISPLATIN (S)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419M

Study ID: D419ML00003

EudraCT No:

Study Design: Not Blinded

Study Description: D419ML00003 TRITON - A Phase IIIb, Randomized, Multicenter, Open-label Study to assess the Efficacy of Durvalumab plus Tremelimumab versus Pembrolizumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Metastatic Non-Small Cell Lung Cancer Patients with Non-squamous histology who have Mutations and/or Co-mutations in STK11, KEAP1, or KRAS (TRITON)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Infections and infestations									
202502GLO015999US	UNITED STATES 71 Years Male	**Sepsis (Sepsis)*** Pneumonia (Lung infection)*	Fatal	05-Feb-2025 3 months 8 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	29-OCT-2024 to 28-JAN-2025 3 months	
Concomitant Medication(s): | Pemetrexed (S) | Cisplatin (S) | Dexamethasone (C) | Pantoprazole (C) | Tadalafil (C) | Memantine (C) | Lorazepam (C) | Enoxaparin (C) | Famotidine (C) | Olanzapine (C) | Jardiance (C) | Miralax (C) | Marinol (C) | Tramadol (C) | Dobutamine (C) | Oxygen (C)									
202506GLO012772US	UNITED STATES 66 Years Male	**Abdominal infection (Abdominal infection)***	Recovered with Sequelae	09-Jun-2025 6 months 6 days	PEMETREXED	Infusion	500 milligram/sq. meter q3w Intravenous use	04-DEC-2024 to 06-MAY-2025 5 months 3 days	Patient experienced Abdominal infection Investigator causality: RELATED with Pembrolizumab, Pemetrexed Company causality was NOT RELATED with Pembrolizumab
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CARBOPLATIN (S) | Ibuprofen (C) | Nystatin (C) | Prednisolone (C) | Dicyclomine (C) | Alprazolam (C) | Aspirin (C) | Zofran (C) | Folic acid (C)									
202508GLO025775US	UNITED STATES 78 Years Male	**Sepsis (Sepsis)***	Recovered	28-Aug-2025 nk	PEMBROLIZUMAB	Solution for infusion	Intravenous use	to	
Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | | PEMETREXED (S) | CARBOPLATIN (S) | CISPLATIN (S)									
SOC:Injury, poisoning and procedural complications									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419M

Study ID: D419ML00003

EudraCT No:

Study Design: Not Blinded

Study Description: D419ML00003 TRITON - A Phase IIIb, Randomized, Multicenter, Open-label Study to assess the Efficacy of Durvalumab plus Tremelimumab versus Pembrolizumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Metastatic Non-Small Cell Lung Cancer Patients with Non-squamous histology who have Mutations and/or Co-mutations in STK11, KEAP1, or KRAS (TRITON)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202506GLO014401US	UNITED STATES 61 Years Female	**Infusion related reaction (Infusion related reaction)***	Recovered	13-Jun-2025 22 days	TREMELIMUMAB	Infusion	75 milligram q3w Intravenous use	23-MAY-2025 to 13-JUN-2025 22 days	

Concomitant Medication(s): | DURVALUMAB (S) | Pemetrexed (S) | Carboplatin (S) | Oxycodone (C) | Metformin (C) | Methocarbamol (C) | Metoprolol (C) | Ozempic (C) | Vitamin b12 (C) | Vitamin d3 (C) | Tylenol (C) | Pepcid (C) | Folic acid (C) | Dexamethasone (C) | Iron ferrous (C) | Cyanocobalamin (C)

SOC:Musculoskeletal and connective tissue disorders

202510GLO012301US	UNITED STATES 71 Years Female	**Arthralgia (Shoulder pain)***	Not Recovered	06-Oct-2025 8 months 12 days 15 hrs 2 min	TREMELIMUMAB	Infusion	75 milligram q3w Intravenous use	03-APR-2025 10:10 to 03-APR-2025 11:10 1 hr	
						Infusion	75 milligram q3w Intravenous use	06-MAR-2025 10:50 to 06-MAR-2025 11:58 1 hr 8 min	
						Infusion	75 milligram q3w Intravenous use	13-FEB-2025 10:04 to 13-FEB-2025 11:04 1 hr	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419M

Study ID: D419ML00003

EudraCT No:

Study Design: Not Blinded

Study Description: D419ML00003 TRITON - A Phase IIIb, Randomized, Multicenter, Open-label Study to assess the Efficacy of Durvalumab plus Tremelimumab versus Pembrolizumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Metastatic Non-Small Cell Lung Cancer Patients with Non-squamous histology who have Mutations and/or Co-mutations in STK11, KEAP1, or KRAS (TRITON)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	75 milligram q3w Intravenous use	22-MAY-2025 09:39 to 22-MAY-2025 10:39 1 hr	
						Infusion	75 milligram q3w Intravenous use	23-JAN-2025 08:58 to 23-JAN-2025 10:00 1 hr 2 min	
					CARBOPLATIN	Infusion	Intravenous use	03-APR-2025 13:51 to 03-APR-2025 14:51 1 hr	
						Infusion	Intravenous use	06-MAR-2025 14:22 to 06-MAR-2025 15:22 1 hr	
						Infusion	Intravenous use	13-FEB-2025 13:18 to 13-FEB-2025 14:18 1 hr	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419M

Study ID: D419ML00003

EudraCT No:

Study Design: Not Blinded

Study Description: D419ML00003 TRITON - A Phase IIIb, Randomized, Multicenter, Open-label Study to assess the Efficacy of Durvalumab plus Tremelimumab versus Pembrolizumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Metastatic Non-Small Cell Lung Cancer Patients with Non-squamous histology who have Mutations and/or Co-mutations in STK11, KEAP1, or KRAS (TRITON)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	23-JAN-2025 14:18 to 23-JAN-2025 15:18 1 hr	

Concomitant Medication(s): DURVALUMAB (S) | | CARBOPLATIN (S) | PEMETREXED (S) | Albuterol (C) | Buspar (C) | Fosamax (C) | Synthroid (C) | Midodrine (C) | Polyethylene glycol 3350 (C) | Stiolto respimat (C) | Ultram (C) | Anoro ellipta (C) | Vitamin d (C) | Percocet (C) | Oxycontin (C) | Florinef (C) | Slow fe (C) | Phenazopyridine hydrochloride (C) | Ciprofloxacin (C) | Deltasone (C) | Duoneb (C) | Perforomist (C) | Pulmicort (C) | Peri-colace (C) | Xanax (C) | Zofran (C) | Dilaudid (C) | Decadron (C) | Catapres (C) | Ativan (C) | Vueway (C) | Zithromax (C) | Protonix (C) | Roxicodone (C) | Polyethylene glycol (C) | Lidocaine (C) | Morphine (C) | Toradol (C) | Robaxin (C) | Tynelol (C) | Ms contin (C) | Remeron (C) | Glycolax (C) | Zosyn (C) | Magnesium sulfate (C) | Mag-ox (C) | Potassium chloride (C) | Ferrous sulfate (C) | Marinol (C) | Mycostatin (C) | Augmentin (C) | LInzess (C) | Lovenox (C) | Oxygen (C) | Aloxi (C) | Emend (C) | Zyprexa (C) | Vitamin b 12 (C) | Dulcolax (C) | Lactulose (C) | Neurontin (C) | Benadryl (C) | Peridex (C) | Duragesic (C) | Tylenol (C) | Lasix (C)

SOC:Psychiatric disorders

202510GLO014845US	UNITED STATES 59 Years Female	**Disorientation (Disorientation)***	Not Recovered	09-Oct-2025 nk	CARBOPLATIN	Infusion	Unknown	to	
					CISPLATIN	Infusion	Unknown	to	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419M

Study ID: D419ML00003

EudraCT No:

Study Design: Not Blinded

Study Description: D419ML00003 TRITON - A Phase IIIb, Randomized, Multicenter, Open-label Study to assess the Efficacy of Durvalumab plus Tremelimumab versus Pembrolizumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Metastatic Non-Small Cell Lung Cancer Patients with Non-squamous histology who have Mutations and/or Co-mutations in STK11, KEAP1, or KRAS (TRITON)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion	Intravenous use	to	
					PEMBROLIZUMAB	Solution for infusion	Intravenous use	to	
					PEMETREXED	Infusion	Unknown	to	
					TREMELIMUMAB	Infusion	Intravenous use	to	

Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | PEMBROLIZUMAB (S) | PEMETREXED (S) | | CISPLATIN (S)

SOC:Renal and urinary disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419M

Study ID: D419ML00003

EudraCT No:

Study Design: Not Blinded

Study Description: D419ML00003 TRITON - A Phase IIIb, Randomized, Multicenter, Open-label Study to assess the Efficacy of Durvalumab plus Tremelimumab versus Pembrolizumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Metastatic Non-Small Cell Lung Cancer Patients with Non-squamous histology who have Mutations and/or Co-mutations in STK11, KEAP1, or KRAS (TRITON)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO018263US	UNITED STATES 61 Years Male	**Acute kidney injury (Acute kidney injury)***	Not Recovered	20-Aug-2025 9 days	CARBOPLATIN	Infusion	Intravenous use	12-AUG-2025 to 02-SEP-2025 22 days	

Concomitant Medication(s): PEMBROLIZUMAB (S) | PEMETREXED (S) | | Oxycodone (S) | Cymbalta (S) | Atarax (S) | Norvasc (S) | Jardiance (S) | Lasix (S) | Remeron (S) | Nitroglycerin (S) | Albuterol (C) | Empagliflozin (C) | Furosemide (C) | Folic acid (C) | Levothyroxine (C) | Buspirone (C) | Etomidate (C) | Rocuronium (C) | Cefepime (C) | Vancomycin (C) | Levophed (C) | Epinephrine (C) | Albumin (C)

SOC:Respiratory, thoracic and mediastinal disorders

202507GLO005931US	UNITED STATES 58 Years Male	**Pleural effusion (Pleural effusion)*** Lung consolidation (Lung consolidation)*	Recovered with Sequelae	02-Jul-2025 3 months 19 days	PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	14-MAR-2025 to 27-JUN-2025 3 months 14 days	

Concomitant Medication(s): | PEMETREXED (S) | CARBOPLATIN (S)

SOC:Vascular disorders

202508GLO009628US	UNITED STATES 74 Years Female	**Peripheral ischaemia (Acute limb ischemia)*** Embolic stroke (Thromboembolic stroke)*	Fatal	08-Aug-2025 nk	PEMBROLIZUMAB	Solution for infusion	200 milligram Unknown	to	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D419M

Study ID: D419ML00003

EudraCT No:

Study Design: Not Blinded

Study Description: D419ML00003 TRITON - A Phase IIIb, Randomized, Multicenter, Open-label Study to assess the Efficacy of Durvalumab plus Tremelimumab versus Pembrolizumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Metastatic Non-Small Cell Lung Cancer Patients with Non-squamous histology who have Mutations and/or Co-mutations in STK11, KEAP1, or KRAS (TRITON)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					CARBOPLATIN	Infusion	5 Intravenous use	16-JUL-2025 to 06-AUG-2025 22 days	
					DURVALUMAB	Infusion	1500 milligram Intravenous use	16-JUL-2025 to 06-AUG-2025 22 days	
					PEMETREXED	Infusion	500 milligram/sq. meter Intravenous use	16-JUL-2025 to 06-AUG-2025 22 days	
					TREMELIMUMAB	Infusion	75 milligram Intravenous use	16-JUL-2025 to 06-AUG-2025 22 days	

Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | PEMETREXED (S) | CARBOPLATIN (S) | | Atorvastatin (C) | Nifedipine (C) | Dexamethasone (C) | Cisplatin (C) | Ondansetron (C) | Aprepitant (C) | Folic (C) | Cyanocobalamin (C) | Tenecteplase (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D5083

EudraCT No:

Study Design: Not Blinded

Study ID: D5083C00002

Study Description: The SOUND study will investigate the efficacy and safety of savolitinib plus durvalumab in Chinese locally advanced or metastatic NSCLC patients with MET alteration. - Savolitinib combine with Durvalumab in Chinese EGFR wild-type locally advanced or metastatic NSCLC patients with MET alteration: An open-label, interventional, multiple-center, exploratory trial (SOUND).

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Hepatobiliary disorders									
2023A255322	CHINA 70 Years Male	**Liver injury (Liver injury)*** Drug-induced liver injury (Hy's law case)*	Recovered	04-Sep-2023 4 weeks	DURVALUMAB	Infusion	1500 milligram Intravenous use	07-AUG-2023 to 07-AUG-2023 1 day	Periodic Report Comment. The patient experienced liver function injury and Hys law. Inv: related to study therapy and Study procedure. CCA: related to study therapy and not related to Study procedure.
Concomitant Medication(s): SAVOLITINIB (S) |									
SOC:Infections and infestations									
2023A229500	CHINA 73 Years Male	**Upper respiratory tract infection (Upper respiratory tract infection)***	Recovered	07-Oct-2023 2 weeks 2 days	SAVOLITINIB	Tablet	200 milligram qd Oral use	09-MAR-2025 to 28-AUG-2025 5 months 20 days	Periodic Report Comment. The patient experienced upper respiratory tract infection.Investigator-Related to Savolitinib, study procedure and not related to Durvalumab. Company-Not related.;Periodic Report Comments. The patient experienced upper respiratory tract infection. Investigator-Related to Savolitinib and not related to Durvalumab. Company-Not related.
						Tablet	400 milligram qd Oral use	10-OCT-2023 to 10-NOV-2023 4 weeks 4 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D5083

Study ID: D5083C00002

EudraCT No:

Study Design: Not Blinded

Study Description: The SOUND study will investigate the efficacy and safety of savolitinib plus durvalumab in Chinese locally advanced or metastatic NSCLC patients with MET alteration. - Savolitinib combine with Durvalumab in Chinese EGFR wild-type locally advanced or metastatic NSCLC patients with MET alteration: An open-label, interventional, multiple-center, exploratory trial (SOUND).

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Tablet	400 milligram qd Oral use	17-NOV-2023 to 09-FEB-2025 1 year 2 months 24 days	
						Tablet	600 milligram qd Oral use	09-OCT-2023 to 09-OCT-2023 1 day	
						Tablet	600 milligram qd Oral use	11-NOV-2023 to 16-NOV-2023 6 days	
						Tablet	600 milligram qd Oral use	21-SEP-2023 to 06-OCT-2023 2 weeks 2 days	
Concomitant Medication(s): DURVALUMAB (S) |									
202509GLO004503CN	CHINA 73 Male	**Pneumonia (Lung infection)***	Recovered	13-Aug-2025 1 year 10 months 24 days	SAVOLITINIB	Tablet	200 milligram qd Oral use	10-FEB-2025 to 29-AUG-2025 6 months 20 days	Periodic Report Comments. Patient has event pulmonary infection. Action taken with study therapy was Not applicable. Investigator Causality: Related, CC: Not Related

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D5083

Study ID: D5083C00002

EudraCT No:

Study Design: Not Blinded

Study Description: The SOUND study will investigate the efficacy and safety of savolitinib plus durvalumab in Chinese locally advanced or metastatic NSCLC patients with MET alteration. - Savolitinib combine with Durvalumab in Chinese EGFR wild-type locally advanced or metastatic NSCLC patients with MET alteration: An open-label, interventional, multiple-center, exploratory trial (SOUND).

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Tablet	400 milligram qd Oral use	10-OCT-2023 to 10-OCT-2023 1 day	
						Tablet	400 milligram qd Oral use	17-NOV-2023 to 09-FEB-2025 1 year 2 months 24 days	
						Tablet	600 milligram qd Oral use	11-NOV-2023 to 16-NOV-2023 6 days	
						Tablet	600 milligram qd Oral use	21-SEP-2023 to 09-OCT-2023 19 days	

Concomitant Medication(s): DURVALUMAB (S) |

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D5086

Study ID: D5086C00001

EudraCT No: 2022-503105-38-00

Study Design: Single Blinded

Study Description: D5086C00001 SAMETA Ph3 vs Sunitinib in PRCC - A Phase III, Open Label, Randomised, 3-Arm, Multi-Centre Study of Savolitinib plus Durvalumab versus Sunitinib and Durvalumab Monotherapy in Participants with MET Driven, Unresectable and Locally Advanced, or Metastatic Papillary Renal Cell Carcinoma (PRCC) (SAMETA)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Renal and urinary disorders									
2023A129187	BRAZIL 66 Years Male	**Acute kidney injury (Acute renal failure)*** Hyperkalaemia (Hyperkalemia)* Drug-induced liver injury (Hy's law case)*	Not Recovered	31-May-2023 2 weeks 6 days					
Concomitant Medication(s):									
SOC:Respiratory, thoracic and mediastinal disorders									
2023A225356	BRAZIL 56 Years Male	**Dyspnoea (Dyspnea)***	Recovered	02-Oct-2023 2 months	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	03-AUG-2023 to 28-SEP-2023 1 month 26 days	Periodic Report Comment. Patient experienced dehydration, vomiting, pneumonitis related to Savolitinib, not related to Durvalumab, generalized musculoskeletal pain not related, dyspnea related to both drugs. CCA: Not related to study therapies.
		Dyspnoea (Dyspnea)* Dehydration (Dehydration)* Vomiting (Vomiting) Pneumonitis (Pneumonitis)*	Recovered	02-Oct-2023 2 months	SAVOLITINIB	Tablet	600 milligram qd Oral use	03-AUG-2023 to 27-SEP-2023 1 month 25 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D5086

Study ID: D5086C00001

EudraCT No: 2022-503105-38-00

Study Design: Single Blinded

Study Description: D5086C00001 SAMETA Ph3 vs Sunitinib in PRCC - A Phase III, Open Label, Randomised, 3-Arm, Multi-Centre Study of Savolitinib plus Durvalumab versus Sunitinib and Durvalumab Monotherapy in Participants with MET Driven, Unresectable and Locally Advanced, or Metastatic Papillary Renal Cell Carcinoma (PRCC) (SAMETA)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Tablet	600 milligram qd Oral use	22-DEC-2023 to 06-MAR-2024 2 months 14 days	

Concomitant Medication(s): SAVOLITINIB (S) | | DIPYRONE (C) | GABAPENTIN (C) | BISACODYL (C) | MORPHINE (C) | METADONE (C) | OMEPRAZOLE (C) | ONDANSETRON (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D5330

Study ID: D5330C00004

EudraCT No: 2023-505006-41-00

Study Design: Not Blinded

Study Description: D5330C00004 AZD6738 Modular Combination Solid Tmr MAD/POP PH1/2A - A modular phase I, open-label, multicentre study to assess the safety, tolerability, pharmacokinetics and preliminary anti-tumour activity of ascending doses of AZD6738 in combination with cytotoxic chemotherapy and/or DNA damage repair/novel anti-cancer agents in patients with advanced solid malignancies

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
2024A080439	FRANCE 64 Years Female	**Pancytopenia (Pancytopenia)***	Recovered	01-Apr-2024 1 year 1 month 24 days	AZD6738	Tablet	80 milligram qd Oral use	09-FEB-2023 to 24-DEC-2023 10 months 16 days	Periodic Report Comment. Patient experienced pancytopenia , Inves: related to study therapy.CCA : not related to study therapy
						Tablet	80 milligram qd Oral use	11-APR-2024 to 11-APR-2024 1 day	
						Tablet	80 milligram qd Oral use	11-JAN-2024 to 13-MAR-2024 2 months 3 days	
					OLAPARIB	Tablet	100 milligram qd Oral use	09-FEB-2023 to 10-JAN-2024 11 months 2 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D5330

Study ID: D5330C00004

EudraCT No: 2023-505006-41-00

Study Design: Not Blinded

Study Description: D5330C00004 AZD6738 Modular Combination Solid Tmr MAD/POP PH1/2A - A modular phase I, open-label, multicentre study to assess the safety, tolerability, pharmacokinetics and preliminary anti-tumour activity of ascending doses of AZD6738 in combination with cytotoxic chemotherapy and/or DNA damage repair/novel anti-cancer agents in patients with advanced solid malignancies

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Tablet	100 milligram qd Oral use	11-APR-2024 to 11-APR-2024 1 day	
						Tablet	100 milligram qd Oral use	11-JAN-2024 to 13-MAR-2024 2 months 3 days	

Concomitant Medication(s): | OLAPARIB (S) | DEPAMIDE (C) | Naproxen sodium (C) | AUGMENTIN (C) | ROCEPHINE (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D533B

Study ID: D533BC00001

EudraCT No: 2023-509429-37-00

Study Design: Not Blinded

Study Description: D533BC00001 ceralasertib+Imfinzi post-IO NSCLC PH3 - A Phase III, Open-label, Randomised, Multicentre Study of Ceralasertib Plus Durvalumab Versus Docetaxel in Patients With Advanced or Metastatic Non-Small Cell Lung Cancer Without Actionable Genomic Alterations, and Whose Disease Has Progressed On or After Prior Anti PD (L)1 Therapy and Platinum-based Chemotherapy: LATIFY

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
2024A060579	GERMANY 73 Years Female	**Bicytopenia (Bicytopenia)***	Recovered	05-Mar-2024 9 days	DOCETAXEL	Infusion	60 milligram/sq. meter Intravenous use	18-MAR-2024 to 18-MAR-2024 1 day	Periodic Report Comment. Patient experienced bizytopenia. Inv: Related to study therapy. CCA: Not related to study therapy.; Periodic Report Comments. Patient has event: BICYTOPENIA, Action Taken: Study therapy was Withdraw. Investigator Causality: Related, Company Causality: Not Related.
						Infusion	76 milligram/sq. meter Intravenous use	26-FEB-2024 to 26-FEB-2024 1 day	
Concomitant Medication(s): | METOPROLOL (C) | CANDESARTAN (C) | VITAMIN B12 (C) | PANTOPRAZOL (C) | NOVAMINSULFON (C) | LORAZEPAM (C) | ZOPICLON (C) | Calcium carbonate (C) | Folverlan (C)									
202504GLO014553ES	SPAIN 72 Years Male	**Pancytopenia (Pancytopenia)*** Anaemia (Anemia)	Not Recovered	10-Apr-2025 2 years 13 days	AZD6738	Tablet	Oral use	29-MAR-2023 to 05-MAR-2025 1 year 11 months 5 days	Periodic Report Comments. Patient experienced pancytopenia Inv causality: RELATED to Azd6738, Durvalumab CCC: NOT RELATED to Azd6738, Durvalumab
						Tablet	240 milligram bid Oral use	27-MAR-2025 to 28-MAR-2025 2 days	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D533B

Study ID: D533BC00001

EudraCT No: 2023-509429-37-00

Study Design: Not Blinded

Study Description: D533BC00001 ceralasertib+Imfinzi post-IO NSCLC PH3 - A Phase III, Open-label, Randomised, Multicentre Study of Ceralasertib Plus Durvalumab Versus Docetaxel in Patients With Advanced or Metastatic Non-Small Cell Lung Cancer Without Actionable Genomic Alterations, and Whose Disease Has Progressed On or After Prior Anti PD (L)1 Therapy and Platinum-based Chemotherapy: LATIFY

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Tablet	240 milligram bid Oral use	30-MAR-2025 to 02-APR-2025 4 days	
						Tablet	240 milligram qd Oral use	29-MAR-2025 to 29-MAR-2025 1 day	
		Pancytopenia (Pancytopenia)* Anaemia (Anemia)*	Not Recovered	10-Apr-2025 2 years 6 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	05-APR-2023 to 06-MAR-2025 1 year 11 months 2 days	

Concomitant Medication(s): DURVALUMAB (S) | | Insulina glargina (C) | Amlodipino (C) | Atorvastatin (C) | Calcium/Vitamin D3 (C) | Diazepam (C) | Lisinopril (C) | Pregabalina (C) | Insulin Rapid (C) | Apixaban (C) | Vitamin c (C) | Vitamin b (C) | Vitamin b12 (C) | Mst (C) | Valsartan (C) | Hydrapres (C) | Famotidina (C)

SOC:Gastrointestinal disorders

2024A059602	FRANCE 65 Years Male	**Colitis ischaemic (Ischemic colitis)***	Recovered	01-Mar-2024 5 months 14 days 13 hrs 8 min	DURVALUMAB	Infusion	1500 milligram single Intravenous use	15-SEP-2023 10:52 to 01-MAR-2024 12:00 5 months 15 days 1 hr 8 min	Periodic Report Comment. Pt exp ischemic sigmoid colitis. Inv: event related to Durvalumab, unrelated to AZD6738. Comp: event unrelated to Durvalumab and AZD6738.

Concomitant Medication(s): | AZD6738 (S) | Hydrocortisone (C) | Perindopril (C) | Kardegic (C) | Largactil (C) | Setofilm (C) | Xanax (C) | Paracetamol (C) | Olanzapine (C) | Calcidose (C) | Tamsulosine (C) | Zophren (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D533B

Study ID: D533BC00001

EudraCT No: 2023-509429-37-00

Study Design: Not Blinded

Study Description: D533BC00001 ceralasertib+Imfinzi post-IO NSCLC PH3 - A Phase III, Open-label, Randomised, Multicentre Study of Ceralasertib Plus Durvalumab Versus Docetaxel in Patients With Advanced or Metastatic Non-Small Cell Lung Cancer Without Actionable Genomic Alterations, and Whose Disease Has Progressed On or After Prior Anti PD (L)1 Therapy and Platinum-based Chemotherapy: LATIFY

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Infections and infestations									
2023A214716	BRAZIL 70 Years Female	**Sepsis (Sepsis)***	Not Recovered	10-Sep-2023 6 days					
Concomitant Medication(s):									
2023A290648	UNITED STATES 74 Years Female	**Sepsis (Sepsis)*** Pulmonary embolism (Pulmonary embolism)* Diarrhoea (Diarrhea)	Recovered	10-Dec-2023 10 days 10 hrs 29 min	DOCETAXEL	Infusion Infusion	Intravenous use Intravenous use	05-JAN-2024 11:16 to 29-NOV-2023 13:31 to 29-NOV-2023 14:40 1 hr 9 min	Periodic Report Comment. The patient experienced sepsis, pulmonary embolism, diarrhea. Investigator: related. Company: Not related.;PRC. The patient experienced Sepsis, Pulmonary embolism and Diarrhea. Investigator: related to DOCETAXEL Company physician: Not related to study therapy.; periodic report comment. Patient experienced sepsis, pulmonary embolism, investigator: related to docetaxel, company: not related to docetaxel, diarrhea: investigator: related to docetaxel, company: related to docetaxel.
Concomitant Medication(s): | Tizanidine (C) | Pregabalin (C) | Escitalopram (C) | Fluticasone (C) | Albuterol sulfate (C) | Umeclidinium bromide (C) | Vilanterol (C) | Oxycodone (C) | Acetaminophen (C) | Amlodipine (C) | Morphine (C) | Zolpidem (C) | Vitamin d3 (C) | Ranitidine (C) | Metoprolol (C) | Apixaban (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D533B

Study ID: D533BC00001

EudraCT No: 2023-509429-37-00

Study Design: Not Blinded

Study Description: D533BC00001 ceralasertib+Imfinzi post-IO NSCLC PH3 - A Phase III, Open-label, Randomised, Multicentre Study of Ceralasertib Plus Durvalumab Versus Docetaxel in Patients With Advanced or Metastatic Non-Small Cell Lung Cancer Without Actionable Genomic Alterations, and Whose Disease Has Progressed On or After Prior Anti PD (L)1 Therapy and Platinum-based Chemotherapy: LATIFY

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A292602	AUSTRALIA 72 Years Male	**Pneumonia (Lung infection)***	Not Recovered	18-Dec-2023 1 month 1 day 13 hrs 6 min					
Concomitant Medication(s):									
2024A025394	CHINA 60 Years Male	**Upper respiratory tract infection (Upper respiratory infection)***	Not Recovered	16-Jan-2024 nk					
Concomitant Medication(s):									
2024A040920	UNITED STATES 63 Years Male	**Sepsis (Sepsis)***	Fatal	14-Feb-2024 3 months 27 days 3 hrs 16 min	AZD6738	Tablet	240 milligram bid Oral use	07-FEB-2024 to 12-FEB-2024 6 days	Periodic Report Comment. The patient experienced dyspnea and sepsis. investigator-Related to ceralacertib. Company-Not related.
						Tablet	240 milligram bid Oral use	10-JAN-2024 to 16-JAN-2024 7 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D533B

Study ID: D533BC00001

EudraCT No: 2023-509429-37-00

Study Design: Not Blinded

Study Description: D533BC00001 ceralasertib+Imfinzi post-IO NSCLC PH3 - A Phase III, Open-label, Randomised, Multicentre Study of Ceralasertib Plus Durvalumab Versus Docetaxel in Patients With Advanced or Metastatic Non-Small Cell Lung Cancer Without Actionable Genomic Alterations, and Whose Disease Has Progressed On or After Prior Anti PD (L)1 Therapy and Platinum-based Chemotherapy: LATIFY

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Tablet	240 milligram bid Oral use	13-DEC-2023 to 19-DEC-2023 7 days	
						Tablet	240 milligram bid Oral use	15-NOV-2023 to 21-NOV-2023 7 days	
						Tablet	240 milligram bid Oral use	18-OCT-2023 to 24-OCT-2023 7 days	
Concomitant Medication(s): | DURVALUMAB (S) | Atorvastatin (C) | Metformin (C) | Rivaroxaban (C) | Metoprolol (C) | Albuterol (C) | Pantoprazole (C) | Clonazepam (C) | Lorazepam (C) | Simethicone (C) | Bismuth (C) | Compazine (C) | Budesonide and Formoterol (C) | Metoprolol succinate (C) | Senna (C) | Miralax (C) | Mucinex (C)									
2024A043200	CHINA 70 Years Male	**Pneumonia bacterial (Pneumonia bacterial)***	Fatal	20-Jan-2024 28 days 12 hrs 31 min	DOCETAXEL	Infusion	75 milligram/sq. meter Intravenous use	22-DEC-2023 11:29 to 22-DEC-2023 13:00 1 hr 31 min	Periodic Report Comment. Patient with history of Cough, NSCLS, hypoalbuminemia, hypochlorhydria and hypomagnesemia. INV: related to study therapy. CCA: Not related to study therapy.
Concomitant Medication(s): | Cimetidine (C) | Levofloxacin (C) | Sulfamet (C) | Cefoperazone Sodium and Sulbactam (C) | Amikacin (C) | Fluconazole (C) | Voriconazole (C) | Potassium chloride (C) | Ferrous succinate (C) | Megestrol acetate (C) | Methylprednisolone sodium succinate (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D533B

Study ID: D533BC00001

EudraCT No: 2023-509429-37-00

Study Design: Not Blinded

Study Description: D533BC00001 ceralasertib+Imfinzi post-IO NSCLC PH3 - A Phase III, Open-label, Randomised, Multicentre Study of Ceralasertib Plus Durvalumab Versus Docetaxel in Patients With Advanced or Metastatic Non-Small Cell Lung Cancer Without Actionable Genomic Alterations, and Whose Disease Has Progressed On or After Prior Anti PD (L)1 Therapy and Platinum-based Chemotherapy: LATIFY

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A083360	JAPAN 55 Years Male	**Pneumonia (Pneumonia)***	Recovering	17-Jan-2024 10 weeks					
Concomitant Medication(s):									
202505GLO007393PL	POLAND 75 Years Male	**Pneumonia (Pneumonia)*** White blood cell count decreased (Leukocyte count decreased)*	Recovered	23-Apr-2025 1 year 1 month 12 days	DOCETAXEL	Infusion	75 milligram/sq. meter q3w Intravenous use	06-AUG-2024 to 27-AUG-2024 22 days	patient experienced CTC 3 Pneumonia, Inv. causa.: not reported, CCA: not related. ; Patient experienced pneumonia and leukopenia: investigator causality not related to study therapy. CCA: not related.
						Infusion	75 milligram/sq. meter q3w Intravenous use	12-MAR-2024 to 02-APR-2024 22 days	
						Infusion	75 milligram/sq. meter q3w Intravenous use	14-JAN-2025 to 19-MAR-2025 2 months 6 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D533B

Study ID: D533BC00001

EudraCT No: 2023-509429-37-00

Study Design: Not Blinded

Study Description: D533BC00001 ceralasertib+Imfinzi post-IO NSCLC PH3 - A Phase III, Open-label, Randomised, Multicentre Study of Ceralasertib Plus Durvalumab Versus Docetaxel in Patients With Advanced or Metastatic Non-Small Cell Lung Cancer Without Actionable Genomic Alterations, and Whose Disease Has Progressed On or After Prior Anti PD (L)1 Therapy and Platinum-based Chemotherapy: LATIFY

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	75 milligram/sq. meter q3w Intravenous use	15-APR-2025 to 15-APR-2025 1 day	
						Infusion	75 milligram/sq. meter q3w Intravenous use	19-NOV-2024 to 19-NOV-2024 1 day	
						Infusion	75 milligram/sq. meter q3w Intravenous use	26-SEP-2024 to 15-OCT-2024 20 days	
						Infusion	75 milligram/sq. meter q3w Intravenous use	30-APR-2024 to 02-JUL-2024 2 months 3 days	

Concomitant Medication(s): | Pantoprazole (C) | Hydroxizine (C) | Ropinirol (C) | Dexamethasone (C) | Ondansetron (C) | Rivanol (C) | Hascofungin (C) | Akneroxid (C) | Sorbifer Durules (C) | Noliprel (C) | Madopar (C) | Torsemide (C) | Tramadol (C) | Paracetamol (C) | Neurolipon (C) | Feroplex (C) | Akineton (C) | Lyrica (C) | Gabapentin (C) | Levoxa (C) | Eubiotic (C) | Dulsevia (C)

SOC:Metabolism and nutrition disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D533B

Study ID: D533BC00001

EudraCT No: 2023-509429-37-00

Study Design: Not Blinded

Study Description: D533BC00001 ceralasertib+Imfinzi post-IO NSCLC PH3 - A Phase III, Open-label, Randomised, Multicentre Study of Ceralasertib Plus Durvalumab Versus Docetaxel in Patients With Advanced or Metastatic Non-Small Cell Lung Cancer Without Actionable Genomic Alterations, and Whose Disease Has Progressed On or After Prior Anti PD (L)1 Therapy and Platinum-based Chemotherapy: LATIFY

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A089873	KOREA, REPUBLIC OF 65 Years Male	**Hypophagia (Oral intake reduced)***	Recovered	08-Apr-2024 1 week					

Concomitant Medication(s):

SOC:Respiratory, thoracic and mediastinal disorders

2023A241776	JAPAN 74 Years Male	**Interstitial lung disease (Interstitial pneumonia)***	Fatal	17-Oct-2023 28 days	DOCETAXEL	Infusion	75 milligram/sq. meter q3w Intravenous use	20-SEP-2023 to	Periodic Report Comment. the patient experienced grade three interstitial pneumonia,. Inv causality related to Docetaxel. Company causality related to Docetaxel.;Periodic Report Comments. the patient experienced grade three interstitial pneumonia,. Inv causality related to Docetaxel. Company causality unrelated to Docetaxel.

Concomitant Medication(s): | Calonal (C) | Tarlige (C) | Prazaxa (C) | Olmesartan (C) | Amlodipine (C) | Lansoprazole (C) | Oxinorm (C) | Ketoprofen (C) | Oxycodone (C) | Loxoprofen (C) | Prednisolone (C) | Pitavastatin (C) | Ms contin (C) | Opso (C) | Morphine hydrochloride (C) | Eliquis (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D533B

Study ID: D533BC00001

EudraCT No: 2023-509429-37-00

Study Design: Not Blinded

Study Description: D533BC00001 ceralasertib+Imfinzi post-IO NSCLC PH3 - A Phase III, Open-label, Randomised, Multicentre Study of Ceralasertib Plus Durvalumab Versus Docetaxel in Patients With Advanced or Metastatic Non-Small Cell Lung Cancer Without Actionable Genomic Alterations, and Whose Disease Has Progressed On or After Prior Anti PD (L)1 Therapy and Platinum-based Chemotherapy: LATIFY

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A012088	CHINA 69 Years Male	**Cough (Cough aggravated)***	Recovering	05-Jan-2024 13 days 12 hrs 31 min	DOCETAXEL	Infusion	75 milligram/sq. meter single Intravenous use	22-DEC-2023 11:29 to 22-DEC-2023 13:00 1 hr 31 min	Periodic Report Comment. male pt experienced cough serious event Inv: related to study drug, company : not related
Concomitant Medication(s): | Budesonide (C) | Acetylcysteine (C) | Megestrol acetate (C) | Short peptide enteral nutrition powder (C) | Codeine phosphate (C) | Dexamethasone acetate (C)									
2024A046779	UNITED STATES 48 Years Male	**Pneumothorax (Pneumothorax)***	Recovered	19-Feb-2024 nk	BLINDED AZD6738	Infusion	Intravenous use	to	
						Infusion	Oral use	to	
					D533BC00001 ceralasertib+Imfinzi post-IO NSCLC PH3	Tablet	Oral use	to	
Concomitant Medication(s): D533BC00001 ceralasertib+Imfinzi post-IO NSCLC PH3 (S) | | | Lidocaine (C) | Hydrocodone/acetaminophen (C) | Lactulose (C) | Pepcid (C) | Protonix (C) | Folvite (C) | Senna (C) | Vitamin C (C) | Miralax (C) | Ativan (C) | Gas X (C) | Pepcid (C) | Motrin (C) | Naloxegol (C) | Eliquis (C) | Dilaudid (C) | Ondansetron (C) | Zometa (C) | Narcan (C) | Reglan (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D533B

Study ID: D533BC00001

EudraCT No: 2023-509429-37-00

Study Design: Not Blinded

Study Description: D533BC00001 ceralasertib+Imfinzi post-IO NSCLC PH3 - A Phase III, Open-label, Randomised, Multicentre Study of Ceralasertib Plus Durvalumab Versus Docetaxel in Patients With Advanced or Metastatic Non-Small Cell Lung Cancer Without Actionable Genomic Alterations, and Whose Disease Has Progressed On or After Prior Anti PD (L)1 Therapy and Platinum-based Chemotherapy: LATIFY

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A108547	KOREA, REPUBLIC OF 78 Years Male	**Interstitial lung disease (Interstitial lung disease)***	Recovered	02-May-2024 9 weeks					

Concomitant Medication(s):

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
202411GLO009482TH	THAILAND 59 Years Female	**Neutropenia (Neutropenia)***	Recovering	28-Aug-2024 nk	GEMCITABINE	Infusion	800 milligram/sq. meter Intravenous use	26-JUN-2024 to 08-JAN-2025	
					CARBOPLATIN	Infusion	Intravenous use	18-SEP-2024 to 18-SEP-2024 1 day	
						Infusion	Intravenous use	21-AUG-2024 to 28-AUG-2024 8 days	
						Infusion	Intravenous use	26-JUN-2024 to 31-JUL-2024 1 month 6 days	

Concomitant Medication(s): PEMBROLIZUMAB (S) | CARBOPLATIN (S) | | Optive fusion (C) | Olanzapine (C) | Akynzeo (C) | Cetirizine (C)

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Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202412GLO005596AR	ARGENTINA 76 Years Female	**Leukocytosis (Leukocytosis)***	Fatal	05-Dec-2024 nk	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	to	
Concomitant Medication(s):									
202502GLO019767IN	INDIA 45 Years Female	**Pancytopenia (Pancytopenia)***	Recovered	21-Feb-2025 2 months 20 days	CARBOPLATIN	Infusion	Intravenous use	02-DEC-2024 to 11-FEB-2025 2 months 10 days	
						Infusion	2 milligram	02-DEC-2024 to 02-DEC-2024	
						Infusion	2 milligram	04-FEB-2025 to 04-FEB-2025	

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EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	2 milligram	09-DEC-2024 to 09-DEC-2024	
						Infusion	2 milligram	11-FEB-2025 to 11-FEB-2025	
						Infusion	2 milligram	13-JAN-2025 to 13-JAN-2025	
						Infusion	2 milligram	21-JAN-2025 to 21-JAN-2025	
						Infusion	2 milligram	23-DEC-2024 to 23-DEC-2024	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	2 milligram	30-DEC-2024 to 30-DEC-2024	
					GEMCITABINE	Infusion	1000 milligram/sq. meter q3w Intravenous use	02-DEC-2024 to 11-FEB-2025 2 months 10 days	
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	01-APR-2025 to 01-APR-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	02-DEC-2024 to 02-DEC-2024 1 day	
						Solution for infusion	200 milligram Intravenous use	04-FEB-2025 to 04-FEB-2025 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram Intravenous use	11-MAR-2025 to 11-MAR-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	13-JAN-2025 to 13-JAN-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	15-MAY-2025 to 15-MAY-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	23-DEC-2024 to 23-DEC-2024 1 day	
						Solution for infusion	200 milligram Intravenous use	24-APR-2025 to 24-APR-2025 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	02-DEC-2024 to 11-MAR-2025 3 months 10 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | GEMCITABINE (S) | losartan (C) | Atorvastatin (C) | Metformin (C) | Glimepiride (C) | Linagliptin (C) | Gemzar (C) | Ursodeoxycholic acid (C) | Avil (C) | Dexamethasone (C) | Rantac (C) | Thyronorm (C)									
202504GLO020746BR	BRAZIL 57 Years Female	**Anaemia (Anemia)** Thrombocytopenia (Thrombocytopenia)*	Not Recovered	11-Feb-2025 22 days	CARBOPLATIN	Infusion	Intravenous use	21-JAN-2025 to 11-SEP-2025 7 months 22 days	Periodic Report Comments. The patient experienced Anemia and Thrombocytopenia. Investigator causality not related for suspect Pembrolizumab and related for Carboplatin and Gemcitabine. CCA not related.
					GEMCITABINE	Infusion	1000 milligram/sq. meter q3w Intravenous use	21-JAN-2025 to 08-APR-2025 2 months 19 days	
						Infusion	750 milligram/sq. meter q3w Intravenous use	30-APR-2025 to 11-SEP-2025 4 months 13 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | GEMCITABINE (S) | Pegfilgrastim (C) | Escitalopram (C) | Ondansetron (C) | Dexamethasone (C) | Emend (C)									

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO000665BR	BRAZIL 57 Years Female	**Thrombocytopenia (Thrombocytopenia)***	Recovered	20-May-2025 nk	CARBOPLATIN	Infusion	Intravenous use	31-JUL-2025 to 31-JUL-2025 1 day	Periodic Report Comments. Patient experienced the event "Thrombocytopenia" . INV causality related to PEMBROLIZUMAB & CARBOPLATIN & GEMCITABINE. Company causality not related to PEMBROLIZUMAB & CARBOPLATIN & GEMCITABINE.
						Infusion	1 milligram q3w Intravenous use	10-JUL-2025 to 10-JUL-2025 1 day	
						Infusion	1.5 milligram q3w Intravenous use	05-MAY-2025 to 05-MAY-2025 1 day	
						Infusion	1.5 milligram q3w Intravenous use	10-JUN-2025 to 10-JUN-2025 1 day	
						Infusion	1.5 milligram q3w Intravenous use	18-JUN-2025 to 18-JUN-2025 1 day	

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Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

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						Infusion	1.5 milligram q3w Intravenous use	20-MAY-2025 to 20-MAY-2025 1 day	
						Infusion	1.5 milligram q3w Intravenous use	28-MAY-2025 to 28-MAY-2025 1 day	
						Infusion	1.5 milligram q3w Intravenous use	30-APR-2025 to 30-APR-2025 1 day	
						Infusion	2 milligram q3w Intravenous use	02-APR-2025 to 02-APR-2025 1 day	
						Infusion	2 milligram q3w Intravenous use	08-APR-2025 to 08-APR-2025 1 day	

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						Infusion	2 milligram q3w Intravenous use	12-MAR-2025 to 12-MAR-2025 1 day	
						Infusion	2 milligram q3w Intravenous use	18-MAR-2025 to 18-MAR-2025 1 day	
						Infusion	2 milligram q3w Intravenous use	19-FEB-2025 to 19-FEB-2025 1 day	
						Infusion	2 milligram q3w Intravenous use	21-JAN-2025 to 21-JAN-2025 1 day	
						Infusion	2 milligram q3w Intravenous use	26-FEB-2025 to 26-FEB-2025 1 day	

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						Infusion	2 milligram q3w Intravenous use	28-JAN-2025 to 28-JAN-2025 1 day	
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	31-JUL-2025 to 31-JUL-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	02-APR-2025 to 02-APR-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	04-JUL-2025 to 04-JUL-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	11-JUN-2025 to 11-JUN-2025 1 day	

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						Solution for infusion	200 milligram q3w Intravenous use	12-MAR-2025 to 12-MAR-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	19-FEB-2025 to 19-FEB-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	20-MAY-2025 to 20-MAY-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	21-JAN-2025 to 21-JAN-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	30-APR-2025 to 30-APR-2025 1 day	

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					GEMCITABINE	Infusion	1000 milligram/sq. meter q3w Intravenous use	02-APR-2025 to 02-APR-2025 1 day	
						Infusion	1000 milligram/sq. meter q3w Intravenous use	08-APR-2025 to 08-APR-2025 1 day	
						Infusion	1000 milligram/sq. meter q3w Intravenous use	12-MAR-2025 to 12-MAR-2025 1 day	
						Infusion	1000 milligram/sq. meter q3w Intravenous use	18-MAR-2025 to 18-MAR-2025 1 day	
						Infusion	1000 milligram/sq. meter q3w Intravenous use	19-FEB-2025 to 19-FEB-2025 1 day	

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						Infusion	1000 milligram/sq. meter q3w Intravenous use	21-JAN-2025 to 21-JAN-2025 1 day	
						Infusion	1000 milligram/sq. meter q3w Intravenous use	26-FEB-2025 to 26-FEB-2025 1 day	
						Infusion	1000 milligram/sq. meter q3w Intravenous use	28-JAN-2025 to 28-JAN-2025 1 day	
						Infusion	750 milligram/sq. meter q3w Intravenous use	04-JUL-2025 to 04-JUL-2025 1 day	
						Infusion	750 milligram/sq. meter q3w Intravenous use	05-MAY-2025 to 05-MAY-2025 1 day	

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						Infusion	750 milligram/sq. meter q3w Intravenous use	10-JUN-2025 to 10-JUN-2025 1 day	
						Infusion	750 milligram/sq. meter q3w Intravenous use	18-JUN-2025 to 18-JUN-2025 1 day	
						Infusion	750 milligram/sq. meter q3w Intravenous use	20-MAY-2025 to 20-MAY-2025 1 day	
						Infusion	750 milligram/sq. meter q3w Intravenous use	28-MAY-2025 to 28-MAY-2025 1 day	
						Infusion	750 milligram/sq. meter q3w Intravenous use	30-APR-2025 to 30-APR-2025 1 day	

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						Infusion	750 milligram/sq. meter q3w Intravenous use	31-JUL-2025 to 31-JUL-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | GEMCITABINE (S) | Dexamethasone (C) | Emend (C) | Escitalopram (C) | Pegfilgrastim (C) | Triamcinolone acetonide (C) | Red blood cells (C) | Dipyrone (C)									
202510GLO023917CA	CANADA Female	**Pancytopenia (Pancytopenia)***	Not Recovered	17-Oct-2025 nk	CARBOPLATIN	Infusion	1000 milligram Unknown	03-JUN-2025 to 03-JUN-2025 1 day	
						Infusion	1000 milligram Unknown	05-AUG-2025 to 05-AUG-2025 1 day	
						Infusion	1000 milligram Unknown	06-MAY-2025 to 06-MAY-2025 1 day	

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						Infusion	1000 milligram Unknown	07-OCT-2025 to 07-OCT-2025 1 day	
						Infusion	1000 milligram Unknown	08-JUL-2025 to 08-JUL-2025 1 day	
						Infusion	1000 milligram Unknown	09-SEP-2025 to 09-SEP-2025 1 day	
						Infusion	1000 milligram Unknown	13-MAY-2025 to 13-MAY-2025 1 day	
						Infusion	1000 milligram Unknown	15-JUL-2025 to 15-JUL-2025 1 day	

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						Infusion	1000 milligram Unknown	17-JUN-2025 to 17-JUN-2025 1 day	
						Infusion	1000 milligram Unknown	17-SEP-2025 to 17-SEP-2025 1 day	
						Infusion	1000 milligram Unknown	19-AUG-2025 to 19-AUG-2025 1 day	
						Infusion	1000 milligram Unknown	24-JUN-2025 to 24-JUN-2025 1 day	
						Infusion	1000 milligram Unknown	26-AUG-2025 to 26-AUG-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1000 milligram Unknown	27-MAY-2025 to 27-MAY-2025 1 day	
						Infusion	1000 milligram Unknown	29-JUL-2025 to 29-JUL-2025 1 day	
						Infusion	1000 milligram Unknown	30-SEP-2025 to 30-SEP-2025 1 day	
					GEMCITABINE	Infusion	Intravenous use	03-JUN-2025 to 03-JUN-2025 1 day	
						Infusion	Intravenous use	05-AUG-2025 to 05-AUG-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	06-MAY-2025 to 06-MAY-2025 1 day	
						Infusion	Intravenous use	07-OCT-2025 to 07-OCT-2025 1 day	
						Infusion	Intravenous use	08-JUL-2025 to 08-JUL-2025 1 day	
						Infusion	Intravenous use	09-SEP-2025 to 09-SEP-2025 1 day	
						Infusion	Intravenous use	13-MAY-2025 to 13-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	17-JUN-2025 to 17-JUN-2025 1 day	
						Infusion	Intravenous use	17-SEP-2025 to 17-SEP-2025 1 day	
						Infusion	Intravenous use	19-AUG-2025 to 19-AUG-2025 1 day	
						Infusion	Intravenous use	24-JUN-2025 to 24-JUN-2025 1 day	
						Infusion	Intravenous use	26-AUG-2025 to 26-AUG-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	27-MAY-2025 to 27-MAY-2025 1 day	
						Infusion	Intravenous use	29-JUL-2025 to 29-JUL-2025 1 day	
						Infusion	Intravenous use	30-SEP-2025 to 30-SEP-2025 1 day	
						Infusion	milligram Intravenous use	15-JUL-2025 to 15-JUL-2025 1 day	

Concomitant Medication(s): GEMCITABINE (S) | | PEMBROLIZUMAB (S) | Zopiclone (C) | Levothyroxine (C) | Senokot (C)

SOC:Gastrointestinal disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202505GLO002640IN	INDIA 38 Years Female	**Stomatitis (Mucositis oral)***	Recovered	05-May-2025 3 months 27 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	09-JAN-2025 to 25-APR-2025 3 months 17 days	Periodic Report Comments. Patient has event: Oral mucositis. For study therapy DATOPOTAMAB DERUXTECAN and DURVALUMAB Action Taken: no change for both the suspect. The investigator causality: related for therapy DATOPOTAMAB DERUXTECAN, not related for DURVALUMAB and Company causality: not related for both suspect.
Concomitant Medication(s): | DURVALUMAB (S) | Levoflox (C) | Augmentin (C)									
202505GLO012976AR	ARGENTINA 38 Years Female	**Diarrhoea (Diarrhea)***	Recovered	11-May-2025 4 months 25 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	14-JAN-2025 to 14-JAN-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	17-DEC-2024 to 17-DEC-2024 1 day	
Concomitant Medication(s): DURVALUMAB (S) | | Ibuprofen (C) | Ondansetron (C) | Hydrocortisone (C) | Meprednisone (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202506GLO005115BR	BRAZIL 65 Years Female	**Immune-mediated enterocolitis (Immune-mediated colitis)***	Recovered	05-Jun-2025 16 days	CARBOPLATIN	Infusion	Intravenous use	21-MAY-2025 to 02-JUL-2025 1 month 12 days	Patient experienced Immune-mediated enterocolitis. Investigator causality related to study therapy, CCA not related.
					GEMCITABINE	Infusion	1000 milligram/sq. meter Intravenous use	21-MAY-2025 to 02-JUL-2025 1 month 12 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | GEMCITABINE (S) | Losartan (C) | Paracetamol (C) | Bromopride (C) | Ansentron (C) | Ceftriaxone (C) | Metronidazole (C) | Morphine (C) | Scopolamine (C) | Enoxaparin (C) | Meticorten (C)									
202508GLO023704JP	JAPAN 59 Years Female	**Colitis (Colitis)***	Not Recovered	20-Aug-2025 nk	CARBOPLATIN	Infusion	2 milligram Intravenous use	02-MAY-2025 to 02-MAY-2025 1 day	
						Infusion	2 milligram Intravenous use	06-JUN-2025 to 06-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	2 milligram Intravenous use	09-MAY-2025 to 09-MAY-2025 1 day	
						Infusion	2 milligram Intravenous use	11-APR-2025 to 11- APR-2025 1 day	
						Infusion	2 milligram Intravenous use	14-JUL-2025 to 14- JUL-2025 1 day	
						Infusion	2 milligram Intravenous use	18-APR-2025 to 18- APR-2025 1 day	
						Infusion	2 milligram Intravenous use	18-MAR-2025 to 18-MAR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	2 milligram Intravenous use	20-JUN-2025 to 20-JUN-2025 1 day	
						Infusion	2 milligram Intravenous use	22-JUL-2025 to 22-JUL-2025 1 day	
						Infusion	2 milligram Intravenous use	27-JUN-2025 to 27-JUN-2025 1 day	
						Infusion	2 milligram Intravenous use	28-MAR-2025 to 28-MAR-2025 1 day	
						Infusion	2 milligram Intravenous use	30-MAY-2025 to 30-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					GEMCITABINE	Infusion	1000 milligram/sq. meter	14-JUL-2025 to 14-JUL-2025	
						Infusion	1000 milligram/sq. meter	18-MAR-2025 to 18-MAR-2025 1 day	
						Infusion	1000 milligram/sq. meter	27-JUN-2025 to 27-JUN-2025	
						Infusion	1000 milligram/sq. meter Intravenous use	02-MAY-2025 to 02-MAY-2025 1 day	
						Infusion	1000 milligram/sq. meter Intravenous use	06-JUN-2025 to 06-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1000 milligram/sq. meter Intravenous use	09-MAY-2025 to 09-MAY-2025 1 day	
						Infusion	1000 milligram/sq. meter Intravenous use	11-APR-2025 to 11-APR-2025 1 day	
						Infusion	1000 milligram/sq. meter Intravenous use	18-APR-2025 to 18-APR-2025 1 day	
						Infusion	1000 milligram/sq. meter Intravenous use	20-JUN-2025 to 20-JUN-2025 1 day	
						Infusion	1000 milligram/sq. meter Intravenous use	22-JUL-2025 to 22-JUL-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1000 milligram/sq. meter Intravenous use	28-MAR-2025 to 28-MAR-2025 1 day	
						Infusion	1000 milligram/sq. meter Intravenous use	30-MAY-2025 to 30-MAY-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | GEMCITABINE (S) | Apricot kernel water (C) | Diquas (C) | Hyaluronate (C) | Azunol (C) | Dexart (C) | Granisetron (C) | Decadron (C) | Granisetron (C) | Ursodeoxycholic acid (C) | Shakuyaku (C) | Imigran (C) | Esomeprazole (C) | Sodium ferrous citrate (C) | Magnesium oxide (C) | Loxoprofen (C) | Calonal (C)									

SOC:General disorders and administration site conditions

202509GLO006117JP	JAPAN 46 Years Female	**Pyrexia (Pyrexia)***	Recovered	05-Sep-2025 2 months 26 days	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	03-JUL-2025 to 03-JUL-2025 1 day	
						Injection	Intravenous use	11-JUN-2025 to 11-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	Intravenous use	27-AUG-2025 to 27-AUG-2025 1 day	
					DURVALUMAB	Infusion	1120 milligram Intravenous use	11-JUN-2025 to 27-AUG-2025 2 months 17 days	
Concomitant Medication(s): | DURVALUMAB (S) | Pontal (S) | Irbesartan (C) | Carvedilol (C) | Amlodipine (C) | Amlodipine besilate (C) | Loxoprofen sodium (C) | Rabeprazole sodium (C) | Epinastine hydrochloride (C) | Acetaminophen (C) | Aprepitant (C) | Azunol (C) | Dexart (C) | Famotidine (C) | Palonosetron (C) | Restamin kowa (C) | Novamin (C)									

SOC:Hepatobiliary disorders

202504GLO020777CN	CHINA 58 Years Female	**Hepatic function abnormal (Hepatic function abnormal)***	Recovered	25-Mar-2025 8 months 14 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	12-JUL-2024 to 18-JUN-2025 11 months 7 days	Periodic Report Comments. Patient has event Hay's law. Action taken with study therapy was No change. Investigator Causality: Related, CC: Related; Periodic report comment. Patient has event : Hay's law. For study therapy Action Taken: No change, Investigator Causality: Related, CC: Related. Outcome: not Recovered.
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	12-JUL-2024 to 03-APR-2025 8 months 23 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | DURVALUMAB (S) | Acarbose (C) | Paracetamol (C) | Cimetidine (C) | Palonosetron (C) | Insulin aspart (C) | Metformin hydrochloride (C) | Polyene phosphatidylcholine (C) | Bicyclol (C) | Dexamethasone sodium phosphate (C) | Diphenhydramine (C) | Silymarin (C) | Magnesium Isoglycyrrhizinate (C)									
202507GLO026923JP	JAPAN 46 Years Female	**Hepatic function abnormal** **(Hepatic dysfunction NOS)***	Recovered	26-Jul-2025 1 month 16 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram Intravenous use	27-AUG-2025 to 27-AUG-2025 1 day	
						Injection	6 milligram/kilogram Intravenous use	11-JUN-2025 to 03-JUL-2025 23 days	
					DURVALUMAB	Infusion	1120 milligram Intravenous use	11-JUN-2025 to 27-AUG-2025 2 months 17 days	
Concomitant Medication(s): | DURVALUMAB (S) | Irbesartan (C) | Carvedilol (C)									

SOC:Infections and infestations

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202506GLO014464CN	CHINA 42 Years Female	**Pneumonia (Pneumonia)***	Recovered	16-Jun-2025 7 months 19 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	29-OCT-2024 to 19-AUG-2025 9 months 22 days	Periodic Report Comment. Patient experienced pneumonia, Inv: related to Datopotamab Deruxtecan and Durvalumab, CCA: not related to Datopotamab Deruxtecan and Durvalumab.

Concomitant Medication(s): | DURVALUMAB (S) | Budesonide (C) | Terbutaline sulfate (C) | Ambroxol hydrochloride (C) | Cefoperazone sodium and sulbactam sodium (C) | Moxifloxacin hydrochloride (C) | Iopromide (C) | Gadopentetic acid (C)

SOC:Injury, poisoning and procedural complications

202510GLO008998US	UNITED STATES 41 Years	**Spinal fracture (Spinal fracture)***	Not Recovered	nk nk	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	to	

Concomitant Medication(s):

SOC:Investigations

202505GLO010258ZA	SOUTH AFRICA 45 Years Female	**Blood creatine phosphokinase increased (Creatine phosphokinase increased)***	Recovered	09-May-2025 1 month 22 days	DATOPOTAMAB DERUXTECAN	Injection	350 milligram q3w Intravenous use	18-MAR-2025 to 09-APR-2025 23 days	Periodic Report Comments. Patient experienced raised creatine phosphokinase .Inv, related to DATOPOTAMAB DERUXTECAN and DURVALUMAB,Inv, related to DATOPOTAMAB DERUXTECAN and DURVALUMAB CCA :

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
									related to DATOPOTAMAB DERUXTECAN and DURVALUMAB ,Inv, related to DATOPOTAMAB DERUXTECAN and DURVALUMAB ,CCA : related to DATOPOTAMAB DERUXTECAN and DURVALUMAB,Inv, related to DATOPOTAMAB DERUXTECAN and DATOPOTAMAB DERUXTECAN and DURVALUMAB , CCA: not related to DATOPOTAMAB DERUXTECAN and DURVALUMAB,Inv, related to DATOPOTAMAB DERUXTECAN and DURVALUMAB;periodic report comment. Patient experienced raised creatine phosphokinase .Investigator, related to DATOPOTAMAB DERUXTECAN and unrelated to DURVALUMAB, CCA : unrelated to DATOPOTAMAB DERUXTECAN and DURVALUMAB. Action taken with DATOPOTAMAB DERUXTECAN and DURVALUMAB was not applicable.
Concomitant Medication(s): | DURVALUMAB (S) | Panado (C) | Tramal (C) | Prednisone (C) | Ferrous sulphate (C) | Red blood cells (C) | Andolex (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202505GLO013757JP	JAPAN 55 Years Female	**Platelet count decreased (Platelet count decreased)*** Neutrophil count decreased (Neutrophil count decreased)*	Recovered	08-May-2025 8 days	CARBOPLATIN	Infusion	Intravenous use	01-MAY-2025 to 29-MAY-2025 29 days	
						Infusion	Intravenous use	10-JUL-2025 to 31-JUL-2025 22 days	
						Infusion	Intravenous use	19-JUN-2025 to 19-JUN-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | GEMCITABINE (S) | | Arotinolol (C) | Paxil (C) | Rivotril (C) | Transino (C) | Methycobal (C) | Loxonin (C) | Loxonin (C) | Dexart (C) | Granisetron (C) | Metoclopramide (C) | Mentholatum (C) | Fexofenadine (C) | Rinderon (C) | Calonal (C) | Antebate (C) | Fexofenadine (C) | Hirudoid (C)									
202509GLO003472CN	CHINA 33 Years Female	**Alanine aminotransferase increased (Alanine aminotransferase increased)***	Recovered	03-Sep-2025 28 days	CARBOPLATIN	Infusion	Intravenous use	07-AUG-2025 to 28-AUG-2025 22 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	07-SEP-2025 to 07-SEP-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | GEMCITABINE (S)									
202510GLO006552AR	ARGENTINA 72 Years Female	**Amylase increased (Amylase increased)***	Recovering	07-Oct-2025 5 months 13 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	25-APR-2025 to 19-SEP-2025 4 months 26 days	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	25-APR-2025 to 18-SEP-2025 4 months 25 days	
Concomitant Medication(s): | DURVALUMAB (S) | Metformin (C) | Levotiroxin (C) | Carvedilol (C) | Valsartan (C)									

SOC:Metabolism and nutrition disorders

202412GLO000868VN	VIET NAM 35 Years Female	**Acidosis (Acidosis)***	Recovered with Sequelae	02-Dec-2024 4 months 21 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	12-JUL-2024 to 14-NOV-2024 4 months 3 days	Periodic Report Comments. Patient experienced Glucose disorder related with pembrolizumab and not related to paclitaxel.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | PACLITAXEL (S) | Levothyrox (C) | Iopamidol (C) | Dimedrol (C) | Solumedrol (C) | Vinfadin (C) | Degas (C) | Dexamethason (C) | Dimerol (C) | Famotidin (C) | Methylprednisolon (C) | Carvedilol (C) | Levothyroxine (C) | Berlthyrox (C) | Camlyhepatinsof (C) | Ursobil (C) | Vihacaps (C) | Carvestad (C)									
202504GLO014918US	UNITED STATES 63 Years Female	**Hyponatraemia (Hyponatremia)***	Recovered	14-Apr-2025 1 month 2 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	03-APR-2025 to 03-APR-2025 1 day	periodic report comment. Patient has event : Hyponatremia For study therapy Action Taken: drug interrupted, Investigator Causality: Related, CC: Not Related. Outcome: Recovering.
						Injection	6 milligram/kilogram q3w Intravenous use	13-MAR-2025 to 13-MAR-2025 1 day	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	03-APR-2025 to 03-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	13-MAR-2025 to 13-MAR-2025 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | Lipitor (C) | Cozaar (C) | Glucophage xr (C) | Decadron (C) | Zofran (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202505GLO020863CN	CHINA 62 Years Female	**Hypokalaemia (Hypokalemia)***	Recovered	23-May-2025 2 months 13 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w	01-APR-2025 to 01-APR-2025 1 day	Periodic Report Comments. Patient has event : Hypokalemia. For study therapy Action Taken: drug interrupted, Investigator Causality: Related, CC: Not Related. Outcome: not Recovered.;Periodic Report Comments. The patient experienced Hypokalemia. Action taken withdrawn for suspect Dato-DXd and no change for Durvalumab. Investigator causality related for both suspect. CCA not related.
						Injection	6 milligram/kilogram q3w Intravenous use	11-MAR-2025 to 11-MAR-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	22-APR-2025 to 22-APR-2025 1 day	
					DURVALUMAB	Infusion	1120 milligram q3w	01-APR-2025 to 01-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	11-MAR-2025 to 11-MAR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	22-APR-2025 to 22-APR-2025 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | Sodium hyaluronate (C) | Mouth wash (C) | Dexamethasone (C)									
202508GLO017422BR	BRAZIL 74 Years Female	**Hyponatraemia (Hyponatremia)***	Recovered	21-Aug-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	05-SEP-2025 to 05-SEP-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	14-AUG-2025 to 14-AUG-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	16-OCT-2025 to 16-OCT-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	25-SEP-2025 to 25-SEP-2025 1 day	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	05-SEP-2025 to 05-SEP-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-AUG-2025 to 14-AUG-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	16-OCT-2025 to 16-OCT-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	25-SEP-2025 to 25-SEP-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | DURVALUMAB (S) | Losartan (C) | Rosuvastatin (C) | Epez (C) | Somalgin cardio (C) | Captopril (C) | Cimetidine (C) | Clonidine (C) | Cutisanol (C) | Diphenhydramine (C) | Amlodipine (C) | Enoxaparin (C) | Dipyrone (C) | Insulin glulisine (C) | Sodium hyaluronate (C) | Ondansetron (C)									
SOC:Renal and urinary disorders									
202508GLO022692CA	CANADA 68 Years Female	**Immune-mediated nephritis (Immune-mediated nephritis)***	Not Recovered	26-Aug-2025 10 months 24 days	DURVALUMAB	Infusion	1120 milligram Intravenous use	03-OCT-2024 to 07-AUG-2025 10 months 5 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Levothyroxine (C)									
SOC:Reproductive system and breast disorders									
202508GLO023853VN	VIET NAM 65 Years Female	**Breast ulceration (Breast ulceration)***	Recovering	27-Aug-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	to	
Concomitant Medication(s): | PEMBROLIZUMAB (S) | CARBOPLATIN (S) | GEMCITABINE (S)									
SOC:Respiratory, thoracic and mediastinal disorders									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202411GLO002664CN	CHINA 69 Years Female	**Pleural effusion (Pleural effusion)***	Not Recovered	03-Nov-2024 5 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	21-DEC-2024 to 23-JAN-2025 1 month 3 days	
						Solution for infusion	200 milligram q3w Intravenous use	30-OCT-2024 to 11-DEC-2024 1 month 12 days	
Concomitant Medication(s): | NAB-PACLITAXEL (S) | Amlodipine besylate (C) | Codeine phosphate (C) | Polyethylene glycol (C) | Calcium carbonate (C) | Celecoxib (C) | Denosumab (C) | Dolasetron (C) | Ilaprazole sodium (C) | Mecobalamin (C) | Vitamin b complex (C)									
202501GLO009576ZA	SOUTH AFRICA 48 Years Female	**Dyspnoea (Shortness of breath)***	Not Recovered	12-Jan-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	to	Periodic Report Comments. Patient has event: Shortness of breath. For study therapy Action Taken: Not Applicable, Investigator Causality: Not Reported, CC: Not Applicable. Outcome: Not Recovered.
					DURVALUMAB	Infusion	Intravenous use	to	
Concomitant Medication(s): | DURVALUMAB (S) | Actraphane (C) | Panado (C) | Maxolon (C) | Tramal (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202509GLO020241TH	THAILAND 65 Years Female	**Pleural effusion (Pleural effusion)***	Not Recovered	22-Sep-2025 nk	PEMBROLIZUMAB	Solution for infusion	q3w Intravenous use	to	
Concomitant Medication(s):									
202510GLO009267ES	SPAIN Female	**Pleural effusion (Pleural effusion)***	Not Recovered	09-Oct-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	to	
					DURVALUMAB	Infusion	Intravenous use	to	
Concomitant Medication(s): DURVALUMAB (S) |									

SOC:Skin and subcutaneous tissue disorders

202501GLO008003TW	TAIWAN 38 Years Female	**Urticaria (Urticaria)***	Not Recovered	03-Jan-2025 5 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	03-MAR-2025 to 03-MAR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	05-MAY-2025 to 05-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	11-FEB-2025 to 11-FEB-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-APR-2025 to 14-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-JAN-2025 to 20-JAN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	25-MAR-2025 to 25-MAR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D7630

Study ID: D7630C00001

EudraCT No: 2023-503675-24-00

Study Design: Not Blinded

Study Description: D7630C00001 Pivotal Comparator 2 Study (Multiple Analysis) - A Phase III, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Compared with Investigator's Choice of Chemotherapy (Paclitaxel, Nab-paclitaxel or Gemcitabine + Carboplatin) in Combination With Pembrolizumab in Patients with PD-L1 Positive Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer (TROPION-Breast05)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	30-DEC-2024 to 30-DEC-2024 1 day	

Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Dexamethasone (C) | Palonosetron (C) | Diphenhydramine (C) | Zepsin (C)

SOC:Vascular disorders

202506GLO000033MX	MEXICO 51 Years Female	**Deep vein thrombosis (Deep vein thrombosis)*** Pulmonary embolism (Pulmonary thromboembolism)*	Recovered	31-May-2025 4 months 4 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram Intravenous use	16-APR-2025 to 29-MAY-2025 1 month 14 days	Patient exp deep vein thrombosis and right segmental pulmonary thromboembolism Inv: Related to DATOPOTAMAB DERUXTECAN and not related DURVALUMAB , CCA: Not related.
						Injection	6 milligram/kilogram Intravenous use	28-JAN-2025 to 13-MAR-2025 1 month 14 days	

Concomitant Medication(s): | DURVALUMAB (S) | Paracetamol (C) | Tramadol (C) | Buprenorphine (C) | Aprepitant (C) | Dexamethasone (C) | Diphenhydramine (C) | Palonosetron (C) | Olanzapine (C) | Ondansetron (C) | Sodium hyaluronate (C) | Trehalose (C) | Vitamin e (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D781P

EudraCT No:

Study Design: Not Blinded

Study ID: D781PC00001

Study Description: DESTINY-Biliary Tract Cancer-01: A Phase 3 Study of Trastuzumab Deruxtecan (T-DXd) and Rilvegostomig versus Standard-of-Care gemcitabine, cisplatin, and durvalumab for first line locally advanced or metastatic HER2-expressing Biliary Tract Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:General disorders and administration site conditions									
202509GLO025655CN	CHINA Female	**Fatigue (Fatigue)***	Recovered	23-Aug-2025 nk	DURVALUMAB	Infusion	1500 milligram Intravenous use	09-AUG-2025 to 09-AUG-2025	
						Infusion	1500 milligram Intravenous use	09-SEP-2025 to 09-SEP-2025 1 day	

Concomitant Medication(s): | CISPLATIN (S) | GEMCITABINE (S) | Irbesartan (C) | Concentrated sodium chloride (C) | Fosaprepitant dimeglumine (C) | Human insulin (C) | Lidocaine hydrochloride (C) | Ondansetron hydrochloride (C) | Potassium chloride (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9075

Study ID: D9075C00001

EudraCT No: 2023-506891-28-00

Study Design: Double Blinded

Study Description: D9075C00001 Imfinzi+ TIGIT Loc Adv Stage 3 NSCLC (PACIFIC-8) - A Phase III, Randomised, Double blind, Placebo controlled, Multicentre, International Study of Durvalumab plus Domvanalimab (AB154) in Participants with Locally Advanced (Stage III), Unresectable Non small Cell Lung Cancer Whose Disease has not Progressed Following Definitive Platinum based Concurrent Chemoradiation Therapy (PACIFIC-8)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Cardiac disorders									
202505GLO023694GB	UNITED KINGDOM 75 Years Male	**Immune-mediated myocarditis (Immune-mediated myocarditis)***	Not Recovered	25-May-2025 1 month 19 days					
Concomitant Medication(s):									
SOC:Endocrine disorders									
202508GLO017058CL	CHILE 70 Years Male	**Hypothyroidism (Hypothyroidism)***	Recovering	06-Aug-2025 nk					
Concomitant Medication(s):									
SOC:Gastrointestinal disorders									
2023A158359	TURKEY 80 Years Male	**Autoimmune colitis (Autoimmune colitis)***	Recovered with Sequelae	04-Jul-2023 14 weeks 5 days					

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9075

Study ID: D9075C00001

EudraCT No: 2023-506891-28-00

Study Design: Double Blinded

Study Description: D9075C00001 Imfinzi+ TIGIT Loc Adv Stage 3 NSCLC (PACIFIC-8) - A Phase III, Randomised, Double blind, Placebo controlled, Multicentre, International Study of Durvalumab plus Domvanalimab (AB154) in Participants with Locally Advanced (Stage III), Unresectable Non small Cell Lung Cancer Whose Disease has not Progressed Following Definitive Platinum based Concurrent Chemoradiation Therapy (PACIFIC-8)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s):									
2024A118823	TURKEY 62 Years Male	**Autoimmune pancreatitis (Autoimmune pancreatitis)***	Not Recovered	20-May-2024 10 months 17 days					
Concomitant Medication(s):									
202506GLO011673JP	JAPAN 64 Years Male	**Pancreatitis (Pancreatitis)***	Not Recovered	12-Jun-2025 nk					
Concomitant Medication(s):									
202506GLO014488GB	UNITED KINGDOM 78 Years Male	**Colitis microscopic (Colitis collagenous)***	Recovered with Sequelae	07-Jun-2025 2 days					
Concomitant Medication(s):									

SOC:Hepatobiliary disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9075

Study ID: D9075C00001

EudraCT No: 2023-506891-28-00

Study Design: Double Blinded

Study Description: D9075C00001 Imfinzi+ TIGIT Loc Adv Stage 3 NSCLC (PACIFIC-8) - A Phase III, Randomised, Double blind, Placebo controlled, Multicentre, International Study of Durvalumab plus Domvanalimab (AB154) in Participants with Locally Advanced (Stage III), Unresectable Non small Cell Lung Cancer Whose Disease has not Progressed Following Definitive Platinum based Concurrent Chemoradiation Therapy (PACIFIC-8)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO004988NO	NORWAY 51 Years Female	**Hepatitis (Hepatitis)***	Recovered	05-May-2025 nk					
Concomitant Medication(s):									
202509GLO016122GB	UNITED KINGDOM 68 Years Female	**Liver injury (Liver injury)***	Not Recovered	17-Sep-2025 7 months 9 days 10 hrs 1 min					
Concomitant Medication(s):									
SOC:Infections and infestations									
202506GLO011026BR	BRAZIL 69 Years Male	**Pneumonia (Pneumonia)***	Recovered	13-Jun-2025 nk					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9075

Study ID: D9075C00001

EudraCT No: 2023-506891-28-00

Study Design: Double Blinded

Study Description: D9075C00001 Imfinzi+ TIGIT Loc Adv Stage 3 NSCLC (PACIFIC-8) - A Phase III, Randomised, Double blind, Placebo controlled, Multicentre, International Study of Durvalumab plus Domvanalimab (AB154) in Participants with Locally Advanced (Stage III), Unresectable Non small Cell Lung Cancer Whose Disease has not Progressed Following Definitive Platinum based Concurrent Chemoradiation Therapy (PACIFIC-8)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO021908GB	UNITED KINGDOM 73 Years Female	**Pneumonia (Pneumonia)***	Recovering	26-Aug-2025 nk					
Concomitant Medication(s):									
202510EEA014185GB	UNITED KINGDOM Unknown	**Influenza (Influenza)*** Leukopenia (Leukopenia)*	Unknown	nk nk					
Concomitant Medication(s):									
202510GLO007843KR	KOREA, REPUBLIC OF 70.7 Years Male	**Pneumocystis jirovecii pneumonia (Pneumocystis pneumonia)***	Fatal	30-Sep-2025 nk					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9075

Study ID: D9075C00001

EudraCT No: 2023-506891-28-00

Study Design: Double Blinded

Study Description: D9075C00001 Imfinzi+ TIGIT Loc Adv Stage 3 NSCLC (PACIFIC-8) - A Phase III, Randomised, Double blind, Placebo controlled, Multicentre, International Study of Durvalumab plus Domvanalimab (AB154) in Participants with Locally Advanced (Stage III), Unresectable Non small Cell Lung Cancer Whose Disease has not Progressed Following Definitive Platinum based Concurrent Chemoradiation Therapy (PACIFIC-8)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Nervous system disorders									
2022A283391	TURKEY 66 Years Male	**IIIrd nerve paresis (IIIrd nerve paresis)***	Recovered	02-Jun-2022 10 weeks 6 days					
Concomitant Medication(s):									
SOC:Respiratory, thoracic and mediastinal disorders									
2023A232682	BELGIUM 78.8 Years Male	**Pneumonitis (Pneumonitis)***	Recovered	04-Oct-2023 1 month 26 days					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9075

Study ID: D9075C00001

EudraCT No: 2023-506891-28-00

Study Design: Double Blinded

Study Description: D9075C00001 Imfinzi+ TIGIT Loc Adv Stage 3 NSCLC (PACIFIC-8) - A Phase III, Randomised, Double blind, Placebo controlled, Multicentre, International Study of Durvalumab plus Domvanalimab (AB154) in Participants with Locally Advanced (Stage III), Unresectable Non small Cell Lung Cancer Whose Disease has not Progressed Following Definitive Platinum based Concurrent Chemoradiation Therapy (PACIFIC-8)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A290319	CHILE 78 Years Female	**Pneumonitis (Pneumonitis)***	Fatal	12-Dec-2023 1 month 27 days					
Concomitant Medication(s):									
2024A177559	POLAND 63 Years Male	**Respiratory failure (Respiratory insufficiency)***	Recovered	01-Aug-2024 19 weeks 3 days					
Concomitant Medication(s):									
202504GLO021774GR	GREECE 81.3 Years Male	**Pneumonitis (Pneumonitis)***	Not Recovered	12-Apr-2025 11 days					
Concomitant Medication(s):									
202506GLO001644JP	JAPAN 73 Years Male	**Pneumonitis (Pneumonitis)***	Recovering	30-May-2025 nk					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9075

Study ID: D9075C00001

EudraCT No: 2023-506891-28-00

Study Design: Double Blinded

Study Description: D9075C00001 Imfinzi+ TIGIT Loc Adv Stage 3 NSCLC (PACIFIC-8) - A Phase III, Randomised, Double blind, Placebo controlled, Multicentre, International Study of Durvalumab plus Domvanalimab (AB154) in Participants with Locally Advanced (Stage III), Unresectable Non small Cell Lung Cancer Whose Disease has not Progressed Following Definitive Platinum based Concurrent Chemoradiation Therapy (PACIFIC-8)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202506GLO015435CL	CHILE 76 Years Male	**Lung disorder (Pneumopathy)***	Recovered	17-Jun-2025 2 months 17 days					
Concomitant Medication(s):									
202507GLO009875DE	GERMANY 61.5 Years Female	**Pneumonitis (Pneumonitis)***	Not Recovered	10-Jul-2025 nk					
Concomitant Medication(s):									
202508GLO012267US	UNITED STATES 78 Years Male	**Pneumonitis (Pneumonitis)***	Recovering	12-Aug-2025 21 days					
Concomitant Medication(s):									
202509GLO004727CL	CHILE 63 Years Female	**Pneumonitis (Pneumonitis)***	Recovered	28-Apr-2025 3 months 3 days 11 hrs 20 min					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9075

Study ID: D9075C00001

EudraCT No: 2023-506891-28-00

Study Design: Double Blinded

Study Description: D9075C00001 Imfinzi+ TIGIT Loc Adv Stage 3 NSCLC (PACIFIC-8) - A Phase III, Randomised, Double blind, Placebo controlled, Multicentre, International Study of Durvalumab plus Domvanalimab (AB154) in Participants with Locally Advanced (Stage III), Unresectable Non small Cell Lung Cancer Whose Disease has not Progressed Following Definitive Platinum based Concurrent Chemoradiation Therapy (PACIFIC-8)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202510GLO008735BR	BRAZIL 67 Years Female	**Pneumonitis (Pneumonitis)***	Recovered	07-Oct-2025 nk					

Concomitant Medication(s):

SOC:Skin and subcutaneous tissue disorders

202507GLO025726HU	HUNGARY 75 Years Female	**Urticaria (Urticaria)***	Recovering	25-Jul-2025 5 months 14 days					

Concomitant Medication(s):

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9077

Study ID: D9077C00001

EudraCT No: 2023-508852-21-00

Study Design: Not Blinded

Study Description: D9077C00001 NeoAdjuvant & Adjuvant treatment in Resectable NSCLC (NeoCOAST 2.0) - A Phase II Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
2024A160065	ITALY 73 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	08-Jul-2024 1 week 3 days	CARBOPLATIN	Infusion	Intravenous use	28-JUN-2024 to 04-OCT-2024 3 months 7 days	Patient experienced Febrile neutropenia. Inv, not related to pemetrexed, and company causality not related.
					PEMETREXED	Infusion	Intravenous use	28-JUN-2024 to 04-OCT-2024 3 months 7 days	
Concomitant Medication(s): MEDI 5752 (S) | PEMETREXED (S) | | Deltacortene (C) | Zopraz (C) | Tabumol (C)									
202505GLO014166ES	SPAIN 54 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	13-May-2025 12 days 14 hrs 10 min	AZD2936	Solution	Intravenous use	20-MAY-2025 to 01-JUL-2025 13:55 1 month 11 days 13 hrs 55 min	Periodic Report Comments. The patient experienced Febrile neutropenia. Investigator causality related for suspect Rilvestomig, Paclitaxel and Carboplatin. CCA not related.
						Solution	750 milligram q3w Intravenous use	30-APR-2025 09:50 to 30-APR-2025 10:50 1 hr	
Concomitant Medication(s): | PACLITAXEL (S) | CARBOPLATIN (S) | Lorazepam (C) | Paracetamol (C) | Prednisone (C) | Dexclorfeniramina (C) | Dexamethasone (C) | Ondansetron (C) | Famotidine (C) | Methylprednisolone (C) | Metoclopramide (C) | Pantoprazole (C) | Enoxaparin (C) | Metamizole (C) | Dexketoprofen (C) | Sulfamethoxazole (C)									

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9077

Study ID: D9077C00001

EudraCT No: 2023-508852-21-00

Study Design: Not Blinded

Study Description: D9077C00001 NeoAdjuvant & Adjuvant treatment in Resectable NSCLC (NeoCOAST 2.0) - A Phase II Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Cardiac disorders									
2024A196185	SPAIN 60 Years Female	**Immune-mediated myocarditis (Immune-mediated myocarditis)*** Respiratory failure (Respiratory failure)*	Recovered	22-Aug-2024 2 weeks	MEDI5752	Infusion	750 milligram Intravenous use	08-AUG-2024 to	
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | Simvastatin (C) | Lisinopril (C) | Prednisone (C) | Mycophenolate (C)									
SOC:Gastrointestinal disorders									
2023A239225	PORTUGAL 78 Years Male	**Intestinal ischaemia (Intestinal ischemia)*** Septic shock (Septic shock)* Febrile neutropenia (Febrile neutropenia)	Fatal	17-Oct-2023 5 weeks	CARBOPLATIN	Infusion	380 milligram Intravenous use	06-OCT-2023 to 06-OCT-2023 1 day	Periodic Report Comment. patient experience serious intestinal ischemia. Inv related to Study Procedure. CCA: not related to IP.
						Infusion	380 milligram Intravenous use	12-SEP-2023 to 12-SEP-2023 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9077

Study ID: D9077C00001

EudraCT No: 2023-508852-21-00

Study Design: Not Blinded

Study Description: D9077C00001 NeoAdjuvant & Adjuvant treatment in Resectable NSCLC (NeoCOAST 2.0) - A Phase II Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PACLITAXEL	Infusion	175 milligram/sq. meter Intravenous use	06-OCT-2023 to 06-OCT-2023 1 day	
						Infusion	175 milligram/sq. meter Intravenous use	12-SEP-2023 to 12-SEP-2023 1 day	
Concomitant Medication(s): DURVALUMAB (S) | OLECLUMAB (S) | | PACLITAXEL (S) | METFORMINE (C) | FENOFIBRATE (C) | Acetylsalicylic acid (C) | BISOPROLOL (C) | GLICLAZIDE (C) | RILMENIDINE (C) | RUSCOGENINA (C) | BIOFLAVONOIDS (C) | FLUOCORTOLONA (C) | FILGRASTIM (C) | Acacia (C) | MEROPENEM (C) | PROPOFOL (C) | NORADRENALINE (C) | KETAMINE (C) | FENTANYL (C) | MIDAZOLAM (C) | Pegfilgrastim (C) | Piperacillin/tazobactam (C) | Ciprofloxacin (C) | Rocuronium bromide (C) | Vancomycin (C) | Hydrocortisone (C) | Potassium chloride (C) | Fludrocortisone (C) | Insulin (C) | Pantoprazole (C) | Vasopressin (C) | Albumin (C) | Methylene Blue (C) | Atorvastatine (C)									
2024A053385	SPAIN 81 Years Male	**Abdominal pain (Abdominal pain)***	Recovered	23-Dec-2023 14 weeks 1 day	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	11-OCT-2023 to 11-DEC-2023 8 weeks 6 days	Periodic Report Comment. Patient experience Abdominal pain serious and Inv. Related to Durvalumab, Datopotamab Deruxtecan Comp: Not related to Durvalumab, Datopotamab Deruxtecan.
						Injection	504 milligram/kilogram Intravenous use	15-SEP-2023 to 15-SEP-2023 1 day	
Concomitant Medication(s): DURVALUMAB (S) | | Carboplatin (S) | Olanzapine (C) | Dexamethasone (C) | Paracetamol (C) | Dexchlorpheniramine (C) | Vilanterol (C) | Alopurinol (C) | Metformin (C) | Doxazosin (C) | Olmesartan (C) | Omeprazole (C) | Simvastatin (C) | Dapagliflozin (C) | Diltiazem (C) | Acetylsalicylic acid (C) | Furoato de fluticasona (C) | Umeclidinium (C)									

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9077

Study ID: D9077C00001

EudraCT No: 2023-508852-21-00

Study Design: Not Blinded

Study Description: D9077C00001 NeoAdjuvant & Adjuvant treatment in Resectable NSCLC (NeoCOAST 2.0) - A Phase II Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO010747PT	PORTUGAL 62 Years Male	**Immune-mediated enterocolitis (Immune-mediated colitis)***	Recovered	07-Jul-2025 1 year 5 months 9 days	CARBOPLATIN	Infusion	524 milligram q3w Intravenous use	29-JAN-2024 to 02-APR-2024 2 months 5 days	Patient experienced immune-mediated colitis. Investigator causality related to durvalumab, not reported to carboplatin and datopotamab deruxtecan. CCA not related.;Periodic Report Comments. Male Patient experienced immune-mediated colitis. Investigator causality related to durvalumab, not related to carboplatin and datopotamab deruxtecan. CCA not related.
					DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	29-JAN-2024 to 03-APR-2024 2 months 6 days	
Concomitant Medication(s): DURVALUMAB (S) | | DATOPOTAMAB DERUXTECAN (S) | Artelac (C) | Blephaclean (C) | Metoclopramide (C) | Loperamide (C) | Pantoprazole (C) | Aspirin (C) | Atorvastatin (C)									
202509GLO027484KR	KOREA, REPUBLIC OF 66 Years Female	**Diarrhoea (Diarrhea)***	Recovered	23-Sep-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	02-OCT-2025 10:09 to 02-OCT-2025 11:39 1 hr 30 min	
Concomitant Medication(s): AZD2936 (S) | | PEMETREXED (S) | Glimel (C) | Lipinon (C) | Zemimet (C) | Dapalon (C) | Slivan (C) | Perphenazine (C) | Concor (C)									
202509GLO028076IT	ITALY 70 Years Female	**Diarrhoea (Diarrhea)***	Not Recovered	18-Sep-2025 2 months 1 day	AZD2936	Solution	750 milligram q3w Unknown	18-JUL-2025 to	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9077

Study ID: D9077C00001

EudraCT No: 2023-508852-21-00

Study Design: Not Blinded

Study Description: D9077C00001 NeoAdjuvant & Adjuvant treatment in Resectable NSCLC (NeoCOAST 2.0) - A Phase II Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DATOPOTAMAB DERUXTECAN	Injection	Unknown	18-JUL-2025 to	

Concomitant Medication(s): | DATOPOTAMAB DERUXTECAN (S) | CARBOPLATIN (S) | PEMETREXED (S) | Alprazolam (C) | Ondansetron (C) | Dexamethasone (C)

SOC:General disorders and administration site conditions

202501GLO019123FR	FRANCE 59 Years Male	**General physical health deterioration (General physical health deterioration)***	Not Recovered	16-Jan-2025 10 months 19 days	DURVALUMAB	Infusion	1500 milligram Intravenous use	01-AUG-2024 13:16 to 01-AUG-2024 14:18 1 hr 2 min
						Infusion	1500 milligram Intravenous use	03-MAY-2024 15:00 to 03-MAY-2024 16:00 1 hr
						Infusion	1500 milligram Intravenous use	04-JUL-2024 11:20 to 04-JUL-2024 12:20 1 hr

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-508852-21-00

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram Intravenous use	12-APR-2024 15:30 to 12-APR-2024 16:30 1 hr	
						Infusion	1500 milligram Intravenous use	21-NOV-2024 11:45 to 21-NOV-2024 12:45 1 hr	
						Infusion	1500 milligram Intravenous use	21-NOV-2024 13:10 to 19-DEC-2024 27 days 10 hrs 50 min	
						Infusion	1500 milligram Intravenous use	22-MAR-2024 15:16 to 22-MAR-2024 16:15 59 min	
						Infusion	1500 milligram Intravenous use	24-OCT-2024 12:00 to 24-OCT-2024 13:00 1 hr	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9077

Study ID: D9077C00001

EudraCT No: 2023-508852-21-00

Study Design: Not Blinded

Study Description: D9077C00001 NeoAdjuvant & Adjuvant treatment in Resectable NSCLC (NeoCOAST 2.0) - A Phase II Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram Intravenous use	26-SEP-2024 12:00 to	
						Infusion	1500 milligram Intravenous use	27-AUG-2024 12: 00 to 27-AUG-2024 13:00 1 hr	
						Infusion	1500 milligram Intravenous use	29-FEB-2024 to 19-DEC-2024 9 months 21 days	

Concomitant Medication(s): | DATOPOTAMAB DERUXTECAN (S) | CARBOPLATIN (S) | Lercanidipine (C) | Metformin (C) | Aprepitant (C) | Trelegy (C) | Ondansetron (C) | Methylprednisolone (C) | Polaramine (C) | Terbutaline (C) | Pelmeg (C) | Rozex (C) | Dexamethasone (C) | Diprosone (C) | Paracetamol (C) | Acupan (C) | Tramadol (C) | Macrogol (C) | Lovenox (C) | Tiorfan (C) | Entocort (C) | Loperamide (C) | Lamaline (C) | Eliquis (C) | Nicopatchlib (C) | Nicotine (C) | Oxycodone (C) | Melatonine (C) | Zopiclone (C)

SOC:Hepatobiliary disorders

202509GLO013490PT	PORTUGAL 51 Years Male	**Hepatotoxicity (Hepatotoxicity)** *	Recovering	11-Sep-2025 1 year 2 months 16 days	CISPLATIN	Infusion	75 milligram/sq. meter Unknown	27-JUN-2024 to 16-AUG-2024 1 month 21 days	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9077

Study ID: D9077C00001

EudraCT No: 2023-508852-21-00

Study Design: Not Blinded

Study Description: D9077C00001 NeoAdjuvant & Adjuvant treatment in Resectable NSCLC (NeoCOAST 2.0) - A Phase II Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PEMETREXED	Infusion	500 milligram/sq. meter Unknown	27-JUN-2024 to 16-AUG-2024 1 month 21 days	
Concomitant Medication(s): MEDI5752 (S) | PEMETREXED (S) | | Naproxen (C) | Omeprazole (C)									
202510GLO004048BE	BELGIUM 71 Years Male	**Hepatitis acute (Hepatitis acute) ***	Unknown	01-Oct-2025 nk	PEMETREXED	Infusion	Intravenous use	20-AUG-2025 to	Periodic Report Comments. Patient had Alanine aminotransferase & aspartate aminotransferase elevation Related to study therapy AZD2936. Did not assess causality for study therapy Carboplatin, Cisplatin, Pemetrexed. Company causality assessment is not related.
					AZD2936	Solution	750 milligram q3w Intravenous use	20-AUG-2025 to 10-SEP-2025 22 days	
					CISPLATIN	Infusion	Intravenous use	20-AUG-2025 to	
					CARBOPLATIN	Infusion	Intravenous use	10-SEP-2025 to	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9077

Study ID: D9077C00001

EudraCT No: 2023-508852-21-00

Study Design: Not Blinded

Study Description: D9077C00001 NeoAdjuvant & Adjuvant treatment in Resectable NSCLC (NeoCOAST 2.0) - A Phase II Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): AZD2936 (S) | | CARBOPLATIN (S) | CISPLATIN (S) | Coversyl (C) | Spironolactone (C) | L-Thyroxine (C) | Metformine (C) | Nexiam (C) | Toularynx codeini (C) | Paracodine (C) | Solumedrol (C) | Medrol (C) | Fraxiparine (C) | Novorapid (C) | Pantomed (C) | Riopan (C) | Litican (C) | Lactulose (C) | Corsodyl (C) | Lyrica (C)									
SOC:Infections and infestations									
2024A178862	FRANCE 57 Years Female	**Device related infection (Device related infection)***	Recovered	28-Jul-2024 5 days	CARBOPLATIN	Infusion	545 milligram q3w Intravenous use	03-SEP-2024 to 03-SEP-2024 1 day	Periodic Report Comment. the patient experienced grade two intravenous device infection,not related Medi5752. Com causality not related.
						Infusion	545 milligram q3w Intravenous use	15-OCT-2024 to 15-OCT-2024 1 day	
						Infusion	545 milligram q3w Intravenous use	23-JUL-2024 to 23-JUL-2024 1 day	
						Infusion	545 milligram q3w Intravenous use	24-SEP-2024 to 24-SEP-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9077

Study ID: D9077C00001

EudraCT No: 2023-508852-21-00

Study Design: Not Blinded

Study Description: D9077C00001 NeoAdjuvant & Adjuvant treatment in Resectable NSCLC (NeoCOAST 2.0) - A Phase II Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PEMETREXED	Infusion	500 milligram/sq. meter q3w Intravenous use	03-SEP-2024 to 03-SEP-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	15-OCT-2024 to 15-OCT-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	23-JUL-2024 to	
						Infusion	500 milligram/sq. meter q3w Intravenous use	24-SEP-2024 to 24-SEP-2024 1 day	
Concomitant Medication(s): MEDI 5752 (S) | | PEMETREXED (S) | Ezetimibe & simvastatin (C) | Trelegy ellipta (C) | Vitamin b12 (C) | SOLUPRED (C) | SOLUMEDROL (C) | FULPHILA (C)									
202507GLO020225CA	CANADA 69 Years Male	**Encephalitis (Encephalitis)***	Recovered	16-Jul-2025 11 months 25 days	CARBOPLATIN	Infusion	520 milligram Intravenous use	22-JUL-2024 to	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9077

Study ID: D9077C00001

EudraCT No: 2023-508852-21-00

Study Design: Not Blinded

Study Description: D9077C00001 NeoAdjuvant & Adjuvant treatment in Resectable NSCLC (NeoCOAST 2.0) - A Phase II Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					MEDI5752	Infusion	250 milligram Intravenous use	22-JUL-2024 to	
					PEMETREXED	Infusion	970 milligram Intravenous use	22-JUL-2024 to	
Concomitant Medication(s): MEDI5752 (S) | PEMETREXED (S) |									

SOC:Musculoskeletal and connective tissue disorders

202504GLO026377FR	FRANCE 72 Years Female	**Fasciitis (Fasciitis)***	Recovering	10-Apr-2025 1 year 1 month 15 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	27-FEB-2024 to 04-FEB-2025 11 months 9 days	Subject experienced event Fascitis: Inv. related to Suspects Durvalumab and Monalizumab. Company not related to Durvalumab and Monalizumab.
					MONALIZUMAB	Infusion	1500 milligram q3w Intravenous use	27-FEB-2024 to 04-FEB-2025 11 months 9 days	
Concomitant Medication(s): | MONALIZUMAB (S) | PEMETREXED (S) | Atorvastatine (C) | Timolol (C) | Latanoprost (C) | Prednisolone (C) | Methotrexate (C) | Foldine (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9077

Study ID: D9077C00001

EudraCT No: 2023-508852-21-00

Study Design: Not Blinded

Study Description: D9077C00001 NeoAdjuvant & Adjuvant treatment in Resectable NSCLC (NeoCOAST 2.0) - A Phase II Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202506GLO010302ES	SPAIN 72 Years Male	**Muscular weakness (Myasthenia)***	Fatal	07-Jun-2025 26 days	AZD2936	Solution	750 milligram q4w Intravenous use	03-JUN-2025 to	
						Solution	750 milligram q4w Intravenous use	13-MAY-2025 to	

Concomitant Medication(s): | DATOPOTAMAB DERUXTECAN (S) | CARBOPLATIN (S) | Tramadol (C) | Casenlax (C) | Paracetamol (C) | Prednisone (C) | Omeprazole (C)

SOC:Nervous system disorders

202506GLO013150IT	ITALY 74 Years Female	**Vocal cord paralysis (Vocal cord paralysis)***	Recovered	06-Jun-2025 10 months 5 days	CARBOPLATIN	Infusion	Intravenous use	02-AUG-2024 to 04-OCT-2024 2 months 3 days	Patient experienced laryngeal stenosis. Investigator causality not related to MEDI5752 not reported to carboplatin and paclitaxel. CCA, not related.; Periodic Report Comments. Patient experienced Bilateral cordal paralysis. Investigator causality not related to MEDI5752 not reported to carboplatin and paclitaxel. CCA, not related.
					PACLITAXEL	Infusion	245 milligram q3w Unknown	02-AUG-2024 to 04-OCT-2024 2 months 3 days	

Concomitant Medication(s): MEDI5752 (S) | PACLITAXEL (S) | | Calcitriol (C) | Levotiroxin (C) | Escitalopram (C) | Risedronato (C) | Atorvastatin (C) | Lansoprazole (C) | Betamethasone (C) | Dexamethasone (C) | Chlorphenamine (C) | Paracetamol (C) | Pregabalin (C) | Vortioxetine (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9077

Study ID: D9077C00001

EudraCT No: 2023-508852-21-00

Study Design: Not Blinded

Study Description: D9077C00001 NeoAdjuvant & Adjuvant treatment in Resectable NSCLC (NeoCOAST 2.0) - A Phase II Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202509GLO027179US	UNITED STATES 76 Years Male	**Encephalopathy (Encephalopathy)***	Recovering	25-Feb-2025 7 months 3 days	MEDI5752	Infusion	Intravenous use	23-JUL-2024 to 25-SEP-2024 2 months 3 days	
Concomitant Medication(s): | PEMETREXED (S) | CARBOPLATIN (S)									

SOC:Renal and urinary disorders

2022A411583	PORTUGAL 54 Years Male	**Acute kidney injury (Acute kidney injury)***	Recovered	12-Dec-2022 5 days 9 hrs 20 min	CISPLATIN	Infusion	75 milligram/sq. meter single Intravenous use	06-DEC-2022 14:40 to 06-DEC-2022 16:50 2 hr 10 min	
Concomitant Medication(s): DURVALUMAB (S) | MONALIZUMAB (S) | | PEMETREXED (C) | PANTOPRAZOL (C) | MORFIN (C) | SEVREDOL (C) | GABAPENTIN (C) | BISACODILO (C) | ALPRAZOLAM (C) | Folic acid (C) | NEUROBION (C) | METOCLOPRAMIDA (C) | QUETIAPINE (C) | ENALAPRIL (C) | LERCANIDIPINA (C) | ATENOLOL (C) | ESCITALOPRAM (C) | VELLOFENT (C)									

SOC:Respiratory, thoracic and mediastinal disorders

2023A251534	ITALY 58 Years Female	**Haemoptysis (Hemoptysis)***	Recovered	25-Aug-2023 nk	DATOPOTAMAB DERUXTECAN	Injection		to	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9077

Study ID: D9077C00001

EudraCT No: 2023-508852-21-00

Study Design: Not Blinded

Study Description: D9077C00001 NeoAdjuvant & Adjuvant treatment in Resectable NSCLC (NeoCOAST 2.0) - A Phase II Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion		to	
					MEDI5752	Infusion			
					MEDI9447	Infusion		to	
					MONALIZUMAB	Infusion		to	
Concomitant Medication(s): DURVALUMAB (S) | MONALIZUMAB (S) | MEDI9447 (S) | | MEDI5752 (S)									
202509GLO027487CA	CANADA 66 Years Female	**Pneumonitis (Pneumonitis)***	Recovering	25-Sep-2025 3 months 7 days	AZD2936	Solution	750 milligram Intravenous use	19-JUN-2025 to 21-AUG-2025 2 months 3 days	Periodic Report Comment. Patient experienced pneumonitis, Inv: related to Azd2936, study procedure and not related to Carboplatin, Pemetrexed, CCA: not related to study

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9077

Study ID: D9077C00001

EudraCT No: 2023-508852-21-00

Study Design: Not Blinded

Study Description: D9077C00001 NeoAdjuvant & Adjuvant treatment in Resectable NSCLC (NeoCOAST 2.0) - A Phase II Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
									therapy.
Concomitant Medication(s): | PEMETREXED (S) | CARBOPLATIN (S) | Tylenol (C) | Rosuvastatin (C) | Amlodipine (C) | Gabapentine (C) | Codeine (C) | Dexamethasone (C) | Diphenhydramine (C) | Ranitidine (C) | Restoralax (C) | Polyethylene glycol (C) | Zofran (C) | Hydromorphone (C) | Folic acid (C) | Fentanyl (C) | Diphenhydramine (C)									
202510GLO005356FR	FRANCE	**Lung disorder (Pneumopathy)***	Not Recovered	28-Sep-2025 1 year 3 days	CARBOPLATIN	Infusion	Intravenous use	26-SEP-2024 to 28-NOV-2024 2 months 3 days	
					PACLITAXEL	Infusion	200 milligram/sq. meter q3w Intravenous use	26-SEP-2024 to 28-NOV-2024 2 months 3 days	
Concomitant Medication(s): MEDI5752 (S) | PACLITAXEL (S) |									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9078

Study ID: D9078C00001

EudraCT No: 2023-503999-24-00

Study Design: Double Blinded

Study Description: D9078C00001 Imfinzi +- olec +- mona unresectable stage III NSCLC (PACIFIC-9) - A Phase III, double-blind, placebo-controlled, Randomized, Multicenter, International Study of Durvalumab Plus Oleclumab and Durvalumab Plus Monalizumab in Patients With Locally Advanced (Stage III), Unresectable Non-small Cell Lung Cancer (NSCLC) Who Have Not Progressed Following Definitive, Platinum-Based Concurrent Chemoradiation Therapy (PACIFIC-9)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
2024A030827	FRANCE 67.8 Years Male	**Neutropenia (Neutropenia)*** Pancytopenia (Pancytopenia)*	Recovered	06-Feb-2024 19 days					
Concomitant Medication(s):									
2024A178269	CHINA 69.4 Years Male	**Immune thrombocytopenia (Immune thrombocytopenia)***	Recovered	05-Aug-2024 10 months 17 days					
Concomitant Medication(s):									
202508GLO001546US	UNITED STATES 75 Years Male	**Anaemia (Anemia)***	Recovering	28-Jul-2025 19 days					
Concomitant Medication(s):									
SOC:Ear and labyrinth disorders									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9078

Study ID: D9078C00001

EudraCT No: 2023-503999-24-00

Study Design: Double Blinded

Study Description: D9078C00001 Imfinzi +- olec +- mona unresectable stage III NSCLC (PACIFIC-9) - A Phase III, double-blind, placebo-controlled, Randomized, Multicenter, International Study of Durvalumab Plus Oleclumab and Durvalumab Plus Monalizumab in Patients With Locally Advanced (Stage III), Unresectable Non-small Cell Lung Cancer (NSCLC) Who Have Not Progressed Following Definitive, Platinum-Based Concurrent Chemoradiation Therapy (PACIFIC-9)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202503GLO020854PL	POLAND 68 Years Male	**Vertigo (Vertigo)*** Neuropathy peripheral (Neuropathy)*	Not Recovered	20-Mar-2025 nk					

Concomitant Medication(s):

SOC:Gastrointestinal disorders

202503GLO012394KR	KOREA, REPUBLIC OF 73.1 Years Male	**Colitis (Colitis)***	Recovered	05-Feb-2025 2 months 26 days					

Concomitant Medication(s):

202507GLO013485US	UNITED STATES 77 Years Male	**Diarrhoea (Diarrhea)***	Not Recovered	12-Jul-2025 nk					

Concomitant Medication(s):

SOC:General disorders and administration site conditions

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9078

Study ID: D9078C00001

EudraCT No: 2023-503999-24-00

Study Design: Double Blinded

Study Description: D9078C00001 Imfinzi +- olec +- mona unresectable stage III NSCLC (PACIFIC-9) - A Phase III, double-blind, placebo-controlled, Randomized, Multicenter, International Study of Durvalumab Plus Oleclumab and Durvalumab Plus Monalizumab in Patients With Locally Advanced (Stage III), Unresectable Non-small Cell Lung Cancer (NSCLC) Who Have Not Progressed Following Definitive, Platinum-Based Concurrent Chemoradiation Therapy (PACIFIC-9)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A142378	VIET NAM 73 Years Male	**Pyrexia (Fever of unknown origin)*** Cardio-respiratory arrest (Cardiopulmonary arrest)*	Fatal	18-Jun-2023 4 days					
Concomitant Medication(s):									
2024A119074	UNITED STATES 60 Years Female	**Chest pain (Chest pain)*** Non-cardiac chest pain (Chest pain (non-cardiac))*	Fatal	19-May-2024 1 month 4 days					
Concomitant Medication(s):									
202507GLO010569US	UNITED STATES 67 Years Female	**Asthenia (Weakness generalized)***	Recovered with Sequelae	10-Jul-2025 3 months 10 days					
Concomitant Medication(s):									

SOC:Infections and infestations

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9078

Study ID: D9078C00001

EudraCT No: 2023-503999-24-00

Study Design: Double Blinded

Study Description: D9078C00001 Imfinzi +- olec +- mona unresectable stage III NSCLC (PACIFIC-9) - A Phase III, double-blind, placebo-controlled, Randomized, Multicenter, International Study of Durvalumab Plus Oleclumab and Durvalumab Plus Monalizumab in Patients With Locally Advanced (Stage III), Unresectable Non-small Cell Lung Cancer (NSCLC) Who Have Not Progressed Following Definitive, Platinum-Based Concurrent Chemoradiation Therapy (PACIFIC-9)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A232434	BRAZIL 69 Years Female	**Pneumonia (Lung infection)***	Recovered	07-Oct-2023 1 month					
Concomitant Medication(s):									
202509GLO015419FR	FRANCE 40.6 Years Male	**Influenza (Flu syndrome)***	Recovered	17-Sep-2025 1 day					
Concomitant Medication(s):									

SOC:Injury, poisoning and procedural complications

2023A233651	CHINA 73.8 Years Male	**Radiation pneumonitis (Radiation pneumonitis)*** Pneumonia (Pneumonia)*	Recovered with Sequelae	10-Oct-2023 1 month 12 days					
Concomitant Medication(s):									

SOC:Investigations

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9078

Study ID: D9078C00001

EudraCT No: 2023-503999-24-00

Study Design: Double Blinded

Study Description: D9078C00001 Imfinzi +- olec +- mona unresectable stage III NSCLC (PACIFIC-9) - A Phase III, double-blind, placebo-controlled, Randomized, Multicenter, International Study of Durvalumab Plus Oleclumab and Durvalumab Plus Monalizumab in Patients With Locally Advanced (Stage III), Unresectable Non-small Cell Lung Cancer (NSCLC) Who Have Not Progressed Following Definitive, Platinum-Based Concurrent Chemoradiation Therapy (PACIFIC-9)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202412GLO016035CN	CHINA 63.8 Years Male	**Hepatic enzyme increased (Hepatic enzyme increased)***	Recovered	17-Dec-2024 11 months 26 days					
Concomitant Medication(s):									
202505GLO016999DE	GERMANY 63.2 Years Female	**Lipase increased (Lipase increased)***	Recovered	10-Mar-2025 3 months 21 days					
Concomitant Medication(s):									
202505GLO027656DE	GERMANY 62 Years Female	**Amylase increased (Amylase increased)***	Recovered	17-Apr-2025 nk					
Concomitant Medication(s):									
202507GLO016461CN	CHINA 69 Years Male	**Blood creatine phosphokinase increased (Creatine phosphokinase increased)***	Not Recovered	02-Jun-2025 9 months 19 days					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9078

Study ID: D9078C00001

EudraCT No: 2023-503999-24-00

Study Design: Double Blinded

Study Description: D9078C00001 Imfinzi +- olec +- mona unresectable stage III NSCLC (PACIFIC-9) - A Phase III, double-blind, placebo-controlled, Randomized, Multicenter, International Study of Durvalumab Plus Oleclumab and Durvalumab Plus Monalizumab in Patients With Locally Advanced (Stage III), Unresectable Non-small Cell Lung Cancer (NSCLC) Who Have Not Progressed Following Definitive, Platinum-Based Concurrent Chemoradiation Therapy (PACIFIC-9)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO016615CN	CHINA 70.3 Years Male	**Blood creatine phosphokinase increased (Blood creatine phosphokinase increased)***	Recovered	02-Jun-2025 9 months 19 days					
Concomitant Medication(s):									
202508GLO022722CN	CHINA 70.5 Years Male	**Blood creatine phosphokinase increased (Blood creatine phosphokinase increased)***	Recovered	25-Aug-2025 1 year 11 days					
Concomitant Medication(s):									
SOC:Metabolism and nutrition disorders									
202409GLO009344CO	COLOMBIA 79 Years Male	**Hypokalaemia (Hypokalemia)***	Recovered	17-Jun-2024 nk					
Concomitant Medication(s):									
SOC:Nervous system disorders									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9078

Study ID: D9078C00001

EudraCT No: 2023-503999-24-00

Study Design: Double Blinded

Study Description: D9078C00001 Imfinzi +- olec +- mona unresectable stage III NSCLC (PACIFIC-9) - A Phase III, double-blind, placebo-controlled, Randomized, Multicenter, International Study of Durvalumab Plus Oleclumab and Durvalumab Plus Monalizumab in Patients With Locally Advanced (Stage III), Unresectable Non-small Cell Lung Cancer (NSCLC) Who Have Not Progressed Following Definitive, Platinum-Based Concurrent Chemoradiation Therapy (PACIFIC-9)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A122369	FRANCE 53.1 Years Male	**Encephalopathy (Encephalopathy)*** Adrenal insufficiency (Adrenal cortical insufficiency)* Hypophysitis (Hypophysitis)*	Not Recovered	16-May-2024 5 months 18 days					
Concomitant Medication(s):									
202503GLO020854PL	POLAND 68 Years Male	**Neuropathy peripheral (Neuropathy)***	Not Recovered	20-Mar-2025 8 months 23 days					
Concomitant Medication(s):									
202508GLO018703ES	SPAIN 65.6 Years Male	**Myasthenic syndrome (Myasthenic syndrome)***	Not Recovered	14-Aug-2025 2 months 19 days					
Concomitant Medication(s):									

SOC:Respiratory, thoracic and mediastinal disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9078

Study ID: D9078C00001

EudraCT No: 2023-503999-24-00

Study Design: Double Blinded

Study Description: D9078C00001 Imfinzi +- olec +- mona unresectable stage III NSCLC (PACIFIC-9) - A Phase III, double-blind, placebo-controlled, Randomized, Multicenter, International Study of Durvalumab Plus Oleclumab and Durvalumab Plus Monalizumab in Patients With Locally Advanced (Stage III), Unresectable Non-small Cell Lung Cancer (NSCLC) Who Have Not Progressed Following Definitive, Platinum-Based Concurrent Chemoradiation Therapy (PACIFIC-9)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A216813	CHINA 67.9 Years Male	**Immune-mediated lung disease (Immune-mediated pneumonitis)***	Recovered	19-Sep-2023 1 month 24 days					
Concomitant Medication(s):									
202403GLO002301CN	CHINA Male	**Pneumonitis (Pneumonitis)***	Unknown	10-Jan-2024 nk					
Concomitant Medication(s):									
202412GLO014654CN	CHINA 64 Years Male	**Interstitial lung disease (Interstitial pneumonitis)***	Recovered with Sequelae	17-Dec-2024 5 months 14 days					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9078

Study ID: D9078C00001

EudraCT No: 2023-503999-24-00

Study Design: Double Blinded

Study Description: D9078C00001 Imfinzi +- olec +- mona unresectable stage III NSCLC (PACIFIC-9) - A Phase III, double-blind, placebo-controlled, Randomized, Multicenter, International Study of Durvalumab Plus Oleclumab and Durvalumab Plus Monalizumab in Patients With Locally Advanced (Stage III), Unresectable Non-small Cell Lung Cancer (NSCLC) Who Have Not Progressed Following Definitive, Platinum-Based Concurrent Chemoradiation Therapy (PACIFIC-9)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A018573	CHINA 69 Years Male	**Interstitial lung disease (Interstitial pneumonitis)***	Fatal	26-Dec-2023 nk					
Concomitant Medication(s):									
2024A019170	CHINA 65 Years Male	**Pneumonitis (Pneumonitis)***	Not Recovered	22-Jan-2024 7 weeks 4 days					
Concomitant Medication(s):									
2024A098927	FRANCE 69.4 Years Male	**Interstitial lung disease (Interstitial lung disease)***	Not Recovered	10-Apr-2024 1 month 2 days 8 hrs 25 min					
Concomitant Medication(s):									
2024A118844	GERMANY 62 Years Female	**Dyspnoea (Dyspnoea)***	Recovered	18-May-2024 6 months 12 days					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9078

Study ID: D9078C00001

EudraCT No: 2023-503999-24-00

Study Design: Double Blinded

Study Description: D9078C00001 Imfinzi +- olec +- mona unresectable stage III NSCLC (PACIFIC-9) - A Phase III, double-blind, placebo-controlled, Randomized, Multicenter, International Study of Durvalumab Plus Oleclumab and Durvalumab Plus Monalizumab in Patients With Locally Advanced (Stage III), Unresectable Non-small Cell Lung Cancer (NSCLC) Who Have Not Progressed Following Definitive, Platinum-Based Concurrent Chemoradiation Therapy (PACIFIC-9)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A144390	UNITED KINGDOM 69 Years Male	**Pneumonitis (Pneumonitis)***	Fatal	18-Jun-2024 3 weeks 1 day					
Concomitant Medication(s):									
2024A180804	CHINA 62.6 Years Male	**Immune-mediated lung disease (Immune-mediated pneumonitis)***	Recovered	07-Aug-2024 9 months 7 days					
Concomitant Medication(s):									
202504GLO024931GB	UNITED KINGDOM 76 Years Female	**Pneumonitis (Pneumonitis)***	Not Recovered	18-Apr-2025 8 months 21 days					
Concomitant Medication(s):									
202506GLO006981US	UNITED STATES 71 Years Male	**Pneumonitis (Pneumonitis)***	Fatal	09-Jun-2025 7 days					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9078

Study ID: D9078C00001

EudraCT No: 2023-503999-24-00

Study Design: Double Blinded

Study Description: D9078C00001 Imfinzi +- olec +- mona unresectable stage III NSCLC (PACIFIC-9) - A Phase III, double-blind, placebo-controlled, Randomized, Multicenter, International Study of Durvalumab Plus Oleclumab and Durvalumab Plus Monalizumab in Patients With Locally Advanced (Stage III), Unresectable Non-small Cell Lung Cancer (NSCLC) Who Have Not Progressed Following Definitive, Platinum-Based Concurrent Chemoradiation Therapy (PACIFIC-9)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO001537US	UNITED STATES 75 Years Male	**Hypoxia (Hypoxia)***	Not Recovered	24-Jul-2025 15 days					
Concomitant Medication(s):									
202508GLO001553US	UNITED STATES 75 Years Male	**Pneumothorax (Pneumothorax)***	Not Recovered	29-Jul-2025 20 days					
Concomitant Medication(s):									
202509GLO019905AU	AUSTRALIA 78.7 Years Male	**Pneumonitis (Pneumonitis)***	Recovered	23-Sep-2025 nk					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9103

Study ID: D9103C00001

EudraCT No: 2018-002572-41

Study Design: Double Blinded

Study Description: D9103C00001 Imfinzi following SBRT Stage 1/2 Unresectable NSCLC. PACIFIC 4 - A Phase III, Randomized, Placebo-controlled, Double-blind, Multi-center, International Study of Durvalumab with Stereotactic Body Radiation Therapy (SBRT) for the Treatment of Patients with unresected Stage I/II, lymph-node negative Non-small Cell Lung Cancer (PACIFIC-4/RTOG-3515)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Cardiac disorders									
202507GLO019245BR	BRAZIL 79 Years Female	**Myocarditis (Myocarditis)***	Recovering	21-Jul-2025 1 year 8 months 22 days					
Concomitant Medication(s):									
SOC:General disorders and administration site conditions									
202506GLO008927CN	CHINA 50 Years Female	**Oedema peripheral (Edema knees)***	Recovered	30-Dec-2021 2 months 21 days					
Concomitant Medication(s):									
SOC:Infections and infestations									
2021A717547	CHINA 72 Years Male	**Pneumonia (Pneumonia)*** Pneumonitis (Pneumonitis)*	Fatal	07-Sep-2021 11 weeks 5 days					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9103

Study ID: D9103C00001

EudraCT No: 2018-002572-41

Study Design: Double Blinded

Study Description: D9103C00001 Imfinzi following SBRT Stage 1/2 Unresectable NSCLC. PACIFIC 4 - A Phase III, Randomized, Placebo-controlled, Double-blind, Multi-center, International Study of Durvalumab with Stereotactic Body Radiation Therapy (SBRT) for the Treatment of Patients with unresected Stage I/II, lymph-node negative Non-small Cell Lung Cancer (PACIFIC-4/RTOG-3515)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2022A266418	UNITED STATES 83.9 Years Female	**Pneumonia (Pneumonia)***	Recovered	23-Jul-2022 7 months 6 days 9 hrs 49 min					
Concomitant Medication(s):									

SOC:Nervous system disorders

202507GLO007157CN	CHINA 69 Years Female	**Transient ischaemic attack (Transient ischemic attack)***	Recovered	16-May-2025 2 years 13 days					
Concomitant Medication(s):									

SOC:Respiratory, thoracic and mediastinal disorders

2020SF18226	UNITED STATES 74 Years Male	**Haemoptysis (Hemoptysis)***	Fatal	13-Sep-2020 46 weeks 3 days					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9103

Study ID: D9103C00001

EudraCT No: 2018-002572-41

Study Design: Double Blinded

Study Description: D9103C00001 Imfinzi following SBRT Stage 1/2 Unresectable NSCLC. PACIFIC 4 - A Phase III, Randomized, Placebo-controlled, Double-blind, Multi-center, International Study of Durvalumab with Stereotactic Body Radiation Therapy (SBRT) for the Treatment of Patients with unresected Stage I/II, lymph-node negative Non-small Cell Lung Cancer (PACIFIC-4/RTOG-3515)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202310GLO000572US	UNITED STATES Male	**Chronic obstructive pulmonary disease (Chronic obstructive pulmonary disease exacerbation)***	Not Recovered	23-Oct-2023 1 month 10 days					
Concomitant Medication(s):									
2023A277484	CHINA 75 Years Male	**Chronic obstructive pulmonary disease (Chronic obstructive pulmonary disease)***	Recovered	05-Dec-2023 7 months 9 days					
Concomitant Medication(s):									
2024A207677	CHINA 68 Years Male	**Immune-mediated lung disease (Immune-mediated pneumonitis)***	Recovered	14-Aug-2024 1 year 4 months 22 days					
Concomitant Medication(s):									
202504GLO029323CN	CHINA 76 Years Male	**Chronic obstructive pulmonary disease (Chronic obstructive pulmonary disease)***	Not Recovered	28-Feb-2025 1 year 10 months 2 days					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9106

Study ID: D9106C00002

EudraCT No:

Study Design: Not Blinded

Study Description: A multicentre, Phase II, single-arm, interventional study of neoadjuvant durvalumab and platinum-based chemotherapy (CT), followed by either surgery and adjuvant durvalumab or chemoradiotherapy (CRT) and consolidation durvalumab, in participants with resectable or borderline resectable stage IIB-IIIB Non-small Cell Lung Cancer (NSCLC)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:General disorders and administration site conditions									
202502GLO025941DE	GERMANY 80 Years Male	**General physical health deterioration (General physical health deterioration)***	Recovered with Sequelae	19-Feb-2025 1 month 4 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	16-JAN-2025 to 06-FEB-2025 22 days	
Concomitant Medication(s): | Paclitaxel (S) | Carboplatin (S) | Acetylsalicylic acid (C) | Allopurinol (C) | Semaglutide (C) | Insulin glargine (C) | Dapagliflozine (C) | Ginkgo (C) | Silymarin (C) | Metoprolol (C) | Candes (C) | Dexamethasone (C) | Pantoprazole (C) | Torasemide (C)									
SOC:Respiratory, thoracic and mediastinal disorders									
202502GLO002892IT	ITALY 70 Years Male	**Interstitial lung disease (Interstitial lung disease)***	Fatal	12-Jan-2025 3 months 20 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	02-DEC-2024 to 02-DEC-2024 1 day	
						Infusion	1500 milligram q3w Intravenous use	22-OCT-2024 to 22-OCT-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9106

Study ID: D9106C00002

EudraCT No:

Study Design: Not Blinded

Study Description: A multicentre, Phase II, single-arm, interventional study of neoadjuvant durvalumab and platinum-based chemotherapy (CT), followed by either surgery and adjuvant durvalumab or chemoradiotherapy (CRT) and consolidation durvalumab, in participants with resectable or borderline resectable stage IIB-IIIB Non-small Cell Lung Cancer (NSCLC)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram q3w Intravenous use	24-SEP-2024 to 24-SEP-2024 1 day	

Concomitant Medication(s): | Carboplatin (S) | Pemetrexed (S) | Xarelto (C) | Atorvastatin (C) | Amiodarone (C) | Clopidogrel (C) | Bisoprolol (C) | Triatec (C) | Pantoprazole (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910D

Study ID: D910DC00001

EudraCT No: 2023-507689-26-00

Study Design: Double Blinded

Study Description: D910DC00001 Durvalumab in Adjuvant Therapy in Patients with HCC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of Durvalumab Monotherapy or in Combination With Bevacizumab as Adjuvant Therapy in Patients with Hepatocellular Carcinoma Who Are at High Risk of Recurrence After Curative Hepatic Resection or Ablation

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Endocrine disorders									
2021A009321	CHINA 76 Years Male	**Hyperthyroidism (Hyperthyroidism)*** Pneumonia (Lung infection)*	Recovered	14-Jan-2021 1 month 14 days					
Concomitant Medication(s):									
SOC:Gastrointestinal disorders									
202410GLO008861JP	JAPAN 48 Years Female	**Colitis (Colitis)***	Recovering	08-Aug-2024 3 years 6 days					
Concomitant Medication(s):									
SOC:Musculoskeletal and connective tissue disorders									
2022A310678	UNITED STATES 65 Years Male	**Arthralgia (Polyarthralgia)***	Not Recovered	01-Aug-2022 49 weeks 4 days					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910D

Study ID: D910DC00001

EudraCT No: 2023-507689-26-00

Study Design: Double Blinded

Study Description: D910DC00001 Durvalumab in Adjuvant Therapy in Patients with HCC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of Durvalumab Monotherapy or in Combination With Bevacizumab as Adjuvant Therapy in Patients with Hepatocellular Carcinoma Who Are at High Risk of Recurrence After Curative Hepatic Resection or Ablation

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910G

Study ID: D910GC00001

EudraCT No: 2023-507338-26-00

Study Design: Double Blinded

Study Description: D910GC00001 Phase 3 Perioperative Imfinzi + FLOT in Gastric Cancer - A Randomized, Double-blind, Placebo-controlled, Phase III Study of Neoadjuvant-Adjuvant Durvalumab and FLOT Chemotherapy Followed by Adjuvant Durvalumab in Patients with Resectable Gastric and Gastroesophageal Junction Cancer (GC/GEJC) (MATTERHORN)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
2021A905153	TURKEY 39 Years Female	**Neutropenia (Neutropenia)***	Recovered	27-Dec-2021 25 weeks 3 days					
Concomitant Medication(s):									
SOC:Gastrointestinal disorders									
2021A776679	TURKEY 57 Years Male	**Enterocolitis (Enterocolitis)***	Recovered	13-Oct-2021 5 days					
Concomitant Medication(s):									
SOC:Hepatobiliary disorders									
2022A406279	JAPAN 75 Years Male	**Hepatic function abnormal (Hepatic function disorder)***	Not Recovered	08-Nov-2022 7 months 24 days					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910G

Study ID: D910GC00001

EudraCT No: 2023-507338-26-00

Study Design: Double Blinded

Study Description: D910GC00001 Phase 3 Perioperative Imfinzi + FLOT in Gastric Cancer - A Randomized, Double-blind, Placebo-controlled, Phase III Study of Neoadjuvant-Adjuvant Durvalumab and FLOT Chemotherapy Followed by Adjuvant Durvalumab in Patients with Resectable Gastric and Gastroesophageal Junction Cancer (GC/GEJC) (MATTERHORN)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Metabolism and nutrition disorders									
2022A406279	JAPAN 75 Years Male	**Decreased appetite (Anorexia)** Hepatic function abnormal (Hepatic function disorder)*	Not Recovered	08-Nov-2022 7 months 24 days					
Concomitant Medication(s):									
SOC:Musculoskeletal and connective tissue disorders									
2024A160280	BRAZIL 64 Years Male	**Myalgia (Polymyalgia)***	Not Recovered	10-Jun-2024 1 year 9 months 19 days					

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910G

Study ID: D910GC00001

EudraCT No: 2023-507338-26-00

Study Design: Double Blinded

Study Description: D910GC00001 Phase 3 Perioperative Imfinzi + FLOT in Gastric Cancer - A Randomized, Double-blind, Placebo-controlled, Phase III Study of Neoadjuvant-Adjuvant Durvalumab and FLOT Chemotherapy Followed by Adjuvant Durvalumab in Patients with Resectable Gastric and Gastroesophageal Junction Cancer (GC/GEJC) (MATTERHORN)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s):									
SOC:Nervous system disorders									
2022A094254	BELGIUM 61 Years Female	**Guillain-Barre syndrome (Guillain-Barre syndrome)***	Fatal	17-Feb-2022 2 months 26 days					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910P

Study ID: D910PC00001

EudraCT No: 2023-507342-84-00

Study Design: Not Blinded

Study Description: D910PC00001 Ph3 Study - Imfinzi + treme ± EV in MIBC Cis-Ineligible - A Phase III Randomized, Open-Label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab in Combination With Tremelimumab and Enfortumab Vedotin or Durvalumab in Combination With Enfortumab Vedotin for Perioperative Treatment in Patients Ineligible for Cisplatin or Who Refuse Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Cardiac disorders									
202411GLO027984IT	ITALY 81 Years Male	**Cardiac failure (Heart failure)***	Not Recovered	01-Jan-2025 10 months 20 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	13-FEB-2024 to 27-MAR-2024 1 month 15 days	
						Infusion	1500 milligram q4w Intravenous use	26-AUG-2024 to 24-SEP-2024 30 days	
						Infusion	1500 milligram single Intravenous use	10-DEC-2024 to 10-DEC-2024 1 day	
Concomitant Medication(s): | ENFORTUMAB VEDOTIN (S) | Lanoxin (C) | Bisoprolol (C) | Eliquis (C) | Pantoprazole (C) | Lasix (C) | Zoloft (C) | Cotareg (C)									
SOC:Endocrine disorders									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910P

Study ID: D910PC00001

EudraCT No: 2023-507342-84-00

Study Design: Not Blinded

Study Description: D910PC00001 Ph3 Study - Imfinzi + treme ± EV in MIBC Cis-Ineligible - A Phase III Randomized, Open-Label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab in Combination With Tremelimumab and Enfortumab Vedotin or Durvalumab in Combination With Enfortumab Vedotin for Perioperative Treatment in Patients Ineligible for Cisplatin or Who Refuse Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202503GLO008698DE	GERMANY 68 Years Male	**Adrenal insufficiency (Adrenal insufficiency)*** Pneumonitis (Pneumonitis)*	Recovered	10-Feb-2025 1 month 2 days 14 hrs	TREMELIMUMAB	Infusion	75 milligram single Intravenous use	04-FEB-2025 12:50 to 04-FEB-2025 13:50 1 hr	Periodic Report Comments. The patient experienced pneumonitis and adrenal insufficiency. Investigator: related to Durvalumab, Tremelimumab, Enfortumab Vedotin, Study procedure. Company: related to Durvalumab, Tremelimumab, not related to Enfortumab Vedotin, Study procedure.
						Infusion	75 milligram single Intravenous use	07-JAN-2025 10:00 to 07-JAN-2025 11:00 1 hr	
					DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	07-JAN-2025 to 18-FEB-2025 1 month 12 days	
					ENFORTUMAB VEDOTIN	Powder for solution for infusion	Intravenous use	07-JAN-2025 to 25-FEB-2025 1 month 19 days	

Concomitant Medication(s): DURVALUMAB (S) | | ENFORTUMAB VEDOTIN (S) | Amlodipin (C) | Ramipril (C) | Cetirizine (C)

SOC:Eye disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910P

Study ID: D910PC00001

EudraCT No: 2023-507342-84-00

Study Design: Not Blinded

Study Description: D910PC00001 Ph3 Study - Imfinzi + treme ± EV in MIBC Cis-Ineligible - A Phase III Randomized, Open-Label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab in Combination With Tremelimumab and Enfortumab Vedotin or Durvalumab in Combination With Enfortumab Vedotin for Perioperative Treatment in Patients Ineligible for Cisplatin or Who Refuse Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A133787	ITALY 73 Years Male	**Diplopia (Diplopia)***	Recovered with Sequelae	05-May-2024 10 months 13 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	23-JUN-2023 to 25-AUG-2023 2 months 3 days	Periodic Report Comment. Pt exp. diplopia. Inv: event related to Durvalumab and EV. CCA: event unrelated to Durvalumab and EV.
						Infusion	1500 milligram q4w Intravenous use	30-NOV-2023 to 18-APR-2024 4 months 20 days	
					ENFORTUMAB VEDOTIN	Powder for solution for infusion	Intravenous use	04-AUG-2023 to 01-SEP-2023 29 days	
						Powder for solution for infusion	Intravenous use	23-JUN-2023 to 30-JUN-2023 8 days	

Concomitant Medication(s): | ENFORTUMAB VEDOTIN (S) | OXATOMIDE (C) | PREDNISONE (C) | DELTACORTENE (C) | SILODOSINA (C) | CARDIRENE (C) | TIROSINT (C) | Perindopril (C) | ATORVASTATINA (C) | ALLOPURINOLO (C) | LANSOPRAZOLE (C)

SOC:Gastrointestinal disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910P

Study ID: D910PC00001

EudraCT No: 2023-507342-84-00

Study Design: Not Blinded

Study Description: D910PC00001 Ph3 Study - Imfinzi + treme ± EV in MIBC Cis-Ineligible - A Phase III Randomized, Open-Label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab in Combination With Tremelimumab and Enfortumab Vedotin or Durvalumab in Combination With Enfortumab Vedotin for Perioperative Treatment in Patients Ineligible for Cisplatin or Who Refuse Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A000583	FRANCE 80 Years Female	**Immune-mediated enterocolitis (Immune-mediated colitis)***	Recovered	23-Dec-2022 1 month 7 days	DURVALUMAB	Infusion	Intravenous use	12-JAN-2023 to 12-JAN-2023 1 day	Periodic Report Comment. Pt exp. immunotherapy induced inflammatory colitis, bacterial pyelonephritis (enterococcus faecalis),disorientation about time and place.Inv: Immunotherapy induced inflammatory colitis related to study therapy.
						Infusion	1.25 milligram/kilogram single Intravenous use	17-NOV-2022 to 12-DEC-2022 26 days	
					ENFORTUMAB VEDOTIN	Powder for solution for infusion	1.25 milligram/kilogram single Intravenous use	17-NOV-2022 to 19-DEC-2022 1 month 3 days	
						Powder for solution for infusion	1.25 milligram/kilogram single Intravenous use	19-DEC-2022 13:20 to 19-DEC-2022 13:20	
					TREMELIMUMAB	Infusion	75 milligram single Intravenous use	17-NOV-2022 to 19-DEC-2022 1 month 3 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910P

Study ID: D910PC00001

EudraCT No: 2023-507342-84-00

Study Design: Not Blinded

Study Description: D910PC00001 Ph3 Study - Imfinzi + treme ± EV in MIBC Cis-Ineligible - A Phase III Randomized, Open-Label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab in Combination With Tremelimumab and Enfortumab Vedotin or Durvalumab in Combination With Enfortumab Vedotin for Perioperative Treatment in Patients Ineligible for Cisplatin or Who Refuse Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): ENFORTUMAB VEDOTIN (S) | | TREMELIMUMAB (S) | Nivolumab (S) | SPASFON (C) | TIMOFEROL (C) | DEPAKINE (C) | DERMOVAL (C) | METFORMINE (C) | ATORVASTATINE (C) | LANTUS (C) | Xalatan (C) | PLAVIX (C) | PARACETAMOL (C) | COVERAM (C)									
202412GLO014742DE	GERMANY 57 Years Male	**Pancreatitis (Pancreatitis)***	Recovered	16-Dec-2024 3 months 3 days 12 hrs	ENFORTUMAB VEDOTIN	Powder for solution for infusion	Intravenous use	09-OCT-2024 to 17-OCT-2024 9 days	Periodic Report Comment. patient experienced RECURRENCE OF CHECKPOINT INHIBITOR-ASSOCIATED PANCREATITIS: Investigator: related to DURVALUMAB, ENFORTUMAB VEDOTIN, CCA: related to DURVALUMAB, not related to ENFORTUMAB VEDOTIN.
						Powder for solution for infusion	Intravenous use	31-OCT-2024 to 08-NOV-2024 9 days	
						Powder for solution for infusion	1.25 milligram/kilogram single Intravenous use	12-SEP-2024 12:00 to 12-SEP-2024 12:30 30 min	
						Powder for solution for infusion	1.25 milligram/kilogram single Intravenous use	24-SEP-2024 09:57 to 24-SEP-2024 10:27 30 min	
Concomitant Medication(s): DURVALUMAB (S) | | Omeprazol (C) | Telmisartan (C) | Lercanidipina (C) | Nitrospray (C) | L-thyroxin (C) | Nitrendipine (C) | Prednisolone (C) | Indapamid (C) | Doxazosin (C) | Pantoprazol (C) | Colecalciferol (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910P

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2024A051974	UNITED STATES 78 Years Male	**Large intestine perforation (Colonic perforation)*** Pneumonia aspiration (Aspiration pneumonia)*	Fatal	26-Feb-2024 4 months 2 days 10 hrs 15 min	TREMELIMUMAB	Infusion	75 milligram single Intravenous use	23-OCT-2023 13:45 to 23-OCT-2023 14:49 1 hr 4 min	Periodic Report Comment. Inv: Related to all the suspects with respect to event colonic perforation and aspiration pneumonia, and not related to event sepsis. Company: study therapy Not related to colonic perforation, aspiration pneumonia, sepsis.
						Infusion	75 milligram single Intravenous use	28-NOV-2023 11:48 to 28-NOV-2023 12:54 1 hr 6 min	
					DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	20-NOV-2023 to 12-DEC-2023 23 days	
						Infusion	1500 milligram single Intravenous use	23-OCT-2023 15:57 to 23-OCT-2023 17:06 1 hr 9 min	
					ENFORTUMAB VEDOTIN	Powder for solution for infusion	Intravenous use	20-NOV-2023 to 19-DEC-2023 1 month	

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						Powder for solution for infusion	Intravenous use	23-OCT-2023 to 30-OCT-2023 8 days	
Concomitant Medication(s): DURVALUMAB (S) | | ENFORTUMAB VEDOTIN (S) | Albuterol (C) | Fluticasone propionate (C) | Salmeterol (C) | Lisinopril (C) | Atorvastatin (C) | Zolpidem (C) | Acetaminophen (C) | Docusate sodium (C) | Loratadine (C) | Compazine (C) | Ondansetron (C) | Melatonin (C) | Methimazole (C) | Fluconazole (C) | Vancomycine (C) | Metronidazole (C) | Formoterol (C) | Pantoprazole (C) | Cefepime (C) | Enoxaparin (C) | Metoclopramide HCL (C) | Furosemide (C) | Chlorhexidine (C)									
2024A162162	ARGENTINA 55 Years Male	**Abdominal pain upper (Epigastric pain)***	Recovered	11-Jul-2024 6 months 2 days	DURVALUMAB	Infusion	1500 milligram single Intravenous use	01-FEB-2024 to 01-FEB-2024 1 day	Periodic Report Comment. Male patient with event: Epigastric Pain (hospitalisation), reporter causality: related, company causality: not related.
						Infusion	1500 milligram single Intravenous use	07-FEB-2025 to 07-FEB-2025 1 day	
						Infusion	1500 milligram single Intravenous use	10-JAN-2024 to 10-JAN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D910PC00001

EudraCT No: 2023-507342-84-00

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						Infusion	1500 milligram single Intravenous use	10-JAN-2025 to 10-JAN-2025 1 day	
						Infusion	1500 milligram single Intravenous use	13-DEC-2024 to 13-DEC-2024 1 day	
						Infusion	1500 milligram single Intravenous use	15-NOV-2024 to 15-NOV-2024 1 day	
						Infusion	1500 milligram single Intravenous use	18-OCT-2024 to 18-OCT-2024 1 day	
						Infusion	1500 milligram single Intravenous use	20-SEP-2024 to 20-SEP-2024 1 day	

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						Infusion	1500 milligram single Intravenous use	22-AUG-2024 to 22-AUG-2024 1 day	
						Infusion	1500 milligram single Intravenous use	23-FEB-2024 to 23-FEB-2024 1 day	
						Infusion	1500 milligram single Intravenous use	26-JUL-2024 to 26-JUL-2024 1 day	
						Infusion	1500 milligram single Intravenous use	27-JUN-2024 to 27-JUN-2024 1 day	
					TREMELIMUMAB	Infusion	75 milligram single Intravenous use	08-FEB-2024 to 08-FEB-2024 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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						Infusion	75 milligram single Intravenous use	10-JAN-2024 to 10-JAN-2024 1 day	
						Infusion	75 milligram single Intravenous use	27-JUN-2024 to 27-JUN-2024 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S) | ENFORTUMAB VEDOTIN (S) | Prednisone (C) | Loratadine (C) | Iron sucrose (C) | Famoditine (C) | Erythropoietin (C) | Sucralfate (C) | Imipenem (C) | Diclofenac (C) | Dexamethasone (C) | Metoclopramide (C)									
202504GLO000794PT	PORTUGAL 75 Years Female	**Immune-mediated enterocolitis (Immune-mediated enterocolitis)***	Recovered	19-Feb-2025 8 months 13 days 9 hrs 20 min	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	14-NOV-2024 to 05-MAR-2025 3 months 20 days	
						Infusion	1500 milligram single Intravenous use	02-JUL-2024 13:15 to 02-JUL-2024 14:15 1 hr	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-507342-84-00

Study Design: Not Blinded

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						Infusion	1500 milligram single Intravenous use	05-JUN-2024 14:40 to 05-JUN-2024 15:40 1 hr	
						Infusion	1500 milligram single Intravenous use	24-JUL-2024 13:00 to 24-JUL-2024 14:00 1 hr	

Concomitant Medication(s): | ENFORTUMAB VEDOTIN (S) | Pravastatin (C) | Daflon (C) | Sertraline (C) | Ethyl loflazepate (C) | Bilastin (C) | Viterra (C) | Ferrous sulfate folic acid (C) | Levotiroxin (C) | Amoxicilina + clavulanico (C) | Clotrimazole (C) | Desloratadine (C)

SOC:General disorders and administration site conditions

202411GLO009388NL	NETHERLANDS 72 Years Female	**Malaise (Malaise)***	Recovered	08-Nov-2024 4 days	ENFORTUMAB VEDOTIN	Powder for solution for infusion	Intravenous use	03-DEC-2024 to 03-DEC-2024 1 day	
						Powder for solution for infusion	Intravenous use	05-NOV-2024 to 05-NOV-2024 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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						Powder for solution for infusion	Intravenous use	17-DEC-2024 to 17-DEC-2024 1 day	
						Powder for solution for infusion	Intravenous use	19-NOV-2024 to 19-NOV-2024 1 day	
						Powder for solution for infusion	Intravenous use	24-DEC-2024 to 24-DEC-2024 1 day	
						Powder for solution for infusion	Intravenous use	26-NOV-2024 to 26-NOV-2024 1 day	

Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | | Budesonide | Formoterol (C) | Salbutamol (C) | Dermovate (C) | Cetomacrogol (C) | Macrogol (C) | Ondansetron (C) | Paracetamol (C)

SOC:Hepatobiliary disorders

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2023A143930	SPAIN 72 Years Male	**Drug-induced liver injury (Hy's law case)***	Recovered	14-Jun-2023 1 month 20 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	26-APR-2023 to 07-JUN-2023 1 month 13 days	Periodic Report Comment. Investigator: hepatitis was related to Durvalumab, Tremelimumab and Enfortumab Vedotin. LDH: 292, ALT: 432, AST: 385, GGT: 507. Company: event was unrelated to Enfortumab Vedotin, but related to Durvalumab, Tremelimumab.
					ENFORTUMAB VEDOTIN	Powder for solution for infusion	Intravenous use	26-APR-2023 to 07-JUN-2023 1 month 13 days	
					TREMELIMUMAB	Infusion	Intravenous use	26-APR-2023 to 24-MAY-2023 29 days	

Concomitant Medication(s): | TREMELIMUMAB (S) | ENFORTUMAB VEDOTIN (S) | Todacitan (C)

SOC:Infections and infestations

2023A281909	BRAZIL 63 Years Female	**Urinary tract infection (Urinary tract infection)***	Recovered	08-Dec-2023 2 days	D910PC00001 Ph3 Study	Powder for solution for infusion	1.25 milligram/kilogram single Intravenous use	04-JAN-2024 14:35 to 04-JAN-2024 15:15 40 min	Periodic Report Comment. Female patient experienced urinary tract infection. Investigator: event was related to enfortumab vedotin and not related to durvalumab. Company: event was unrelated to enfortumab vedotin and durvalumab.

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						Powder for solution for infusion	1.25 milligram/kilogram single Intravenous use	06-DEC-2023 12:05 to 06-DEC-2023 12:35 30 min	
						Powder for solution for infusion	1.25 milligram/kilogram single Intravenous use	14-DEC-2023 16:10 to 14-DEC-2023 16:40 30 min	
						Powder for solution for infusion	1.25 milligram/kilogram single Intravenous use	18-JAN-2024 15:55 to 18-JAN-2024 16:25 30 min	
						Powder for solution for infusion	1.25 milligram/kilogram single Intravenous use	24-JAN-2024 14:30 to 24-JAN-2024 15:00 30 min	
						Powder for solution for infusion	1.25 milligram/kilogram single Intravenous use	28-DEC-2023 12:55 to 28-DEC-2023 13:25 30 min	

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Concomitant Medication(s): | BLINDED DURVALUMAB (S) | Metoclopramide (C) | Dipyrone (C) | Piperacilin (C) | Tazobactam (C) | Amoxicillin (C) | Clavulanic acid (C) | Ceftriaxon (C) | Pantoprazole (C) | Morphine (C) | Enoxaparin (C) | Bromopride (C) | Neostigmine (C) | Azithromycin (C) | Levothyroxine (C) | Simeticone (C)									
2024A110213	GERMANY 73 Years Male	**Sepsis (Sepsis)***	Recovered	07-May-2024 1 month 22 days 13 hrs 10 min					
Concomitant Medication(s):									

SOC:Investigations

202509GLO020310JP	JAPAN 74 Years Male	**Blood creatinine increased (Creatinine increased)***	Not Recovered	24-Jun-2025 7 months 24 days	TREMELIMUMAB	Infusion	75 milligram Intravenous use	01-NOV-2024 to 01-NOV-2024 1 day
						Infusion	75 milligram Intravenous use	04-MAR-2025 to 04-MAR-2025 1 day

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						Infusion	75 milligram Intravenous use	29-NOV-2024 to 29-NOV-2024 1 day	

Concomitant Medication(s): DURVALUMAB (S) | | ENFORTUMAB VEDOTIN (S) | Imeglimin hydrochloride (C) | Clobetasol propionate (C) | Bilastine (C) | Heparinoid (C) | Daikenchuto (C) | Miya-bm (C) | Sodium zirconium cyclosilicate hydrate (C) | Bilanoa (C) | Betamethasone (C)

SOC:Metabolism and nutrition disorders

202409GLO006108DE	GERMANY 76 Years Male	**Dehydration (Dehydration)***	Recovered	17-Sep-2024 1 month 3 days					

Concomitant Medication(s):

2024A133053	NETHERLANDS 58 Years Male	**Diabetic ketoacidosis (Diabetic ketoacidosis)*** Multiple organ dysfunction syndrome (Multi organ failure)*	Fatal	04-Jun-2024 17 days 12 hrs 45 min	DURVALUMAB	Infusion	1500 milligram single Intravenous use	17-MAY-2024 11:15 to 17-MAY-2024 12:20 1 hr 5 min	Periodic Report Comment. Inv.: diabetic ketoacidosis and Multi organ failure related to study therapy. CCA: not related.

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					ENFORTUMAB VEDOTIN	Powder for solution for infusion	1.25 milligram/kilogram Intravenous use	17-MAY-2024 to 24-MAY-2024 8 days	
Concomitant Medication(s): | ENFORTUMAB VEDOTIN (S) | RIVAROXABAN (C) | AMLODIPINE (C) | METOCLOPRAMIDE (C) | CEFTRIAXON (C) | Ferric Carboxymaltose (C) | Red blood cells (C) | Paracetamol (C)									
2024A171174	BRAZIL 73 Years Male	**Hyperglycaemia (Hyperglycemia)***	Recovered	15-Jul-2024 8 weeks 5 days					
Concomitant Medication(s):									

SOC:Nervous system disorders

202507GLO013692JP	JAPAN 71 Years Male	**Neuropathy peripheral (Neuropathy peripheral)***	Recovering	04-Jul-2025 5 months 18 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	17-JAN-2025 to 28-FEB-2025 1 month 12 days
						Infusion	1500 milligram q4w Intravenous use	24-JUN-2025 to 24-JUN-2025 1 day
Concomitant Medication(s): ENFORTUMAB VEDOTIN (S) | | Heparinoid (C) | Loratadine (C) | Lubiprostone (C) | Diphenhydramine (C)								

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Renal and urinary disorders									
202412GLO021117ES	SPAIN 67 Years Male	**Acute kidney injury (Acute renal failure)***	Recovering	19-Dec-2024 6 months 7 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	13-JUN-2024 to 04-JUL-2024 22 days	Periodic Report Comments. The Patient experienced ACUTE RENAL FAILURE. Action Taken: Temporarily Withdrawn. For Study therapy: Investigator causality: DURVALUMAB-Related, ENFORTUMAB VEDOTIN- Not related. CC: DURVALUMAB and ENFORTUMAB VEDOTIN- Not related. Outcome: Recovering.; Periodic Report Comments. The Patient experienced ACUTE RENAL FAILURE. Creatine 2.53 mg/dl.Action Taken: Temporarily Withdrawn for Docetaxel, none for Durva.. For Study therapy: Investigator causality: DURVALUMAB-Related, ENFORTUMAB VEDOTIN- Not related. CC: DURVALUMAB and ENFORTUMAB VEDOTIN- Not related. Outcome: Recovering.
						Infusion	1500 milligram q4w Intravenous use	24-OCT-2024 to 21-NOV-2024 29 days	
						Infusion	1500 milligram single Intravenous use	01-AUG-2024 to 01-AUG-2024 1 day	
Concomitant Medication(s): | ENFORTUMAB VEDOTIN (S) | Simvastatina (C) | Fosfomycin (C) | Omeprazol (C) | Iron (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910P

Study ID: D910PC00001

EudraCT No: 2023-507342-84-00

Study Design: Not Blinded

Study Description: D910PC00001 Ph3 Study - Imfinzi + treme ± EV in MIBC Cis-Ineligible - A Phase III Randomized, Open-Label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab in Combination With Tremelimumab and Enfortumab Vedotin or Durvalumab in Combination With Enfortumab Vedotin for Perioperative Treatment in Patients Ineligible for Cisplatin or Who Refuse Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A188346	ARGENTINA 69 Years Male	**Renal failure (Renal insufficiency)***	Recovered	16-Aug-2024 7 months 28 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	20-DEC-2023 to 11-JAN-2024 23 days	Periodic Report Comment. Pt exp. renal insufficiency. Inv: event related to Study procedure, unrelated to Durvalumab, EV. CCA: event ubrelated to Study procedure, Durvalumab and EV.
						Infusion	1500 milligram q4w Intravenous use	06-SEP-2024 to 24-JAN-2025 4 months 19 days	
						Infusion	1500 milligram q4w Intravenous use	24-MAY-2024 to 22-JUL-2024 1 month 29 days	
						Infusion	1500 milligram single Intravenous use	07-FEB-2024 13:25 to 07-FEB-2024 14:25 1 hr	

Concomitant Medication(s): | ENFORTUMAB VEDOTIN (S) | Clobetasol 0.05% (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910P

Study ID: D910PC00001

EudraCT No: 2023-507342-84-00

Study Design: Not Blinded

Study Description: D910PC00001 Ph3 Study - Imfinzi + treme ± EV in MIBC Cis-Ineligible - A Phase III Randomized, Open-Label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab in Combination With Tremelimumab and Enfortumab Vedotin or Durvalumab in Combination With Enfortumab Vedotin for Perioperative Treatment in Patients Ineligible for Cisplatin or Who Refuse Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202505GLO028297BR	BRAZIL 74 Years Male	**Acute kidney injury (Acute renal failure)***	Recovered	21-May-2025 1 year 19 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	03-MAY-2024 to 14-JUN-2024 1 month 12 days	
						Infusion	1500 milligram q4w Intravenous use	09-SEP-2024 to 31-JAN-2025 4 months 23 days	
						Infusion	1500 milligram q4w Intravenous use	21-FEB-2025 to 17-APR-2025 1 month 28 days	
Concomitant Medication(s): | TREMELIMUMAB (S) | ENFORTUMAB VEDOTIN (S) | Levothyroxine (C) | Ceftriaxone (C) | Losartan potassium (C)									

SOC:Respiratory, thoracic and mediastinal disorders

2023A091921	AUSTRIA 75 Years Male	**Pneumonitis (Pneumonitis)***	Recovered	18-Apr-2023 1 month 12 days	DURVALUMAB	Infusion	1496 milligram single Intravenous use	28-MAR-2023 to 18-APR-2023 22 days	Periodic Report Comment. Patient received Durvalumab, Tremelimumab, Enfortumab Vedotin. Inv.: related to study therapy.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910P

Study ID: D910PC00001

EudraCT No: 2023-507342-84-00

Study Design: Not Blinded

Study Description: D910PC00001 Ph3 Study - Imfinzi + treme ± EV in MIBC Cis-Ineligible - A Phase III Randomized, Open-Label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab in Combination With Tremelimumab and Enfortumab Vedotin or Durvalumab in Combination With Enfortumab Vedotin for Perioperative Treatment in Patients Ineligible for Cisplatin or Who Refuse Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1511.39 milligram single Intravenous use	07-MAR-2023 to 07-MAR-2023 1 day	
					ENFORTUMAB VEDOTIN	Powder for solution for infusion	1.25 milligram/kilogram single Intravenous use	04-APR-2023 to 04-APR-2023 1 day	
						Powder for solution for infusion	1.25 milligram/kilogram single Intravenous use	07-MAR-2023 to 07-MAR-2023 1 day	
						Powder for solution for infusion	1.25 milligram/kilogram single Intravenous use	14-MAR-2023 to 14-MAR-2023 1 day	
						Powder for solution for infusion	1.25 milligram/kilogram single Intravenous use	28-MAR-2023 to 28-MAR-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910P

Study ID: D910PC00001

EudraCT No: 2023-507342-84-00

Study Design: Not Blinded

Study Description: D910PC00001 Ph3 Study - Imfinzi + treme ± EV in MIBC Cis-Ineligible - A Phase III Randomized, Open-Label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab in Combination With Tremelimumab and Enfortumab Vedotin or Durvalumab in Combination With Enfortumab Vedotin for Perioperative Treatment in Patients Ineligible for Cisplatin or Who Refuse Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					TREMELIMUMAB	Infusion	75 milligram/sq. meter single Intravenous use	04-APR-2023 to 04-APR-2023 1 day	
						Infusion	75 milligram/sq. meter single Intravenous use	07-MAR-2023 to 07-MAR-2023 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S) | ENFORTUMAB VEDOTIN (S) | DILATREND (C) | LISINOPRIL (C) | NOVALGIN (C) | INHIXA (C) | MOLAXOLE (C) | ADVANTAN (C) | ZINNAT (C) | BANEOCIN (C) | BERODUAL (C) | AMBROXOL (C) | Acemin (C) | Dilatrend (C)									
2024A191019	SPAIN 81 Years Female	**Immune-mediated lung disease (Immune-mediated pneumonitis)***	Fatal	17-Aug-2024 10 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	08-AUG-2024 to 08-AUG-2024 1 day	Periodic Report Comments. Patient has event: IMMUNE-MEDIATED PNEUMONITIS, Action Taken: Study therapy was withdraw. Investigator Causality: related, Company Causality: Related
					ENFORTUMAB VEDOTIN	Powder for solution for infusion	1.25 milligram/kilogram Intravenous use	08-AUG-2024 to 08-AUG-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910P

Study ID: D910PC00001

EudraCT No: 2023-507342-84-00

Study Design: Not Blinded

Study Description: D910PC00001 Ph3 Study - Imfinzi + treme ± EV in MIBC Cis-Ineligible - A Phase III Randomized, Open-Label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab in Combination With Tremelimumab and Enfortumab Vedotin or Durvalumab in Combination With Enfortumab Vedotin for Perioperative Treatment in Patients Ineligible for Cisplatin or Who Refuse Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for infusion	1.25 milligram/kilogram Intravenous use	14-AUG-2024 to 14-AUG-2024 1 day	
					TREMELIMUMAB	Infusion	75 milligram qd Intravenous use	08-AUG-2024 to 08-AUG-2024 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S) | ENFORTUMAB VEDOTIN (S) | Infliximab biosimilar 1 (S) | Enalapril (C) | Hydrochorothiazide (C)									
SOC:Skin and subcutaneous tissue disorders									
2023A068339	ARGENTINA 60 Years Female	**Stevens-Johnson syndrome (Stevens-Johnson syndrome)***	Fatal	18-Mar-2023 1 month 6 days	ENFORTUMAB VEDOTIN	Powder for solution for infusion	1.25 milligram/kilogram Intravenous use	13-FEB-2023 to 13-MAR-2023 1 month 1 day	Periodic Report Comment. pt exp serious stevens-johnson syndrome Inv: event related to Enfortumab Vedotin, unrelated to Durvalumab. Comp causality unrelated tov Enfortumab Vedotin and Durvalumab.
Concomitant Medication(s): DURVALUMAB (S) | | Lisinopril (C) | Atenolol (C) | Lorazepam (C) | Cefatrizine propyleneglycolate (C) | Vitamin A (C) | Allantoin (C)									
2024A164221	ITALY 73 Years Male	**Dermatitis exfoliative (Exfoliative dermatitis)*** Toxic epidermal necrolysis (Toxic epidermal necrolysis)*	Not Recovered	16-Jul-2024 16 days	ENFORTUMAB VEDOTIN	Powder for solution for infusion	1.25 milligram/kilogram Intravenous use	01-JUL-2024 to 01-JUL-2024 1 day	Periodic Report Comment. Patient experienced exfoliative dermatitis and toxic epidermal necrolysis) Investigator causality - related with ENFORTUMAB VEDOTIN

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910P

Study ID: D910PC00001

EudraCT No: 2023-507342-84-00

Study Design: Not Blinded

Study Description: D910PC00001 Ph3 Study - Imfinzi + treme ± EV in MIBC Cis-Ineligible - A Phase III Randomized, Open-Label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab in Combination With Tremelimumab and Enfortumab Vedotin or Durvalumab in Combination With Enfortumab Vedotin for Perioperative Treatment in Patients Ineligible for Cisplatin or Who Refuse Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for infusion	1.25 milligram/kilogram Intravenous use	08-JUL-2024 to 08-JUL-2024 1 day	and NOT RELATED with Durvalumab and Tremelimumab. CCA: not related

Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | | Cardioaspirin (C) | NOBISTAR (C) | PRELECTAL (C) | Paracetamol (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910S

Study ID: D910SC00001

EudraCT No: 2023-506413-22-00

Study Design: Double Blinded

Study Description: D910SC00001 Durva+dCRT in LA unresectable ESCC (KUNLUN) - A Phase III, Randomized, Double-Blind, Placebo Controlled, Multi-Center, International Study of Durvalumab Given Concurrently With Definitive Chemoradiation Therapy in Patients With Locally Advanced, Unresectable Esophageal Squamous Cell Carcinoma (KUNLUN)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
2022A002419	CHINA 54 Years Female	**Myelosuppression (Myelosuppression)***	Recovered	28-Nov-2021 12 days					
Concomitant Medication(s):									
SOC:Skin and subcutaneous tissue disorders									
202502GLO005307MX	MEXICO 75 Years Male	**Dermatitis exfoliative generalised (Erythroderma)***	Recovered	12-Jan-2025 517 days					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
2024A045893	CHINA 50 Years Male	**Myelosuppression (Myelosuppression)***	Recovered	22-Feb-2024 nk	LENVATINIB	Capsule	Oral use	28-APR-2023 to 06-MAY-2023 9 days	Periodic Report Comment. Patient experienced myelosuppression. ,Inv, related to Durvalumab, Lenvatinib, not related to Tremelimumab, Comp: not Related
					DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	28-APR-2023 to 02-APR-2025 1 year 11 months 6 days	
Concomitant Medication(s): DURVALUMAB (S) | | TREMELIMUMAB (S) | Entecavir (C) | Silybin meglumine (C) | Leucogen (C) | Apo levothyroxine (C)									
SOC:Cardiac disorders									
2024A002435	KOREA, REPUBLIC OF 67 Years Female	**Myocarditis (Myocarditis)***	Fatal	22-Dec-2023 3 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	20-DEC-2023 to	Periodic Report Comment. The patient experienced Myocarditis:. Inv causality related toDurvalumab (Durvalumab/Tremelimumab Combo Therapy) And Tremelimumab (Durvalumab/Tremelimumab Combo Therapy), . Comp causality not related to study therapy.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					TREMELIMUMAB	Infusion	300 milligram single Intravenous use	20-DEC-2023 to 20-DEC-2023 1 day	
Concomitant Medication(s): | LENVATINIB (S) | TREMELIMUMAB (S) | Aronamin gold (C) | Ultracet er semi (C) | Causalon (C) | Austrastaph (C) | Enalapril maleate (C) | Furosemide (C) | Huons lidocaine hcl 2% with epinephrine (C) | Septrin (C) | Human albumin 20% behring (C) | Oyster shell cacium with vitamin d (C) | Etomidate hydrochloride (C) | Albumin human (C) | Magnesium sulfate (C) | Mebapenem (C) | Biomed midazolam (C) | Roisol (C) | Sodium bicarbonate (C)									
202503GLO008160CN	CHINA 57 Years Male	**Acute myocardial infarction (Acute myocardial infarction)***	Recovered	05-Mar-2025 nk	DURVALUMAB	Infusion	Intravenous use	29-NOV-2024 to 20-MAR-2025 3 months 20 days	
						Infusion	1500 milligram Intravenous use	04-SEP-2024 to 04-SEP-2024 1 day	
						Infusion	1500 milligram Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram Intravenous use	08-DEC-2023 to 08-DEC-2023 1 day	
						Infusion	1500 milligram Intravenous use	09-JUL-2024 to 09-JUL-2024 1 day	
						Infusion	1500 milligram Intravenous use	11-JAN-2024 to 11-JAN-2024 1 day	
						Infusion	1500 milligram Intravenous use	11-JUN-2024 to 11-JUN-2024 1 day	
						Infusion	1500 milligram Intravenous use	12-SEP-2023 to 12-SEP-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram Intravenous use	15-APR-2024 to 15-APR-2024 1 day	
						Infusion	1500 milligram Intravenous use	15-MAY-2024 to 15-MAY-2024 1 day	
						Infusion	1500 milligram Intravenous use	19-FEB-2024 to 19-FEB-2024 1 day	
						Infusion	1500 milligram Intravenous use	19-MAR-2024 to 19-MAR-2024 1 day	
						Infusion	1500 milligram Intravenous use	29-OCT-2024 to 29-OCT-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram Intravenous use	30-SEP-2024 to 30-SEP-2024 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | Euthyrox (C) | Entecavir (C)									
202507GLO009955CA	CANADA 66.5 Years Male	**Cardiac failure acute (Acute heart failure)***	Recovered	11-Jul-2025 nk	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	06-JUN-2024 to 24-JUN-2025 1 year 19 days	
					TREMELIMUMAB	Infusion	300 milligram q3w Intravenous use	06-JUN-2024 to 06-JUN-2024 1 day	
Concomitant Medication(s): | LENVATINIB (S) | TREMELIMUMAB (S) | Hydrochlorothiazide (C) | Nifedipine er (C) | Ramipril (C) | Triamterene (C) | Acetaminophen (C) | Gravol (C) | Ipratropium bromide (C) | Salbutamol (C) | Levothyroxine (C) | Polyethylene glycol (C) | Bismuth subsalicylate (C) | Loperamide (C)									

SOC:Gastrointestinal disorders

2023A100612	CANADA 66.3 Years Male	**Colitis (Colitis)***	Recovered	25-Apr-2023 6 days					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A013223	SAUDI ARABIA 63 Years Male	**Diarrhoea (Diarrhea)***	Recovered	27-Dec-2023 nk	LENVATINIB	Capsule	Oral use	06-DEC-2023 to 15-DEC-2023 10 days	
						Capsule	12 milligram qd Oral use	06-DEC-2023 to 24-FEB-2024 2 months 19 days	
Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | | Deflazacort (C) | Ursodeoxycholic acid orion (C) | Aceclofenac (C) | Apo-cefuroxime (C) | Cholestyramine (C) | Atarax (C) | Ondansetron (C) | Methylprednisolone (C) | Midazolam (C) | Potassium Phosphate (C) | Glucose (C) | Mycophenolate mofetil (C) | Prednisolone (C) | Isoniazid (C) | Pyridoxin (C) | Valganciclovir (C) | Docusate (C) | Tacrolimus (C) | Bismuth (C) | Omeprazole (C)									
2024A055777	FRANCE 65.8 Years Male	**Pancreatitis (Pancreatitis)***	Recovered	04-Mar-2024 1 month 3 days	TREMELIMUMAB	Infusion	Intravenous use	02-FEB-2024 to 02-FEB-2024 1 day	Periodic Report Comment. Patient experienced encephalopathy (EXCLUDED PANCREATIC ENCEPHALOPATHY, neutropenia and pancreatitis. INV related to study therapy, comp: not related to study therapy.;Patient experienced encephalopathy (EXCLUDED PANCREATIC ENCEPHALOPATHY, neutropenia and pancreatitis. INV related to study therapy, comp: not related to study therapy.;Periodic Report Comments. The outcome of event Encephalopathy
						Infusion	300 milligram Intravenous use	02-FEB-2024 to 02-FEB-2024 1 day	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
									updated to not recovered. Action taken for suspect drug "Durvalumab" changed from Not Applicable to Temporarily withdrawn. Concomittants are added.
Concomitant Medication(s): DURVALUMAB (S) | | LENVATINIB (S) | Acupan (C) | Atarax (C) | Ondansetrone Teva (C) | Oxynormoro (C) | Alucytosine (C) | Electrolyte (C) | Human insulin (C) | Acunaso (C) | Sodium chlorure nirma (C) | Actynox (C) | Tazocilline (C) | Augmentin (C) | Levemir (C) | Metformine (C) | Alloscan (C) | Lidodan endotracheal (C) | Azithromycin dihydrate (C)									
202510GLO013280VN	VIET NAM 68 Years Male	**Diarrhoea (Acute diarrhea)***	Recovered	11-Oct-2025 2 years 2 months 22 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	20-JUL-2023 to	
					LENVATINIB	Capsule	8 milligram qd	20-JUL-2023 to	
					TREMELIMUMAB	Infusion	300 milligram q3w Intravenous use	20-JUL-2023 to 20-JUL-2023 1 day	
Concomitant Medication(s): | LENVATINIB (S) | TREMELIMUMAB (S)									

SOC:General disorders and administration site conditions

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A070577	JAPAN 64 Years Female	**Pyrexia (Fever)***	Recovered	18-Mar-2023 23 days	TREMELIMUMAB	Infusion	300 milligram single Intravenous use	24-FEB-2023 to 24-FEB-2023 1 day	Periodic Report Comments. The patient experienced Fever Investigator: Related to Durvalumab and Tremelimumab and not related to Lenvatinib. Company physician: Not related to study therapy.
Concomitant Medication(s): DURVALUMAB (S) | | LENVATINIB (S) | Entecavir (C) | Keratinamin (C) | Myser (C) | Nifedipine cr ze (C) | Adona (C) | Cefazolin (C) | Transamin (C) | Daewoongbio loxoprofen (C) | Bfluid (C)									
2023A076348	INDIA 51 Years Male	**Asthenia (Weakness)***	Recovered	28-Mar-2023 1 month 26 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	03-APR-2023 to 15-JUL-2023 3 months 13 days	Periodic Report Comment. Inv: weakness. not related to Durvalumab and Tremelimumab combination therapy, not related to Lenvatinib . Patient had vomiting, diarrhoea, weakness. Patient was admitted and received supportive treatment with IV fluids and IV PPI.;Periodic Report Comments. Patient experience Weakness. Investigator: Related Durvalumab, Tremelimumab and Not related to Lenvatinib . CCA: Not related to Study therapy. Action taken: Drug withdrawn, Not applicable and no change respectively.
						Infusion	1500 milligram q4w Intravenous use	03-FEB-2023 to 03-FEB-2023 1 day	
						Infusion	1500 milligram q4w Intravenous use	27-MAY-2023 to 27-MAY-2023 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					TREMELIMUMAB	Infusion	Intravenous use	03-FEB-2023 to 03-FEB-2023 1 day	
						Infusion	300 milligram single Intravenous use	03-FEB-2023 to 03-FEB-2023 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | 5-Methyltetrahydrofolate (C) | Ag pantoprazole (C) | Looz (C) | Ag metformin (C) | 5-Methyltetrahydrofolate (C) | 1-(p-aethoxyphenyl)-1-diaethylamino-3-m (C) | B complex (b50) (C) | Etoricoxib (C) | Folic (C) | Cardivas (C) | Betnesol (C) | Xylocaine viscous (C) | Cetirizine (C) | Eglucent (C) | Hydralac (C) | Dytor (C) | Acc inject (C) | 5-Methyltetrahydrofolate (C) | Magnex forte (C) | Tramadol (C) | Act levofloxacin (C) | Rifagut (C) | Shelcal (C) | Azithromycin (C) | Chemset (C) | Rantac mps (C) | Becosules (C) | Emeset (C) | Softovac (C) | Cardivas (C) | Propranolol (C) | Metronidazole (C) | Magnex forte (C) | Tramadol (C) | Dytor plus (C) | Rantac (C) | Acetylcysteine (C) | Magnex forte (C) | Tramadol (C) | Pantothenic acid (C) | Levoflox (C) | Lactulose (C) | Metformin (C) | Pyridoxine hydrochloride (C) | Shelcal HD (C) | Avil (C) | Emset (C) | Rantac (C) | Becosules (C) | Pantoprazole (C) | Softovac (C) | B complex (C) | Etoricoxib (C) | Folic acid (C) | Amlodipine besilate (C) | Eglucent (C) | Hydralac (C) | Buscopan (C) | Gabapin (C) | Pantop (C) | Optineuron (C) | Insulin aspart (C) | Furosemide (C) | Toujeo solostar (C) | Vitamin K (C) | Lactobacillus sporogenes (C) | Loperamide (C) | Metronidazole (C) | Normal saline (C) | Ofloxacin (C) | Racecadotril (C) | Hyoscine butylbromide (C) | Albumin (C) | Clonazepam | Escitalopram (C) | Insulin (C) | Propranolol (C) | Protein (C) | Spironolactone (C) | Domperidone (C) | Lactic acid bacteria complex (C) | Blood (C) | Magnesium sulfate (C) | Levoflox (C) | Neurobion forte (C) | Thiamin (C)									
2023A216400	CHINA 75.9 Years Male	**Oedema peripheral (Edema of lower extremities)*** Rash (Localised rash)	Recovered	15-Aug-2023 nk	TREMELIMUMAB	Infusion	Intravenous use	14-JUL-2023 to 14-JUL-2023 1 day	Periodic Report Comment. paitent experianced serious events, INV: related to Durvalumab and Tremelimumab. Comp not related

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	300 milligram single Intravenous use	14-JUL-2023 to 14-JUL-2023 1 day	
Concomitant Medication(s): DURVALUMAB (S) | | LENVATINIB (S) | Amitin (C) | Polyene phosphatidylcholine (C) | Calamine (C)									
SOC:Hepatobiliary disorders									
2023A186622	CHINA 53 Years Male	**Hepatic function abnormal (Hepatic function abnormal)***	Recovered	15-Aug-2023 23 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	06-SEP-2023 to 16-APR-2025 1 year 7 months 11 days	Periodic Report Comment. Male Pt Exp: POTENTIAL HAYS LAW. Related. Serious.;Periodic Report Comments. Patient experienced abnormal liver function .Inv, related to durvalumab and tremelimumab and Lenvatinib,Inv, related to durvalumab and tremelimumab and Lenvatinib CCA : related to durvalumab and tremelimumab and Lenvatinib and DURVALUMAB ,Inv, related to durvalumab and tremelimumab and Lenvatinib,CCA :related to durvalumab and tremelimumab and Lenvatinib ,Inv, related to durvalumab and tremelimumab and Lenvatinib , CCA: not related to durvalumab and
						Infusion	1500 milligram q4w Intravenous use	24-JUL-2023 to 24-JUL-2023 1 day	
					TREMELIMUMAB	Infusion	Intravenous use	18-JUL-2023 to 18-JUL-2023 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	300 milligram Intravenous use	24-JUL-2023 to 24-JUL-2023 1 day	tremelimumab and Lenvatinib ,Inv, related to durvalumab and tremelimumab and Lenvatinib
Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | Pantoprazole sodium (C) | Tenofovir disoproxil fumarate (C) | Perindopril arginine and amlodipine besylate tablets (i) (C) | BICYCLOL (C) | Compound amino acid injection (18aa-ii) (C) | Ilaprazole sodium (C) | Medium and long chain fat emulsion injection (C6-24) (C) | Polyene phosphatidylcholine (C) | REDUCED GLUTATHIONE (C) | Sodium potassium magnesium calcium and glucose (C) | Tropisetron hydrochloride (C) | Ondansetron hydrochloride (C) | Medroxyprogesterone acetate (C) | Calamine lotion phenolated (C) | Benzoic acid (C) | Cetirizine dihydrochloride (C) | BUDESONIDE (C) | Esomeprazole sodium (C) | GLUCOSE INJECTION MP (C) | Alanyl glutamine (C) | Concentrated sodium chloride (C) | Insulin injection (C) | Octreotide acetate (C) | Ammonium chloride (C) | STRUCTURAL FAT EMULSION INJECTION (C6-24) (C) | Vitamin b6 (C) | Rabeprazole sodium (C) | Esomeprazole magnesium (C) | Recombinant human granulocyte colony stimulating factor (C) | Methylprednisolone sodium succinate (C) | Monoammonium Glycyrrhizinate and Cysteine and Sodium Chloride (C) | Ascorbic acid (C) | Propranolol hydrochloride (C) | Cetylpyridinium chloride (C) | Prednisone acetate (C) | CALCITRIOL (C) | Acetylsalicylic acid (C) | Levothyroxine sodium (C) | ENTECAVIR (C) | Tenofovir disoproxil fumarate (C) | Pantoprazole (C)									
2023A216007	CHINA 55 Years Female	**Hepatic function abnormal (Impaired liver function)***	Recovered	20-Sep-2023 29 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	23-AUG-2023 to 23-SEP-2024 1 year 1 month 1 day	Periodic Report Comment. Patient experienced liver function impairment. Inv causality related to study drug and Study procedure. Company causality related to study drug and related to Study procedure.;PRC. Patient experienced Liver function impairment. Investigator: related with study therapy and study procedure. CCA: not related.
					TREMELIMUMAB	Infusion	Intravenous use	23-AUG-2023 to 23-AUG-2023 1 day	

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Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	300 milligram Intravenous use	23-AUG-2023 to 23-AUG-2023 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | ENTECAVIR (C) | Acesulfame potassium (C) | ADEMETIONINE (C) | Actifed Compound (C) | Metoclopramide (C) | Act Esomeprazole (C) | Dexamethasone (C) | 3a magnesia (C) | Adenosine (C) | Diammonium glycyrrhizinate (C) | Actraphan human (C) | Act levofloxacin (C) | Acetic acid (C) | Polyene phosphatidylcholine (C)									
2023A287423	THAILAND 67 Years Male	**Drug-induced liver injury (Drug-induced liver injury)***	Recovered	15-Dec-2023 3 months 4 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	12-SEP-2023 to 20-AUG-2025 1 year 11 months 9 days	Periodic Report Comment. Patient experienced hy's law , Inves: related to study therapy. CCA: Related to study therapies.
					TREMELIMUMAB	Infusion	Intravenous use	12-SEP-2023 to 12-SEP-2023 1 day	
Concomitant Medication(s): | LENVATINIB (S) | TREMELIMUMAB (S) | Enalapril (C) | Glipizide (C) | Metformin (C) | Alogliptin benzoate | Pioglitazone hydrochloride (C) | Cavedil (C) | Folic acid (C) | Multivitamin (C) | Vitamin b complex (C) | Ebanel urea cream (C) | Thyroxine (C) | C (C) | Cellulose microcrystalline | Lactulose | Lignin (C) | Sodium Chloride 0.9% & Dextrose 5% (C) | Pioglitazon (C) | Ferrous fumarate (C)									
202411GLO012805FR	FRANCE 72 Years Male	**Hepatitis (Hepatitis)***	Not Recovered	13-Nov-2024 1 month 13 days					
Concomitant Medication(s):									

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EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A016177	SAUDI ARABIA 63 Years Male	**Suspected drug-induced liver injury (Suspected drug-induced liver injury)***	Recovered	19-Jan-2024 1 month 14 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	06-DEC-2023 to 04-JAN-2024 30 days	Periodic Report Comment. patient experienced CTC 3 hy's law (suspected drug-induced liver) injury and neutropenia. Inv: hy's law (suspected drug-induced liver) injury Related to study therapy and CCC related and neutropenia related to Lenvatinib and not related to Durvalumab, Tremelimumab.;Patient experienced 'Suspected drug-induced liver injury' INV; related to suspects ; CCA ; related to study therapy; Also experience neutropenia not related to suspect except levatinib.
					TREMELIMUMAB	Infusion	Intravenous use	06-DEC-2023 to 06-DEC-2023 1 day	
		Suspected drug-induced liver injury (Suspected drug-induced liver injury)* Neutropenia (Neutropenia)	Recovered	19-Jan-2024 1 month 14 days	LENVATINIB	Capsule	Oral use	06-DEC-2023 to 15-DEC-2023 10 days	
						Capsule	8 milligram qd Oral use	06-DEC-2023 to 24-FEB-2024 2 months 19 days	

Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | Aldioxa (C) | Aceclofenac and paracetamol (C) | Dexamethasone (C) | Acetylsalicylic acid (C) | Acetaminophen (C) | Ondansetron (C) | Actrapid beef (C) | Sodium Chloride 0.9% & Dextrose 5% (C) | Hydroxyzine (C) | Cholestyramine (C) | Fentanyl (C) | Co-trimoxazole (C) | Alta docusate sodium (C) | Pyridoxin (C) | Omeprazole (C) | Tacrolimus (C) | Vitamin A (C)

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Project ID: D910V

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EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO002970TH	THAILAND 56 Years Male	**Drug-induced liver injury (Drug-induced liver injury)***	Recovered	02-Jul-2025 1 year 3 months 7 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	26-MAR-2024 to 14-AUG-2025 1 year 4 months 20 days	
					TREMELIMUMAB	Infusion	300 milligram Intravenous use	26-MAR-2024 to 26-MAR-2024 1 day	
Concomitant Medication(s): | LENVATINIB (S) | TREMELIMUMAB (S) | Fentanyl (C) | Amlodipine (C) | Carvedilol (C)									
202509GLO018830PH	PHILIPPINES 72.7 Years Male	**Hepatic cirrhosis (Liver cirrhosis)***	Not Recovered	21-Sep-2025 2 years 3 months 14 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	08-JUN-2023 to 15-JUL-2025 2 years 1 month 8 days	Periodic Report Comments. Patient has events localized tetanus; Decompensated liver cirrhosis (with hepatic encephalopathy) due to hyponatremia. Action taken with Lenvatinib, Durvalumab was Temporarily withdrawn and with Tremelimumab was Not applicable. Investigator Causality: Related, CC: Not Related of Lenvatinib, Durvalumab for the event Decompensated liver cirrhosis (with hepatic encephalopathy) due to hyponatremia.
					LENVATINIB	Capsule	Oral use	08-JUN-2023 to 03-JUL-2023 26 days	
						Capsule	4 milligram Oral use	08-JUN-2023 to 13-AUG-2025 2 years 2 months 6 days	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | Livolin forte (C)									
202509GLO022754MY	MALAYSIA 68.7 Years Male	**Suspected drug-induced liver injury (Suspected Hy's law case)***	Not Recovered	25-Sep-2025 1 year 6 months 1 day	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	25-MAR-2024 to 14-AUG-2025 1 year 4 months 21 days	
					LENVATINIB	Capsule	12 milligram Oral use	25-MAR-2024 to 14-APR-2024 21 days	
						Capsule	12 milligram Oral use	25-MAR-2024 to 22-MAY-2024 1 month 28 days	
						Capsule	4 milligram Oral use	19-JUN-2025 to 13-AUG-2025 1 month 25 days	
						Capsule	8 milligram Oral use	23-MAY-2024 to 18-JUN-2025 1 year 27 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					TREMELIMUMAB	Infusion	300 milligram q3w Intravenous use	25-MAR-2024 to 25-MAR-2024 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | Entecavir (C) | Gliclazide (C) | Carvediol (C)									
SOC:Immune system disorders									
202501GLO028296FR	FRANCE 75 Years Male	**Haemophagocytic lymphohistiocytosis (Macrophage activation syndrome)***	Fatal	15-Jan-2025 1 year 27 days	DURVALUMAB	Infusion	1500 milligram q4w	17-JAN-2024 to 17-JAN-2024 1 day	Patient experienced Macrophage activation syndrome related to durvalumab and tremelimumab. Not related to lenvatinib. CCA not related.
						Infusion	1500 milligram q4w Intravenous use	03-JUL-2024 to 03-JUL-2024 1 day	
						Infusion	1500 milligram q4w Intravenous use	05-JUN-2024 to 05-JUN-2024	

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EudraCT No: 2021-003822-54

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Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram q4w Intravenous use	07-MAY-2024 to 07-MAY-2024 1 day	
						Infusion	1500 milligram q4w Intravenous use	09-APR-2024 to 09-APR-2024 1 day	
						Infusion	1500 milligram q4w Intravenous use	13-MAR-2024 to 13-MAR-2024 1 day	
						Infusion	1500 milligram q4w Intravenous use	20-DEC-2023 to 20-DEC-2023 1 day	
						Infusion	1500 milligram q4w Intravenous use	25-SEP-2024 to 18-DEC-2024 2 months 24 days	

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EudraCT No: 2021-003822-54

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Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram q4w Intravenous use	28-AUG-2024 to 28-AUG-2024 1 day	
						Infusion	1500 milligram q4w Intravenous use	31-JUL-2024 to 31-JUL-2024 1 day	
					TREMELIMUMAB	Infusion	Intravenous use	20-DEC-2023 to 20-DEC-2023 1 day	

Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | Candesartan (C) | Hydrochlorothiazide (C) | Bisoprolol (C) | Levothyrox (C) | Amoxicilline (C) | Alfuzosine (C) | Desloratadine (C) | Candesartan cilexetil (C) | Acide clavulanique (C) | Paracetamol (C) | Phloroglucinol (C) | Prednisolone (C) | Xylocaine (C)

SOC:Infections and infestations

2023A136414	SPAIN 77 Years Male	**Parotitis (Parotitis)***	Recovered	10-Jun-2023 1 month 1 day	DURVALUMAB	Infusion	Intravenous use	10-MAY-2023 to 06-MAY-2025 1 year 11 months 27 days	Periodic Report Comment. Patient experienced Parotitis, Investigator related to study therapy Durvalumab and Tremelimumab, Comp: not related to study therapy.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					TREMELIMUMAB	Infusion	Intravenous use	10-MAY-2023 to 10-MAY-2023 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S) | Doctamsulosine (C) | Enalapril (C) | Furosemida (C) | Auro sitagliptin (C) | Dapagliflozin (C) | Serum physiological (C) | Apo mometasone (C) | Tamsulosine (C) | Sitagliptin (C) | Mometasone (C)									
2023A153404	CHINA 69 Years Male	**Pneumonia (Pneumonia)***	Not Recovered	27-Jun-2023 1 month 11 days	LENVATINIB	Capsule	Oral use	17-MAY-2023 to 23-MAY-2023 7 days	
						Capsule	12 milligram qd Oral use	17-MAY-2023 to 06-JUL-2023 1 month 20 days	
						Capsule	12 milligram qd Oral use	17-MAY-2023 to 12-JUL-2023 1 month 26 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Capsule	8 milligram qd Oral use	10-JUL-2023 to 17-AUG-2023 1 month 8 days	
						Capsule	8 milligram qd Oral use	13-JUL-2023 to 27-JUL-2023 15 days	
					DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	17-MAY-2023 18:05 to 17-MAY-2023 19:06 1 hr 1 min	
					TREMELIMUMAB	Infusion	Intravenous use	17-MAY-2023 to 17-MAY-2023 1 day	
						Infusion	300 milligram single Intravenous use	17-MAY-2023 15:58 to 17-MAY-2023 16:57 59 min	

Concomitant Medication(s): DURVALUMAB (S) | | TREMELIMUMAB (S) | ENTECAVIR (C) | Metoprolol (C) | Amlodipine besylate (C) | Polaprezinc (C) | Pantoprazole sodium (C) | Lactulose (C) | Gluten (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

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EudraCT No: 2021-003822-54

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Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A262251	JAPAN 79 Years Male	**Pneumonia (Lung infection)***	Recovered	16-Nov-2023 2 months 16 days	DURVALUMAB	Infusion	1500 milligram	01-SEP-2023 to 01-SEP-2023	Periodic Report Comment. The patient experienced lung infection. Inv: related to study therapy and study procedure.. Comp causality not related to study therapy and study procedure.
						Infusion	1500 milligram	27-OCT-2023 to 27-OCT-2023 1 day	
						Infusion	1500 milligram	29-SEP-2023 to 29-SEP-2023	
						Infusion	1500 milligram Intravenous use	01-SEP-2023 to 27-OCT-2023 1 month 27 days	
					TREMELIMUMAB	Infusion	300 milligram Intravenous use	01-SEP-2023 to 01-SEP-2023 1 day	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | TREMELIMUMAB (S) | S-Amlodipine besilate (C) | Betamethasone butyrate propionate (C) | Heparinoid (C) | Acetaminophen (C) | C (C) | 25 billion good bacteria (C) | Dexmedetomid altan (C) | 1,3-dimethylxanthine (C) | Fentanyl citrate (C) | Noradrenaline (C) | Omeprazole sodium (C) | Phenylephrine hydrochloride (C) | Piperacillin hydrate (C) | Prednisolone sodium succinate (C) | Rocuronium bromide (C) | SOLDEM (C) | D'VENTIL (C) | DEXMEDETOMIDINE (C) | Furosemide (C) | Potassium chloride (C) | Prednisolone (C) | Prednisone (C) | DOSOXYGENEE (C) | AMOXYGEN (C) | Sulfamethoxazole (C) | Trimethoprim (C) | Hydrocortisone (C) | Ursodeoxycholic acid (C) | Bilastine (C) | Olopatadine hydrochloride (C) | Amlodipine besilate (C) | Amino acids (C) | Andusomeran (C) | Bacterial (C) | Dexmedetomidine hydrochloride (C) | Methyl (C) | Blood (C) | Soldem 1 (C) | Soldem 3a (C) | Fresh frozen plasma (C) | Oxygen (C)									
2024A058640	INDIA 71 Years Male	**Septic shock (Septic shock)***	Fatal	09-Mar-2024 10 days	LENVATINIB	Capsule	8 milligram qd Oral use	29-FEB-2024 to 08-MAR-2024 9 days	Periodic Report Comment. patient exp septic shock, Inv causality Yes with Lenvatinib; No with Durvalumab, Tremelimumab, CCA : not related
Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | | Torglip m (C) | Taurine (C) | Reheptin (C) | Ultracet (C) | Livogen XT (C) | Nexpro (C) | Desputum (C) | Eltroxin (C) | Anaclover (C) | Betnovate gm (C) | Domstal (C) | Lactulose (C) | Dytor (C) | Aluminium oxide (C) | Mucopain (C) | Xeromed wet spray for dry mouth (C) | Choline salicylate (C) | Avro hb haemoglobin tonic (C) | Basophil (C) | Saltan (C) | Hair volume (C) | Hair volume plus nail strong (C) | Potassium chloride (C) | Rbc (C) | Irradiated red cells concentrates-leukocytes reduced (C) | Tolvaptan (C) | Amikacin (C)									
2024A058804	PHILIPPINES 58 Years Male	**Urosepsis (Urosepsis)*** Acute on chronic liver failure (Acute on chronic liver failure)*	Fatal	08-Mar-2024 1 month 16 days	DURVALUMAB	Infusion	1500 milligram Intravenous use	22-JAN-2024 to 22-JAN-2024 1 day	Periodic Report Comment. Patient experienced urinary tract infection Inves: related to study therapy. Comp: not related to study therapy
					LENVATINIB	Capsule	8 milligram Oral use	14-FEB-2024 to 11-APR-2024 1 month 29 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Capsule	8 milligram qd Oral use	22-JAN-2024 to 13-FEB-2024 23 days	
					TREMELIMUMAB	Infusion	300 milligram Intravenous use	22-JAN-2024 to 22-JAN-2024 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | Insulin glargine (C) | Glyxambi (C) | Losartan (C) | Metoclopramide (C) | Pantoprazole (C) | Prednisone (C) | Ceftriaxone (C) | Hydrocortisone (C) | Octreotide acetate (C) | Anidulafungin (C) | Amoxivan (C) | Valganciclovir (C) | Ethylnorepinephrine (C) | Vasopressin (C) | Mosapride (C) | Methylprednisolone (C) | Omeprazole (C)									
2024A191648	FRANCE 77 Years Male	**Campylobacter gastroenteritis (Campylobacter gastroenteritis)***	Recovered	13-Aug-2024 21 days	LENVATINIB	Capsule	12 milligram qd Oral use	24-JUL-2024 to 21-AUG-2024 29 days	Periodic Report Comment. Pt exp. dehydratation and diarrhea. The investigator did not provide causality for Durvalumab, Tremelimumab and Lenvatinib.
Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | | Nebivolol (C) | Paracetamol (C) | Acetylsalicylic acid (C) | Diclofenac (C) | Hydrochlorothiazide arrow (C) | Hydrochlorothiazide (C) | Irbesartan (C) | Kardegic (C) | Azithromycine (C) | Prednisone (C)									
202509GLO013644VN	VIET NAM 68 Years Male	**Meningitis tuberculous (Tuberculous meningitis)***	Recovering	08-Aug-2025 2 years 2 months 8 days	TREMELIMUMAB	Infusion	Intravenous use	01-JUN-2023 to 01-JUN-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	300 milligram Intravenous use	01-JUN-2023 to 01-JUN-2023 1 day	
		Pulmonary tuberculosis (Pulmonary tuberculosis)* Meningitis tuberculous (Tuberculous meningitis)*	Recovering	08-Aug-2025 2 years 2 months 8 days	DURVALUMAB	Infusion	1500 milligram Intravenous use	01-JUN-2023 to 07-AUG-2025 2 years 2 months 7 days	

Concomitant Medication(s): DURVALUMAB (S) | | Amlodipin (C) | Lipanthyl (C) | Otrivin (C) | Symbicort (C) | Lactated ringer (C) | Oresol (C) | Paracetamol (C) | Cefixim (C)

SOC:Metabolism and nutrition disorders

2023A063691	CHINA 58 Years Male	**Diabetes mellitus (Diabetes mellitus)***	Recovering	14-Mar-2023 26 days	DURVALUMAB	Infusion	1500 milligram single Intravenous use	17-FEB-2023 to 30-DEC-2024 1 year 10 months 14 days	Periodic Report Comment. On 15-Mar-2023, patient blood glucose was 25.5 mmol/L before dinner, 26.5 mmol/L after dinner, 9.9 mmol/L before bedtime. Inv: Diabetes mellitus related to Durvalumab and not related to Tremelimumab.

Concomitant Medication(s): | TREMELIMUMAB (S) | Bicyclol (C) | Polyene phosphatidylcholine (C) | Hydrotalcite (C) | Ilaprazole (C) | Multi-trace elements injection (ii) (C) | Compound Amino Acids (15) and Dipeptides (2) (C) | Esomeprazole magnesium (C) | Fat (C) | Compound amino acid injection (14aa-sf) (C) | Magnesium Isoglycyrrhizinate (C) | Tenofovir amibufenamide (C) | Fat soluble vitamin (C) | Trace elements (C) | Amino acid (C) | Magnesium Isoglycyrrhizinate (C) | Polyene phosphatidylcholine (C) | Insulin aspart (C) | Insulin glargine (C) | Insulin injection (C) | Avatrombopag maleate (C) | Recombinant human thrombopoietin (C) | Levothyroxine sodium (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A257564	BRAZIL 67.7 Years Male	**Hyperglycaemia (Hyperglycemia)***	Recovered	15-Oct-2023 nk	LENVATINIB	Capsule	12 milligram qd Oral use	28-SEP-2023 to 06-NOV-2023 1 month 10 days	Periodic Report Comment. patient experienced Hyperglycemia, investigator event related to treme. Comp not related
Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | | Enalapril (C) | Act metformin (C) | Nph insulin (C) | Acetylsalicylic acid lysin (C) | Allobarbital | Aminophylline | Caffeine | Cephaelis spp. | Ephedrine (C) | Albumin human | Furosemide sodium (C) | Acetiamine hydrochloride | Acetylsalicylic acid (C) | Simvastatin (C) | Actifed chesty coughs (C) | Acetylsalicylic acid (C) | Regular insulin novo nordisk (C) | Adenosine triphosphate, disodium salt | Coenzyme a | Insulin human (C) | Metformin (C) | Omeprazole (C) | Aminophylline (C) | Furosemide (C) | Hydroxyzine (C) | Insulin (C) | Amitriptyline (C) | Empagliflozin (C) | Gliclazide (C) | Ioversol (C) | Fexofenadine (C) | Bilastine (C) | Dexchlorpheniramine (C) | Bisoprolol (C) | Nimesulide (C) | Forxiga (C)									
202410GLO027338FR	FRANCE 72.2 Years Male	**Dehydration (Dehydration)***	Recovered	29-Oct-2024 29 days	DURVALUMAB	Infusion	1500 milligram Unknown	01-OCT-2024 to 01-OCT-2024 1 day	periodic report comments. The patient experienced Dehydration. Causality related to suspect.
					TREMELIMUMAB	Infusion	Intravenous use	01-OCT-2024 to 01-OCT-2024 1 day	
						Infusion	300 milligram Unknown	01-OCT-2024 to	
Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | SPIRONOLACTONE (S) | Abasaglar (C) | Spironolactone (C) | Pregabaline (C) | Vesicare (C) | Vitamine b6 (C) | Levothyrox (C) | Rifampicine/isoniazide (C) | Furosemide (C) | Prednisolone (C) | Cholurso (C) | Umuline (C) | Toujeo (C) | Fiasp (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202505GLO016914US	UNITED STATES 70.7 Years Female	**Hyperlipasaemia (Hyperlipasemia)***	Recovered	22-Nov-2024 5 months 19 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	04-JUN-2024 to 19-NOV-2024 5 months 16 days	Periodic Report Comments. Patient has event Hyperlipasemia (intermittent). Investigator Causality: Related, CC: Not Related for study therapy.; Periodic Report Comments. Patient has event Hyperlipasemia (intermittent). Investigator Causality: Related, CC: Not Related for study therapy. Action taken of Lenvatinib updated.
						Infusion	1500 milligram q3w Intravenous use	11-FEB-2025 to 01-JUL-2025 4 months 21 days	
					TREMELIMUMAB	Infusion	300 milligram q3w Intravenous use	04-JUN-2024 to 04-JUN-2024 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | Metformin (C) | Amaryl (C) | Lisinopril (C) | Lorazepam (C) | Pravastatin (C) | Farxiga (C) | Ferrous sulfate (C) | Trulicity (C)									
202510GLO018495CN	CHINA 68 Years Male	**Diabetes mellitus (Diabetes)***	Recovered	14-Oct-2025 nk	DURVALUMAB	Infusion	1500 milligram qd Intravenous use	01-AUG-2023 to 01-AUG-2023 1 day	
						Infusion	1500 milligram qd Intravenous use	01-SEP-2023 to 01-SEP-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2021-003822-54

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram qd Intravenous use	04-AUG-2025 to 04-AUG-2025 1 day	
						Infusion	1500 milligram qd Intravenous use	04-JUL-2023 to	
						Infusion	1500 milligram qd Intravenous use	05-SEP-2024 to 05-SEP-2024 1 day	
						Infusion	1500 milligram qd Intravenous use	08-AUG-2024 to 08-AUG-2024 1 day	
						Infusion	1500 milligram qd Intravenous use	10-JUN-2025 to 10-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2021-003822-54

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Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram qd Intravenous use	11-JUL-2024 to 11-JUL-2024 1 day	
						Infusion	1500 milligram qd Intravenous use	12-JUN-2024 to 12-JUN-2024 1 day	
						Infusion	1500 milligram qd Intravenous use	13-MAY-2025 to 13-MAY-2025 1 day	
						Infusion	1500 milligram qd Intravenous use	15-APR-2024 to 15-APR-2024 1 day	
						Infusion	1500 milligram qd Intravenous use	15-APR-2025 to 15-APR-2025 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram qd Intravenous use	15-MAY-2024 to 15-MAY-2024 1 day	
						Infusion	1500 milligram qd Intravenous use	17-MAY-2023 to 17-MAY-2023 1 day	
						Infusion	1500 milligram qd Intravenous use	18-FEB-2024 to 18-FEB-2024 1 day	
						Infusion	1500 milligram qd Intravenous use	18-FEB-2025 to 18-FEB-2025 1 day	
						Infusion	1500 milligram qd Intravenous use	18-MAR-2024 to 18-MAR-2024	

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Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram qd Intravenous use	18-MAR-2025 to 18-MAR-2025 1 day	
						Infusion	1500 milligram qd Intravenous use	19-APR-2023 to 19-APR-2023 1 day	
						Infusion	1500 milligram qd Intravenous use	19-JAN-2024 to 19-JAN-2024 1 day	
						Infusion	1500 milligram qd Intravenous use	20-DEC-2023 to 20-DEC-2023 1 day	
						Infusion	1500 milligram qd Intravenous use	21-JAN-2025 to 21-JAN-2025 1 day	

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Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram qd Intravenous use	23-DEC-2024 to 23-DEC-2024 1 day	
						Infusion	1500 milligram qd Intravenous use	23-NOV-2023 to 23-NOV-2023 1 day	
						Infusion	1500 milligram qd Intravenous use	25-NOV-2024 to 25-NOV-2024 1 day	
						Infusion	1500 milligram qd Intravenous use	27-OCT-2023 to 27-OCT-2023 1 day	
						Infusion	1500 milligram qd Intravenous use	27-SEP-2023 to 27-SEP-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram qd Intravenous use	28-OCT-2024 to 28-OCT-2024 1 day	
						Infusion	1500 milligram qd Intravenous use	30-SEP-2024 to 30-SEP-2024 1 day	
Concomitant Medication(s): | LENVATINIB (S) | TREMELIMUMAB (S) | Entecavir (C) | Levothyroxine sodium (C)									

SOC:Musculoskeletal and connective tissue disorders

202503GLO019404JP	JAPAN 80 Years Male	**Myositis (Myositis)** Meningitis (Meningitis)*	Recovered	19-Mar-2025 1 year 8 months 8 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	01-NOV-2023 to 01-NOV-2023 1 day	Periodic Report Comments. The patient Male experienced serious Myositis Suspected, related to study therapy,CCA:Not related.; PRC. The patient experienced myositis and meningitis. Investigator: related to durvalumab, tremelimumab and lenvatinib for both events, company physician: not related to study therapy.;Periodic Report Comments. The patient experienced myositis and meningitis. Investigator: related to durvalumab, tremelimumab and lenvatinib for both events, company
						Infusion	1500 milligram q4w Intravenous use	02-OCT-2024 to 02-OCT-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram q4w Intravenous use	02-SEP-2024 to 02-SEP-2024 1 day	physician: not related to study therapy.
						Infusion	1500 milligram q4w Intravenous use	06-SEP-2023 to 06-SEP-2023 1 day	
						Infusion	1500 milligram q4w Intravenous use	07-AUG-2024 to 07-AUG-2024 1 day	
						Infusion	1500 milligram q4w Intravenous use	09-AUG-2023 to 09-AUG-2023 1 day	
						Infusion	1500 milligram q4w Intravenous use	10-JUL-2024 to 10-JUL-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram q4w Intravenous use	12-JUL-2023 to 12-JUL-2023 1 day	
						Infusion	1500 milligram q4w Intravenous use	12-JUN-2024 to 12-JUN-2024 1 day	
						Infusion	1500 milligram q4w Intravenous use	15-MAY-2024 to 15-MAY-2024 1 day	
						Infusion	1500 milligram q4w Intravenous use	17-APR-2024 to 17-APR-2024 1 day	
						Infusion	1500 milligram q4w Intravenous use	18-MAR-2024 to 18-MAR-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram q4w Intravenous use	19-FEB-2025 to 19-FEB-2025 1 day	
						Infusion	1500 milligram q4w Intravenous use	19-MAR-2025 to 19-MAR-2025 1 day	
						Infusion	1500 milligram q4w Intravenous use	21-FEB-2024 to 21-FEB-2024 1 day	
						Infusion	1500 milligram q4w Intravenous use	22-JAN-2025 to 22-JAN-2025 1 day	
						Infusion	1500 milligram q4w Intravenous use	24-JAN-2024 to 24-JAN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram q4w Intravenous use	25-DEC-2024 to 25-DEC-2024 1 day	
						Infusion	1500 milligram q4w Intravenous use	27-DEC-2023 to 27-DEC-2023 1 day	
						Infusion	1500 milligram q4w Intravenous use	27-NOV-2024 to 27-NOV-2024 1 day	
						Infusion	1500 milligram q4w Intravenous use	29-NOV-2023 to 29-NOV-2023 1 day	
						Infusion	1500 milligram q4w Intravenous use	30-OCT-2024 to 30-OCT-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					TREMELIMUMAB	Infusion	300 milligram single Intravenous use	12-JUL-2023 to 12-JUL-2023 1 day	
					LENVATINIB	Capsule	4 milligram qd Intravenous use	19-MAR-2025 to 20-MAR-2025 2 days	
						Capsule	4 milligram qd Intravenous use	31-JUL-2023 to 18-MAR-2025 1 year 7 months 16 days	
						Capsule	8 milligram qd Intravenous use	12-JUL-2023 to 17-JUL-2023 6 days	

Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | Allopurinol (C) | Atorvastatin (C) | Bayaspirin (C) | Hachimijiogan (C) | Azilva (C) | Esomeprazole (C) | Hishiphagen (C) | Acetaminophen (C) | Povidone-iodine (C) | Bisoprolol fumarate (C) | Thyradin (C) | Azilsartan (C) | Maobushisaishinto (C) | Levofloxacin (C) | Acidum ursodeoxycholicum (C) | Solacet d (C) | Prednisolone (C) | Trimethoprim sulfamethoxazole (C) | Zinc acetate (C)

SOC:Neoplasms benign, malignant and unspecified (incl cysts and polyps)

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EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A212540	PHILIPPINES 52 Years Female	**Tumour haemorrhage (Tumor hemorrhage)***	Fatal	16-Sep-2024 11 months 8 days					

Concomitant Medication(s):

SOC:Nervous system disorders

2024A055777	FRANCE 65.8 Years Male	**Encephalopathy (Encephalopathy)** Pancreatitis (Pancreatitis) Neutropenia (Neutropenia)*	Recovered	04-Mar-2024 1 month 3 days	LENVATINIB	Capsule	Oral use	02-FEB-2024 to 11-FEB-2024 10 days	Periodic Report Comment. Patient experienced encephalopathy (EXCLUDED PANCREATIC ENCEPHALOPATHY, neutropenia and pancreatitis. INV related to study therapy, comp: not related to study therapy.;Patient experienced encephalopathy (EXCLUDED PANCREATIC ENCEPHALOPATHY, neutropenia and pancreatitis. INV related to study therapy, comp: not related to study therapy.;Periodic Report Comments. The outcome of event Encephalopathy updated to not recovered. Action taken for suspect drug "Durvalumab" changed from Not Applicable to Temporarily withdrawn. Concomittants are added.
						Capsule	12 milligram Oral use	02-FEB-2024 to 01-MAR-2024 1 month	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | | Acupan (C) | Atarax (C) | Ondansetrone Teva (C) | Oxynormoro (C) | Alucytosine (C) | Electrolyte (C) | Human insulin (C) | Acunaso (C) | Sodium chlorure nirma (C) | Actynox (C) | Tazocilline (C) | Augmentin (C) | Levemir (C) | Metformine (C) | Alloscan (C) | Lidodan endotracheal (C) | Azithromycin dihydrate (C)									
202504GLO020750CN	CHINA 67 Years Male	**Cerebral ischaemia (Ischemia cerebrovascular)***	Recovering	23-Apr-2025 2 years 24 days	LENVATINIB	Capsule	Oral use	31-MAR-2023 to 08-APR-2023 9 days	Periodic Report Comments. Patient has event Ischemia cerebrovascular. Action taken with Lenvatinib (lenvatinib) was temporarily Withdrawn, Durvalumab (durvalumab) was not changed and with Tremelimumab was Not applicable. Investigator Causality: Related, CC: Not Related for Lenvatinib .
						Capsule	12 milligram qd Intravenous use	20-APR-2023 to 25-APR-2023 6 days	
						Capsule	12 milligram qd Intravenous use	27-APR-2023 to 27-APR-2023 1 day	
						Capsule	12 milligram qd Intravenous use	31-MAR-2023 to 08-APR-2023 9 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Capsule	4 milligram qd Intravenous use	04-OCT-2023 to 20-NOV-2023 1 month 17 days	
						Capsule	8 milligram qd Intravenous use	03-AUG-2023 to 17-AUG-2023 15 days	
						Capsule	8 milligram qd Intravenous use	13-APR-2023 to 19-APR-2023 7 days	
						Capsule	8 milligram qd Intravenous use	28-APR-2023 to 02-AUG-2023 3 months 6 days	
Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | | Entecavir (C) | Nifedipine (C) | Mosapride citrate (C) | Domperidone (C) | Esomeprazole (C)									
202505GLO022196CN	CHINA 70 Years Male	**Cerebral infarction (Cerebral infarction)***	Not Recovered	18-May-2025 2 years 9 days	LENVATINIB	Capsule	12 milligram Oral use	10-MAY-2023 to 15-MAY-2023 6 days	PRC. patient experienced cerebral infarction caused by occlusion or stenosis of the cerebral arteries. Investigator: Not related with Durvalumab and Tremelimumab and related

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Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Capsule	12 milligram Oral use	16-MAY-2023 to 16-MAY-2023 1 day	with Lenvatinib. Company physician : not related with study therapy.
						Capsule	12 milligram qd Oral use	10-MAY-2023 to 15-MAY-2023 6 days	
						Capsule	12 milligram qd Oral use	20-MAY-2023 to 06-JUN-2023 18 days	
						Capsule	8 milligram qd Oral use	07-JUN-2023 to 16-JUN-2023 10 days	
						Capsule	8 milligram qd Oral use	25-OCT-2023 to 24-DEC-2023 2 months	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Capsule	8 milligram qd Oral use	27-SEP-2023 to 19-OCT-2023 23 days	
						Capsule	8 milligram qd Oral use	29-DEC-2023 to 16-APR-2025 1 year 3 months 19 days	

Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | | Tenofovir alafenamide fumarate (C) | Insulin (C) | Levothyroxine sodium (C) | Gliclazide (C) | Dapagliflozin (C)

SOC:Psychiatric disorders

2024A056719	VIET NAM 65 Years Male	**Insomnia (Insomnia)***	Recovering	03-Dec-2023 4 months 6 days

Concomitant Medication(s):

SOC:Renal and urinary disorders

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EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A001714	THAILAND 61 Years Male	**Acute kidney injury (Acute kidney injury)***	Not Recovered	02-Jan-2024 5 months 14 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	20-JUL-2023 to 06-DEC-2023 4 months 17 days	Periodic Report Comment. the patient experienced grade three acute kidney injury, related to Durvalumab (Monotherapy), Durvalumab (Durvalumab/Tremelimumab combo therapy) and Tremelimumab (Durvalumab/Tremelimumab combo therapy).
					TREMELIMUMAB	Infusion	Intravenous use	20-JUL-2023 to 20-JUL-2023 1 day	
						Infusion	300 milligram Intravenous use	20-JUL-2023 to 20-JUL-2023 1 day	

Concomitant Medication(s): | TREMELIMUMAB (S) | Folic acid (C) | Tenofovir alafenamide (C) | Madiplot (C) | Vitamin b complex (C) | Metformin (C) | Novomix (C) | Lantus (C) | Plasil (C) | Simvastatin (C) | Methimazole (C) | Propranolol (C) | Entecavir (C) | Lactulose (C) | Manidipine (C) | Ceftriaxone (C) | Insulin (C) | Sodamint (C) | Calcium carbonate (C) | Ivermectin (C) | Omeprazole (C) | Prednisolone (C) | Aciclovir (C) | Piozon (C) | Caraten (C) | Furosemid (C) | Levothyroxine (C) | Lactulose (C) | Gabapentin (C) | Chlorpheniramine (C) | Fentanyl (C) | Acetylcysteine (C) | Simethicone (C) | Doxazocin (C) | Simvastatin (C)

SOC:Respiratory, thoracic and mediastinal disorders

2023A057639	CHINA 66 Years Female	**Interstitial lung disease (Interstitial pneumonia)** Pneumonia bacterial (Pneumonia bacterial)*	Recovered	06-Mar-2023 13 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	22-FEB-2023 to 23-MAY-2024 1 year 3 months 2 days	Periodic Report Comment. The patient had multiple small nodules were found in both lungs, old lesions in both lungs (no more information). The patient experienced pneumonia (Bacterial inflammation is

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EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					LENVATINIB	Capsule	Oral use	22-FEB-2023 to 25-FEB-2023 4 days	more likely) and Interstitial pneumonia. Action taken with Durvalumab was temporarily withdrawn, Tremelimumab was not applicable and Lenvatinib was continued with respect to these events. Investigator assessed as related while company physician assessed as not related but related to Tremelimumab with Interstitial pneumonia.
						Capsule	4 milligram qd Oral use	20-APR-2023 to 07-MAR-2024 10 months 17 days	
						Capsule	8 milligram qd Oral use	22-FEB-2023 to 08-MAR-2024 1 year 16 days	
					TREMELIMUMAB	Infusion	Intravenous use	22-FEB-2023 to 22-FEB-2023 1 day	
						Infusion	300 milligram single Intravenous use	22-FEB-2023 to 22-FEB-2023 1 day	

Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | Entecavir (C) | Amlodipine and valsartan (C)

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A288576	CHINA 58 Years Male	**Interstitial lung disease (Interstitial pneumonitis)***	Recovered	28-Nov-2023 2 months 24 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	05-SEP-2023 to 29-NOV-2023 2 months 25 days	Periodic Report Comment. Patient experienced interstitial pneumonitis pulmonary edema. Inv: event related to study therapy. CCA : not related.
					TREMELIMUMAB	Infusion	Intravenous use	05-SEP-2023 to 05-SEP-2023 1 day	
						Infusion	300 milligram single Intravenous use	05-SEP-2023 to 05-SEP-2023 1 day	

Concomitant Medication(s): | TREMELIMUMAB (S) | Entecavir (C) | Polyene (C) | Adenosylmethionine (C) | Celecoxib (C) | Diclofenac sodium (C) | Metoclopramide (C) | Ondansetron hydrochloride (C) | Sodium lactate (C) | Polyene phosphatidylcholine (C) | Glutathione (C) | Ceftazidime (C) | Azasetron hydrochloride (C) | Tramadol hydrochloride (C) | Ademetionine 1,4-butanedisulfonate (C) | Esomeprazole sodium (C) | Potassium chloride (C) | Cefazolin sodium (C) | Methylprednisolone sodium succinate (C) | Amino acid (C) | Omeprazole sodium (C) | Tamsulosin (C) | Reduced Glutathione (C) | Doxofylline (C) | Furosemide (C) | Spironolactone (C) | Tenofovir (C)

SOC:Skin and subcutaneous tissue disorders

2022A235499	KOREA, REPUBLIC OF 64 Years Male	**Dermatitis allergic (Allergic dermatitis)***	Recovered	02-Jul-2022 19 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	14-JUN-2022 to 20-FEB-2024 1 year 8 months 7 days	Periodic Report Comment. Pat exp: ischemic colitis & allergic dermatitis. Inv causality: ischemic colitis and allergic dermatitis related to study procedure; allergic dermatitis related Study therapy. Comp causa

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					TREMELIMUMAB	Infusion	300 milligram q3w Intravenous use	14-JUN-2022 to 14-JUN-2022 1 day	related to Study procedure & not to study therapy
Concomitant Medication(s): | TREMELIMUMAB (S) | Viread (C)									
202411GLO007968IT	ITALY 75.9 Years Male	**Urticaria (Wheals)***	Recovered	11-Nov-2024 29 days	DURVALUMAB	Infusion	1500 milligram Intravenous use	14-OCT-2024 to 30-APR-2025 6 months 17 days	The patient experienced diffuse urticarial wheals. Investigator: related to DURVALUMAB and TREMELIMUMAB Company physician: Not related to study therapy.; Periodic Report Comments. Patient experienced diffuse urticarial wheals, in 8 jan 2025 stop widespread urticarial hives but no itching, Inv. Causality: related to Durvalumab CCA: related to Durvalumab
Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | Empagliflozin (C) | Metformin hydrochloride (C) | Acetylsalicylic acid (C) | Rosuvastatin (C) | Ezetimibe (C) | Enalapril maleate (C) | Lercanidipine hydrochloride (C) | Pantoprazole (C) | Colestiramina (C) | Kayexalate (C)									
2024A066739	FRANCE 76.1 Years Female	**Drug eruption (Drug eruption)*** Febrile neutropenia (Febrile neutropenia)*	Recovered	17-Mar-2024 1 month 17 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	01-FEB-2024 to 01-MAR-2024 1 month 1 day	PRC. The patient experienced Lichenoid toxiderma and Febrile neutropenia. Investigator: related to Durvalumab, Tremelimumab and Lenvatinib Company physician: Not related to study therapy.;Patient experienced lichenoid toxiderma, febrile neutropenia Investigator

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					LENVATINIB	Capsule	Oral use	01-FEB-2024 to 16-FEB-2024 16 days	causality: RELATED CCC: NOT RELATED
						Capsule	8 milligram qd Oral use	01-FEB-2024 to 16-FEB-2024 16 days	
						Capsule	8 milligram qd Oral use	22-FEB-2024 to 29-FEB-2024 8 days	
					TREMELIMUMAB	Infusion	Intravenous use	01-FEB-2024 to 01-FEB-2024 1 day	
						Infusion	300 milligram Intravenous use	01-FEB-2024 to 01-FEB-2024 1 day	

Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | Polaramine (C) | Aerius (C) | Dexeryl (C) | Amlor (C)

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A097996	FRANCE 76.2 Years Female	**Pemphigus (Pemphigus)***	Recovered	07-Apr-2024 2 months 7 days	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	01-FEB-2024 to 01-FEB-2024 1 day	Periodic Report Comment. Patient experienced Reccurence of pemphigus. Inv: Related to Durvalumab, Lenvatinib, Durvalumab (durvalumab/tremelimumab combo therapy), tremelimumab (durvalumab/tremelimumab combo therapy). CCA: Not related to Study therapy,
						Infusion	1500 milligram q4w Intravenous use	01-MAR-2024 to 01-MAR-2024 1 day	
					LENVATINIB	Capsule	Oral use	01-FEB-2024 to 16-FEB-2024 16 days	
						Capsule	8 milligram qd Oral use	01-FEB-2024 to 16-FEB-2024 16 days	
						Capsule	8 milligram qd Oral use	22-FEB-2024 to 29-FEB-2024 8 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					TREMELIMUMAB	Infusion	Intravenous use	01-FEB-2024 to 01-FEB-2024 1 day	
						Infusion	300 milligram single Oral use	01-FEB-2024 to 01-FEB-2024 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | Amlor (C) | Aerius (C) | Polaramine (C) | Dexeryl (C) | Hemocal (C) | Tazocilin (C) | Vancomycine (C) | Abdomilon (C) | Uroscan (C) | Daptomycine (C) | Acneskin (C) | Dichlorexan (C) | Fucidine (C) | Herpes (C) | Aciclovir (C) | Cetrizine (C) | Prednisone (C) | Boric vaseline (C) | Sodium chlorure nirma (C) | Valaciclovir (C) | Acupan (C) | Atarax (C) | Daptomycine (C) | Vaseline (C)									
2024A163103	CHINA 72 Years Male	**Psoriasis (Psoriasis)*** Palmar erythema (Palmar erythema)*	Recovered	15-May-2024 nk	LENVATINIB	Capsule	8 milligram qd Oral use	09-JUN-2023 to 08-AUG-2023 2 months	Periodic Report Comment. Patient experienced Adverse Drug Reactions (Psoriasis-Like Changes) and palm toe redness and swelling syndrome. Inves: considered causality for study therapy LENVATINIB, comp: related to Lenvatinib;PRC. The patient experienced event Psoriasis and Swelling. Investigator: related to Lenvatinib and Not related to Durvalumab and Tremelimumab for event Psoriasis and Swelling. Company physician: Not Related lenvatinib, Durvalumab and Tremelimumab;PRC. The patient experienced event adverse drug reactions (

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
									psoriasis-like changes) and palmar toe redness and swelling syndrome (redness, desquamation, cracking) Investigator: related to Lenvatinib and Not related to Durvalumab and Tremelimumab for event adverse drug reactions (psoriasis-like changes) and palmar toe redness and swelling syndrome (redness, desquamation, cracking), Company physician: Not Related lenvatinib, Durvalumab and Tremelimumab.
Concomitant Medication(s): DURVALUMAB (S) | TREMELIMUMAB (S) | | Entecavir (C) | Loratadine (C) | Tenofovir (C) | Ademetionine (C) | Bicyclol (C) | Ilaprazole (C)									
202509GLO024656DE	GERMANY 71 Years Male	**Dermatitis atopic (Atopic eczema)***	Recovering	25-Sep-2025 1 year 3 months 20 days 9 hrs 55 min	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	02-JUL-2024 14:25 to 02-JUL-2024 15:25 1 hr	Periodic Report Comment. Patient experienced papillovesicular skin change, Inv: related to study therapy, CCA: not related to study therapy.;Periodic Report Comment. Patient experienced pruritic atopic eczema. Investigator states event pruritic atopic eczema related to Durvalumab. Investigator states event pruritic atopic eczema unrelated to Tremelimumab and Lenvatinib. Company physician considers event pruritic atopic eczema unrelated to Durvalumab, Tremelimumab and Lenvatinib.
						Infusion	1500 milligram q4w Intravenous use	02-JUL-2025 12:10 to 02-JUL-2025 13:10 1 hr	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram q4w Intravenous use	04-JUN-2024 14:05 to 04-JUN-2024 15:05 1 hr	
						Infusion	1500 milligram q4w Intravenous use	04-JUN-2025 11:55 to 04-JUN-2025 12:55 1 hr	
						Infusion	1500 milligram q4w Intravenous use	07-MAY-2025 11:15 to 07-MAY-2025 12:15 1 hr	
						Infusion	1500 milligram q4w Intravenous use	09-APR-2025 11:55 to 09-APR-2025 13:00 1 hr 5 min	
						Infusion	1500 milligram q4w Intravenous use	12-FEB-2025 11:25 to 12-FEB-2025 12:25 1 hr	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram q4w Intravenous use	12-MAR-2025 13:00 to 12-MAR-2025 14:00 1 hr	
						Infusion	1500 milligram q4w Intravenous use	15-JAN-2025 12:10 to 15-JAN-2025 13:10 1 hr	
						Infusion	1500 milligram q4w Intravenous use	18-DEC-2024 12:00 to 18-DEC-2024 13:00 1 hr	
						Infusion	1500 milligram q4w Intravenous use	19-NOV-2024 12:20 to 19-NOV-2024 13:20 1 hr	
						Infusion	1500 milligram q4w Intravenous use	23-OCT-2024 12:00 to 23-OCT-2024 13:00 1 hr	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram q4w Intravenous use	25-SEP-2024 12:45 to 25-SEP-2024 13:45 1 hr	
						Infusion	1500 milligram q4w Intravenous use	27-AUG-2025 11:10 to 27-AUG-2025 12:10 1 hr	
						Infusion	1500 milligram q4w Intravenous use	28-AUG-2024 11:45 to 28-AUG-2024 12:45 1 hr	
						Infusion	1500 milligram q4w Intravenous use	30-JUL-2024 11:50 to 30-JUL-2024 12:50 1 hr	
						Infusion	1500 milligram q4w Intravenous use	30-JUL-2025 12:30 to 30-JUL-2025 13:30 1 hr	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D910V

Study ID: D910VC00001

EudraCT No: 2021-003822-54

Study Design: Not Blinded

Study Description: D910VC00001 - EMERALD-3 - A Phase III, Randomized, Open-Label, Sponsor-Blinded, Multicenter Study of Durvalumab in Combination with Tremelimumab ± Lenvatinib Given Concurrently with Transarterial Chemoembolization (TACE) Compared to TACE Alone in Patients with Locoregional Hepatocellular Carcinoma (EMERALD-3)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | TREMELIMUMAB (S) | LENVATINIB (S) | Pantoprazol (C) | Ramipril (C) | Carvedilol (C) | Sitagliptin (C) | Simvastatin (C) | Allopurinol (C) | Heparin (C) | Ondansetron (C) | Metformin (C) | Clexane (C) | Acid Acetylsalicylic (C) | Hydrochlorothiazid (C)									
SOC:Vascular disorders									
2023A011302	TAIWAN 86 Years Female	**Hypovolaemic shock (Hypovolemic shock)***	Recovered	13-Jan-2023 10 weeks 2 days					
Concomitant Medication(s):									
2024A094345	SAUDI ARABIA 63 Years Male	**Cryoglobulinaemia (Cryoglobulinemia)***	Recovered	17-Apr-2024 1 month 26 days 11 hrs 20 min	LENVATINIB	Capsule	12 milligram qd Intravenous use	21-FEB-2024 12:40 to 13-MAR-2024 20 days 11 hrs 20 min	
Concomitant Medication(s): DURVALUMAB (S) | | TREMELIMUMAB (S) | Tenofovir (C) | Act levofloxacin (C) | Acetaminophen (C) | Ag amlodipine (C) | Apo levothyroxine (C) | Chlorazepam (C) | Aju ciprofloxacin (C) | Adco-omeprazole (C) | Ondansetron (C) | Prednisolone (C) | Xerostom saliva substitute (C) | Adco-betamethasone (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926F

Study ID: D926FC00001

EudraCT No: 2023-505992-54-00

Study Design: Not Blinded

Study Description: D926FC00001Dato-DXd + Imfinzi+AZD2936+MEDI5752+/-Carbo NSCLC (U104) - A Phase 1b, Multicenter, 2-Part, Open-Label Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Immunotherapy with or without Carboplatin in Participants with Advanced or Metastatic Non-Small Cell Lung Cancer (Tropion-Lung04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
202506GLO002775BE	BELGIUM 68 Years Female	**Neutropenia (Neutropenia)***	Recovered	27-May-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	to	PRC comments. Patient has event: neutropenia, Action Taken: Withdrawn. Investigator Causality: Related, Company Causality: Related
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S)									
202508GLO011246BE	BELGIUM 68 Years Female	**Anaemia (Anemia)***	Not Recovered	14-Aug-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	to	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S)									
SOC:Gastrointestinal disorders									
2022A272635	UNITED STATES 57 Years Female	**Colitis (Colitis)***	Recovered	22-Jul-2022 35 weeks 2 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	08-DEC-2021 12:49 to 08-DEC-2021 14:03 1 hr 14 min	Periodic Report Comment. Patient experienced colitis, investigator : related to durvalumab.;Periodic Report Comments. Patient has event: colitis. Action Taken with study therapy was DATOPOTAMAB DERUXTECAN Dose Decreased. DURVALUMAB No change. DATOPOTAMAB,

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926F

Study ID: D926FC00001

EudraCT No: 2023-505992-54-00

Study Design: Not Blinded

Study Description: D926FC00001Dato-DXd + Imfinzi+AZD2936+MEDI5752+/-Carbo NSCLC (U104) - A Phase 1b, Multicenter, 2-Part, Open-Label Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Immunotherapy with or without Carboplatin in Participants with Advanced or Metastatic Non-Small Cell Lung Cancer (Tropion-Lung04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	08-MAR-2022 13:50 to 08-MAR-2022 14:50 1 hr	CARBOPLATIN Investigator Causality: Not related CC: Not related. DURVALUMAB Causality: related CC: related.
						Infusion	1120 milligram q3w Intravenous use	10-MAY-2022 12:23 to 10-MAY-2022 13:23 1 hr	
						Infusion	1120 milligram q3w Intravenous use	15-FEB-2022 11:16 to 15-FEB-2022 12:16 1 hr	
						Infusion	1120 milligram q3w Intravenous use	17-NOV-2021 12:00 to 17-NOV-2021 13:00 1 hr	
						Infusion	1120 milligram q3w Intravenous use	18-JAN-2022 12:02 to 18-JAN-2022 13:02 1 hr	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926F

Study ID: D926FC00001

EudraCT No: 2023-505992-54-00

Study Design: Not Blinded

Study Description: D926FC00001Dato-DXd + Imfinzi+AZD2936+MEDI5752+/-Carbo NSCLC (U104) - A Phase 1b, Multicenter, 2-Part, Open-Label Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Immunotherapy with or without Carboplatin in Participants with Advanced or Metastatic Non-Small Cell Lung Cancer (Tropion-Lung04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	19-APR-2022 14:25 to 19-APR-2022 15:25 1 hr	
						Infusion	1120 milligram q3w Intravenous use	21-JUN-2022 15:06 to 21-JUN-2022 16:02 56 min	
						Infusion	1120 milligram q3w Intravenous use	28-DEC-2021 10:05 to 28-DEC-2021 11:05 1 hr	
						Infusion	1120 milligram q3w Intravenous use	31-MAY-2022 16:01 to 31-MAY-2022 17:01 1 hr	

Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | CARBOPLATIN (S) | Deltasone (C) | Sodium phosphate dibasic (C) | Glycerol (C) | Acetaminophen (C) | Umeclidinium bromide (C) | Acetylsalicylic acid (C) | Prochlorperazine (C) | Ondansetron (C) | Aspirin (C)

SOC:General disorders and administration site conditions

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926F

Study ID: D926FC00001

EudraCT No: 2023-505992-54-00

Study Design: Not Blinded

Study Description: D926FC00001Dato-DXd + Imfinzi+AZD2936+MEDI5752+/-Carbo NSCLC (U104) - A Phase 1b, Multicenter, 2-Part, Open-Label Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Immunotherapy with or without Carboplatin in Participants with Advanced or Metastatic Non-Small Cell Lung Cancer (Tropion-Lung04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202501GLO007961TR	TURKEY 50 Years Male	**Chest pain (Chest pain)*** Infusion related reaction (Infusion related reaction)*	Recovered	10-Jan-2025 24 days	DATOPOTAMAB DERUXTECAN	Injection	390 milligram Intravenous use	18-DEC-2024 to 09-JAN-2025 23 days	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | NaCl (C) | Parol (C) | Novaqua (C) | Benzydamine (C) | Nystatin (C) | Olanzapine (C) | Desloratadine (C) | Flurbiprofen (C) | Dexamethasone (C) | Pheniramine maleate (C) | Granisetron (C)									
SOC:Immune system disorders									
2022A244556	JAPAN 73 Years Male	**Cytokine release syndrome (Cytokine release syndrome)***	Recovered	03-Jul-2022 1 week 3 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	23-JUN-2022 11:01 to 23-JUN-2022 12:04 1 hr 3 min	Periodic Report Comment. Patient expereenced worsening of ggt increased, febrile neutropenia, cytokine release syndrome, multiple occurrence of neutropenia, Investigator:Related
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Filgrastim biosimilar 1 (C) | Loperamide hydrochloride (C) | Ambroxol hydrochloride (C) | Dexamethasone (C) | Metoclopramide hydrochloride (C) | Cyanocobalamin (C) | Famotidine (C) | Haloperidol (C) | Omeprazole sodium (C) | Chlorpromazine hydrochloride (C) | Baclofen (C) | Olanzapine (C) | Montelukast sodium (C) | Salbutamol sulfate (C)									
SOC:Investigations									
2022A244556	JAPAN 73 Years Male	**Gamma-glutamyltransferase increased (GGT increased)*** Febrile neutropenia (Febrile neutropenia)* Neutropenia (Neutropenia)*	Recovered	30-Jun-2022 6 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	23-JUN-2022 12:51 to 23-JUN-2022 14:26 1 hr 35 min	Periodic Report Comment. Patient expereenced worsening of ggt increased, febrile neutropenia, cytokine release syndrome, multiple occurrence of neutropenia, Investigator:Related
Concomitant Medication(s): | DURVALUMAB (S) | Filgrastim biosimilar 1 (C) | Loperamide hydrochloride (C) | Ambroxol hydrochloride (C) | Dexamethasone (C) | Metoclopramide hydrochloride (C) | Cyanocobalamin (C) | Famotidine (C) | Haloperidol (C) | Omeprazole sodium (C) | Chlorpromazine hydrochloride (C) | Baclofen (C) | Olanzapine (C) | Montelukast sodium (C) | Salbutamol sulfate (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926F

Study ID: D926FC00001

EudraCT No: 2023-505992-54-00

Study Design: Not Blinded

Study Description: D926FC00001Dato-DXd + Imfinzi+AZD2936+MEDI5752+/-Carbo NSCLC (U104) - A Phase 1b, Multicenter, 2-Part, Open-Label Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Immunotherapy with or without Carboplatin in Participants with Advanced or Metastatic Non-Small Cell Lung Cancer (Tropion-Lung04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202506GLO017724TW	TAIWAN 70 Years Female	**Lipase increased (Lipase increased)***	Recovered	14-May-2025 nk	DATOPOTAMAB DERUXTECAN	Injection		to	Periodic Report Comments. Patient has event: LIPASE INCREASED. Action Taken with study therapy was DATOPOTAMAB DERUXTECAN, DURVALUMAB Temporarily Withdrawn, CARBOPLATIN No Change. DATOPOTAMAB DERUXTECAN DURVALUMAB Investigator Causality: Related CC: Not Related. CARBOPLATIN Investigator Causality: Not Related CC: Not Related
					DURVALUMAB	Infusion		to	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S)									

SOC:Respiratory, thoracic and mediastinal disorders

202506GLO002755TR	TURKEY 69 Years Female	**Pulmonary embolism (Pulmonary embolism)***	Recovering	02-Jun-2025 2 months	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	22-APR-2025 to 14-MAY-2025 23 days	Patient experienced acute pulmonary embolism. Investigator causality related to DATOPOTAMAB DERUXTECAN, not related to carboplatin and durvalumab. CCA; not related.
						Injection	468 milligram q3w Intravenous use	03-APR-2025 to 03-APR-2025 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Glifor (C) | Diamicron (C) | Lercadip (C) | Fludex sr (C) | Empagliflozin (C) | Parol (C) | Novaqua (C) | Dekort (C) | Granisetron (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926F

Study ID: D926FC00001

EudraCT No: 2023-505992-54-00

Study Design: Not Blinded

Study Description: D926FC00001Dato-DXd + Imfinzi+AZD2936+MEDI5752+/-Carbo NSCLC (U104) - A Phase 1b, Multicenter, 2-Part, Open-Label Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Immunotherapy with or without Carboplatin in Participants with Advanced or Metastatic Non-Small Cell Lung Cancer (Tropion-Lung04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202510GLO013561TR	TURKEY Unknown	**Pneumonitis (Pneumonitis)***	Fatal	11-Oct-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	to	

Concomitant Medication(s): DURVALUMAB (S) | CARBOPLATIN (S) |

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
2023A084116	SPAIN 62.3 Years Male	**Pancytopenia (Pancytopenia)***	Recovered	05-Apr-2023 14 days	PEMETREXED	Infusion	500 milligram/sq. meter q3w Intravenous use	23-MAR-2023 to 27-APR-2023 1 month 5 days	Periodic Report Comment. Patient experienced serious pancytopenia. Inv: related to Pemetrexed, Carboplatin and not related to pembrolizumab. CCA-Unrelated with study therapy.
						Infusion	500 milligram/sq. meter q3w Intravenous use	27-APR-2023 to 27-APR-2023 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	28-MAR-2023 to 28-MAR-2023 1 day	
					CARBOPLATIN	Infusion	Intravenous use	27-APR-2023 to 27-APR-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	28-MAR-2023 to 28-MAR-2023 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | CARBOPLATIN (S) | | Alfentanyl (C) | Amoxicillin/clavulanic acid (C) | Apo ciprofloxacin (C) | Dexamethasone (C) | Omeprazol (C) | Paracetamol (C) | Fentanyl (C) | Metamizol (C) | Morphine sulfate (C)									
2023A221332	CHINA 66.8 Years Male	**Myelosuppression (Bone marrow suppression)***	Not Recovered	23-Oct-2023 12 days	CARBOPLATIN	Infusion	Intravenous use	12-OCT-2023 to 13-OCT-2023 2 days	Periodic Report Comment. Male patient experienced serious events pulmonary infection and bone marrow suppression and obstructive pneumonia and Investigator related to study drug.
					PACLITAXEL	Infusion	200 milligram/sq. meter q3w Intravenous use	12-OCT-2023 to 12-OCT-2023 1 day	
Concomitant Medication(s): | PACLITAXEL (S) | PEMBROLIZUMAB (S) | Sodium bicarbonate (C) | Buprenorphine (C) | Protein hydrolysate (C) | Sodium potassium magnesium calcium and glucose (C) | Ambroxol hydrochloride (C)									
2023A246373	INDIA 75.8 Years Male	**Thrombocytopenia (Thrombocytopenia)*** Anaemia (Anemia)	Recovered	27-Oct-2023 2 months 4 days	CARBOPLATIN	Infusion	Intravenous use	06-OCT-2023 to 06-OCT-2023 1 day	Periodic Report Comment. Patient experienced serious anemia and Thrombocytopenia related to IP. CCA related to carboplatin for anemia and Thrombocytopenia

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	14-SEP-2023 to 14-SEP-2023 1 day	
						Infusion	Intravenous use	24-AUG-2023 to 24-AUG-2023 1 day	
						Infusion	5 milligram q3w Intravenous use	06-OCT-2023 to 06-OCT-2023 1 day	
						Infusion	5 milligram q3w Intravenous use	14-SEP-2023 to 14-SEP-2023 1 day	
						Infusion	5 milligram q3w Intravenous use	24-AUG-2023 to 24-AUG-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
		Thrombocytopenia (Thrombocytopenia)* Anaemia (Anemia)*	Recovered	27-Oct-2023 2 months 4 days	DATOPOTAMAB DERUXTECAN	Injection	3 milligram/kilogram Intravenous use	06-AUG-2024 to 27-FEB-2025 6 months 22 days	
						Injection	4 milligram/kilogram Intravenous use	06-NOV-2023 to 16-JUL-2024 8 months 11 days	
						Injection	6 milligram/kilogram Intravenous use	24-AUG-2023 to 06-OCT-2023 1 month 13 days	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	24-AUG-2023 to 24-AUG-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	01-FEB-2024 to 01-FEB-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	02-APR-2024 to 02-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	04-JUN-2024 to 04-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-MAY-2025 to 05-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-FEB-2025 to 06-FEB-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	06-NOV-2023 to 06-NOV-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-OCT-2023 to 06-OCT-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-JAN-2024 to 09-JAN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-JUL-2025 to 09-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-OCT-2024 to 09-OCT-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	10-APR-2025 to 10-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	12-MAR-2024 to 12-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	13-DEC-2024 to 13-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-MAY-2024 to 14-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-SEP-2023 to 14-SEP-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	16-JAN-2025 to 16-JAN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	16-JUL-2024 to 16-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-JUN-2025 to 17-JUN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-SEP-2024 to 18-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	19-DEC-2023 to 19-DEC-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	20-AUG-2025 to 20-AUG-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-FEB-2024 to 20-FEB-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-MAR-2025 to 20-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-NOV-2024 to 20-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	23-APR-2024 to 23-APR-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	25-JUN-2024 to 25-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-MAY-2025 to 26-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-FEB-2025 to 27-FEB-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-AUG-2024 to 28-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-NOV-2023 to 28-NOV-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	28-OCT-2024 to 28-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-JUL-2025 to 30-JUL-2025 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | Pantocid (C) | Domstal (C) | Ultranise (C) | Aprecap (C) | Granisetron (C) | Rantac (C) | Avil (C) | Paracetamol (C) | Pegstim (C)									
2023A257439	POLAND 69 Years Male	**Febrile neutropenia (Febrile neutropenia)***	Fatal	09-Nov-2023 1 month 17 days 10 hrs	PACLITAXEL	Infusion	200 milligram/sq. meter q3w Intravenous use	03-NOV-2023 14:10 to 03-NOV-2023 17:10 3 hrs	Periodic Report Comment. patient experience serious sepsis shock and febrile neutropenia. Inv related to study drug of febrile neutropenia.CCA:Not related.;Periodic Report Comments. patient experience serious sepsis shock and febrile neutropenia. Inv related to study drug(Carboplatin and Paclitaxel) of febrile neutropenia. CCA:Not related.
						Infusion	200 milligram/sq. meter q3w Intravenous use	13-OCT-2023 13:05 to 13-OCT-2023 16:05 3 hrs	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	200 milligram/sq. meter q3w Intravenous use	22-SEP-2023 14:00 to 22-SEP-2023 17:00 3 hrs	
					CARBOPLATIN	Infusion	5 q3w Intravenous use	03-NOV-2023 17:40 to 03-NOV-2023 18:10 30 min	
						Infusion	5 q3w Intravenous use	13-OCT-2023 16:35 to 13-OCT-2023 17:05 30 min	
						Infusion	5 q3w Intravenous use	22-SEP-2023 17:30 to 22-SEP-2023 18:00 30 min	

Concomitant Medication(s): PEMBROLIZUMAB (S) | | CARBOPLATIN (S) | Abbott pantoprazol (C) | Atoris (C) | Ezen (C) | Nebilet (C) | Telmizek (C) | Clexane (C) | Cyclonamine (C) | Dexamethason (C) | Actovegin 10%-nacl (C) | Aj ondansetron (C) | Pyralgina (C) | Doreta (C) | Filgrastim (C) | FAMOTYDYNA RANIGAST (C) | Optilyte (C) | Adco meropenem (C) | 8-chlortheophylline (C) | Benzyl nicotinate (C) | Oxygen (C) | PANTOPRAZOLE (C) | ANACLE (C) | Pantoprazol (C) | Famogast (C) | Ondansetron (C) | Eludril care (C) | Famotydyna ranigast (C) | Meropenem (C) | Metamizol (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A260003	POLAND 64 Years Male	**Thrombocytopenia (Thrombocytopenia)***	Recovered	07-Nov-2023 2 months 6 days 21 hrs 28 min	CARBOPLATIN	Infusion	Intravenous use	21-SEP-2023 13:20 to 21-SEP-2023 14:20 1 hr	Periodic Report Comment. Patient experience thrombocytopenia serious and Investigator related to Pembrolizumab, Carboplatin. CCA: related to Pembrolizumab, Carboplatin.
						Infusion	Intravenous use	31-AUG-2023 12:50 to 31-AUG-2023 13:50 1 hr	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	21-SEP-2023 11:40 to 21-SEP-2023 12:10 30 min	
						Solution for infusion	200 milligram q3w Intravenous use	31-AUG-2023 11:10 to 31-AUG-2023 11:40 30 min	

Concomitant Medication(s): PEMBROLIZUMAB (S) | | PEMETREXED (S) | ACARD (C) | ATORVASTEROL (C) | Metformax (C) | Gabapentin (C) | Telmisartanum (C) | Nedal (C) | Oxydolor (C) | Pyralgina (C) | Omeprazol (C) | Dexamethasone (C) | Ondansetron (C) | Clemastine (C) | Neulasta (C) | Folic acid (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A263463	INDIA 77.9 Years Male	**Febrile neutropenia (Febrile neutropenia)***	Recovered	18-Nov-2023 1 month 22 days 18 hrs 30 min	CARBOPLATIN	Infusion	Intravenous use	27-SEP-2023 to 22-DEC-2023 2 months 26 days	Periodic Report Comment. Patient experienced serious febrile neutropenia, Inv: related to IP.CCA-Unrelated.
					DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	02-DEC-2023 to 21-JUN-2024 6 months 20 days	
						Injection	6 milligram/kilogram q3w Intravenous use	27-SEP-2023 to 09-NOV-2023 1 month 14 days	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	27-SEP-2023 to 21-JUN-2024 8 months 26 days	

Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | Amaryl m (C) | Minipress xl (C) | Entecavir (C) | Mucoral (C) | Nykron (C) | Sodabicarb (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A265640	GREECE 56 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	03-Nov-2023 1 week 2 days					
Concomitant Medication(s):									
2023A275764	VIET NAM 69.9 Years Male	**Neutropenia (Neutropenia)*** Anaemia (Anemia)	Recovered	28-Nov-2023 2 months 3 days	CARBOPLATIN	Infusion	Intravenous use	26-SEP-2023 to 13-DEC-2023 2 months 18 days	Periodic Report Comment. The patient experienced NEUTROPENIA. Inv: Related to IP. CCA: Not related to IP.
		Neutropenia (Neutropenia)* Anaemia (Anemia)*	Recovered	28-Nov-2023 2 months 3 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	26-SEP-2023 to 30-DEC-2024 1 year 3 months 5 days	
					DURVALUMAB	Infusion	1120 milligram Intravenous use	26-SEP-2023 to 30-DEC-2024 1 year 3 months 5 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | Dimedrol ubf (C) | Listerine (C) | Sendatron (C) | Sensodyne (C) | Neupogen (C) | Ramlepsa (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202409GLO003380US	UNITED STATES 73.3 Years Male	**Neutropenia (Neutropenia)***	Recovered	16-Apr-2024 22 days	CARBOPLATIN	Infusion	q3w Intravenous use	23-APR-2024 to 23-APR-2024 1 day	Periodic Report Comments. Patient experienced Neutrophil count decreased, Investigator: related with Dato-DXd and Carboplatin. Not related with Durvalumab. Company physician : not related with study therapy.;PRC. Investigator causality is related for the suspect CARBOPLATIN & DATOPOTAMAB DERUXTECAN with the event Neutropenia & not related for the suspect DURVALUMAB. The company causality is not related for all the suspect CARBOPLATIN, DATOPOTAMAB DERUXTECAN & DURVALUMAB with the event Neutropenia.
						Infusion	q3w Intravenous use	25-JUN-2024 to 25-JUN-2024 1 day	
						Infusion	q3w Intravenous use	26-MAR-2024 to 26-MAR-2024 1 day	
					DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	01-APR-2025 to 01-APR-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	03-JUN-2025 to 03-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	4 milligram/kilogram q3w Intravenous use	04-MAR-2025 to 04-MAR-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	05-AUG-2025 to 05-AUG-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	08-OCT-2024 to 08-OCT-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	10-DEC-2024 to 10-DEC-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	4 milligram/kilogram q3w Intravenous use	11-FEB-2025 to 11-FEB-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	13-MAY-2025 to 13-MAY-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	15-JUL-2025 to 15-JUL-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	16-JUL-2024 to 16-JUL-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	17-SEP-2024 to 17-SEP-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	4 milligram/kilogram q3w Intravenous use	19-NOV-2024 to 19-NOV-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	21-JAN-2025 to 21-JAN-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	22-APR-2025 to 22-APR-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	23-APR-2024 to 23-APR-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	24-JUN-2025 to 24-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	4 milligram/kilogram q3w Intravenous use	25-JUN-2024 to 25-JUN-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	29-OCT-2024 to 29-OCT-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	31-DEC-2024 to 31-DEC-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	26-MAR-2024 to 26-MAR-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | Dexamethasone (C) | Palonosetron (C) | Diphenhydramine (C) | Acetaminophen (C) | Famotidine (C) | Allopurinol (C) | Senna (C) | Docusate (C) | Miralax (C) | Listerine (C) | Polyvinyl alcohol | Povidone-iodine | Tetryzoline (C)									
202410GLO008755CN	CHINA 60.6 Years Male	**Anaemia (Anemia)***	Recovered	11-Aug-2024 3 months 18 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	05-SEP-2024 to 05-SEP-2024 1 day	Periodic Report Comments. Patient experienced Anemia with values ranging from 85g/L, 84g/L, 89g/L and 109g/L. INV: Related to Carboplatin, Datopotamab Deruxtecan. Not related to Durvalumab. CCA: Not related to study therapies.
						Injection	6 milligram/kilogram q3w Intravenous use	13-JUN-2024 to 13-JUN-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	25-APR-2024 to 16-MAY-2024 22 days	
						Injection	6 milligram/kilogram q3w Intravenous use	25-JUL-2024 to 25-JUL-2024 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Metformin (C) | Repaglinide (C) | Compound Diclofenac Sodium (C) | Aprepitant (C) | Diphenhydramine hydrochloride (C) | Insulin (C) | Lidocaine hydrochloride(solvent) (C) | Metoclopramide dihydrochloride (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202412GLO012073CN	CHINA 70 Years Male	**Myelosuppression (Myelosuppression)***	Recovered	25-Nov-2024 6 months 27 days	CARBOPLATIN	Infusion	Intravenous use	05-JUL-2024 to 05-JUL-2024 1 day	Patient experienced myelosuppression Inv causality: RELATED with all the suspects CCC: NOT RELATED
						Infusion	Intravenous use	14-JUN-2024 to 14-JUN-2024 1 day	
						Infusion	Intravenous use	23-MAY-2024 to 23-MAY-2024 1 day	
						Infusion	Intravenous use	30-APR-2024 to 30-APR-2024 1 day	
					DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	30-APR-2024 to 06-SEP-2024 4 months 8 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

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Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	30-APR-2024 to 30-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-JUL-2024 to 05-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-SEP-2024 to 06-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-JUN-2024 to 14-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	16-AUG-2024 to 16-AUG-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	23-MAY-2024 to 23-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-JUL-2024 to 26-JUL-2024 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | Bevacizumab (S) | Paclitaxel (S) | Multivitamin (C) | Insulin (C) | Ondansetron (C) | Ondansetron hydrochloride (C) | Sodium lauryl sulfate (C) | Ketoconazole (C) | Oxiconazole (C)									
2024A006574	VIET NAM 70 Years Male	**Anaemia (Anemia)***	Recovered	03-Jan-2024 3 months 9 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	26-SEP-2023 to 30-DEC-2024 1 year 3 months 5 days	Periodic Report Comment. Patient experienced Anemia, Investigator : related with study therapy, CCA : related to Carboplatin, not related to Datopotamab Deruxtecan, Durvalumab;Periodic Report Comments. Patient experienced Anemia, Investigator : related with study therapy, CCA : not related to Datopotamab Deruxtecan, Durvalumab and Carboplatin.
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	26-SEP-2023 to 26-SEP-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	02-APR-2024 to 02-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	04-JUN-2024 to 04-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	07-NOV-2023 to 07-NOV-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-AUG-2024 to 08-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-JAN-2024 to 09-JAN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	10-DEC-2024 to 10-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	10-OCT-2024 to 10-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	12-MAR-2024 to 12-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	13-DEC-2023 to 13-DEC-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-MAY-2024 to 14-MAY-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	17-JUL-2024 to 17-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-OCT-2023 to 17-OCT-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	19-SEP-2024 to 19-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-FEB-2024 to 20-FEB-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-NOV-2024 to 20-NOV-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	23-APR-2024 to 23-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-JUN-2024 to 26-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-AUG-2024 to 29-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-DEC-2024 to 30-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-JAN-2024 to 30-JAN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	31-OCT-2024 to 31-OCT-2024 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Basultam (C) | Natri clorid (C) | NEUPOGEN (C) | VINLUTA (C) | TARDYFERON (C) | AMINOPLASMAL (C) | XENETIX (C)									
2024A072003	POLAND 68 Years Male	**Thrombocytopenia (Thrombocytopenia)*** Neutropenia (Neutropenia)*	Recovered	22-Mar-2024 2 months 21 days	CARBOPLATIN	Infusion	Intravenous use	02-JAN-2024 to 05-MAR-2024 2 months 4 days	Periodic Report Comment. Patient experienced Thrombocytopenia, Neutropenia. Investigator: related to Carboplatin, Pemetrexed and not related to Pembrolizumab. Company: related to Carboplatin, Pemetrexed and not related to Pembrolizumab
					PEMETREXED	Infusion	500 milligram/sq. meter q3w Intravenous use	02-JAN-2024 to 18-APR-2024 3 months 17 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PEMETREXED (S) | | CISPLATIN (S) | Gliclazidum (C) | Sertralinum (C) | Furosemidum (C) | Kalii chloridum (C) | Pantoprazolum (C) | Rosuvastatinum (C) | Ondansetron (C) | Vitamin b12 (C) | Ziextenzo (C) | Folic (C) | No-spa (C) | Loperamid (C) | Magne b6 (C) | Lactulose (C) | Senzop (C)									
2024A112835	FRANCE 55.3 Years Male	**Anaemia (Anemia)*** Neutropenia (Neutropenia)*	Recovered	06-May-2024 3 months 7 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	31-JAN-2024 to 30-SEP-2025 1 year 8 months	Periodic Report Comment. Patient experienced anemia and neutropenia. Inv: anemia related to study drugs carboplatin, datopotamab deruxtecan and Durvalumab, neutropenia related to Datopotamab deruxtecan and Durvalumab. CCA: Anemia related to Carboplatin.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion	1120 milligram q3w	30-SEP-2025 to 30-SEP-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	04-SEP-2024 to 04-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-FEB-2025 to 05-FEB-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-JUL-2024 to 05-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-MAY-2025 to 05-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	06-NOV-2024 to 06-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-JUL-2025 to 08-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-APR-2025 to 14-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-AUG-2024 to 14-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-JAN-2025 to 14-JAN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	14-JUN-2024 to 14-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-APR-2024 to 17-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-JUN-2025 to 17-JUN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-OCT-2024 to 17-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	19-AUG-2025 to 19-AUG-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	21-MAR-2025 to 21-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	22-FEB-2024 to 22-FEB-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	24-MAY-2024 to 24-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	25-JUL-2024 to 25-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-DEC-2024 to 26-DEC-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

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EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	27-MAY-2025 to 27-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-SEP-2024 to 27-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-FEB-2025 to 28-FEB-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-JUL-2025 to 29-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-MAR-2024 to 29-MAR-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	29-NOV-2024 to 29-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	31-JAN-2024 to 31-JAN-2024 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Anoro (C) | Vitamin b12 nos (C) | Buglac mouthwash (C) | Aconitum kusnezoffii root tuber (C) | 3,3'-Diindolylmethane (C) | Tretinoin (C)									
2024A159456	FRANCE 64.5 Years Male	**Thrombocytopenia (Thrombopenia)*** Device related infection (Catheter infection)*	Not Recovered	08-Jul-2024 5 days	CARBOPLATIN	Infusion	3.5 milligram q3w Intravenous use	26-JUL-2024 to 26-JUL-2024 1 day	Periodic Report Comment. Patient experienced port a cath enterobacter hormachei infection and thombopenia. Inv: events related to Carboplatin, Pemetrexed not related to Pembrolizumab. CCA: not related.;
						Infusion	5 milligram q3w Intravenous use	04-JUL-2024 to 04-JUL-2024 1 day	PERIODIC REPORT COMMENT. Patient has event : THOMBOPENIA, PORT A CATH ENTEROBACTER HORMACHEI INFECTION. For study therapy Action Taken: No change, dose decrease, dose decrease respectively, Investigator Causality: not Related, related, related respectively. CC: Not Related. Outcome: not

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PEMETREXED	Infusion	350 milligram/sq. meter Intravenous use	26-JUL-2024 to 26-JUL-2024 1 day	Recovered, recovered respectively with adverse events.
						Infusion	500 milligram/sq. meter Intravenous use	04-JUL-2024 to 04-JUL-2024 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PEMETREXED (S) | Nycoplus (C) | Folic acid (C) | Galways pure liquid parafin (C) | Glucose (C) | Titanorein lidocaina (C) | Alfuzosine (C) | Acriflavinium (C) | Tramadol (C) | Amoxicillin (C) | Octreotide (C) | Alverine (C) | Paracetamol (C) | Ambroxol (C) | Prednisolone (C) | Pegfilgrastim (C) | Ondansetron (C) | Phloroglucinol (C) | Piperacillin (C) | Cefepime (C) | Amikacine (C) | Naloxegol (C) | Rosuvastatine (C) | Nefopam (C) | Alfuzosine (C) | Macrogol (C) | Lansoprazole (C) | Metoclopramide (C) | Oxycodone (C) | Terbutaline (C)									
2024A164133	AUSTRIA 77 Years Male	**Thrombocytopenia (Thrombocytopenia)*** Febrile neutropenia (Febrile neutropenia)*	Recovered	17-Jul-2024 7 days	CARBOPLATIN	Infusion	Intravenous use	11-JUL-2024 to 11-JUL-2024 1 day	Periodic Report Comment. The patient experienced febrile neutropenia and thrombozytopenia. Inv. related to Pemetrexed and Carboplatin, CCA: Not related to study therapy.
						Infusion	4 milligram q3w Intravenous use	06-AUG-2024 to 28-AUG-2024 23 days	

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Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PEMETREXED	Infusion	400 milligram/sq. meter q3w Intravenous use	06-AUG-2024 to 28-AUG-2024 23 days	
						Infusion	500 milligram/sq. meter q3w Intravenous use	11-JUL-2024 to 11-JUL-2024 1 day	
Concomitant Medication(s): | PEMBROLIZUMAB (S) | PEMETREXED (S) | Acetylsalicylic acid (C) | Apo trazodone (C) | Apixaban (C) | Amlodipine (C) | Nebivolol (C) | Calcium phosphate (C) | Baclofen (C) | Molaxole (C) | Salmeterol/fluticasonpropionat AL (C) | Salbutamol (C) | Combivent (C) | Hydal (C) | Novalgin (C) | Paspertin (C) | Fortecortin (C) | Lovenox (C) | Advantan (C) | Flucloxacillin (C) | Aeromuc (C) | Bepanthen (C) | Elomel (C) | Bioplatelet (C) | Irradiated platelet concentrate hla (C) | Amoxygen (C) | Athrombone (C)									
2024A200972	PERU 52.7 Years Male	**Anaemia (Anemia)***	Recovered	02-Sep-2024 3 months 5 days	CARBOPLATIN	Infusion	Intravenous use	14-AUG-2024 to 14-AUG-2024 1 day	
						Infusion	Intravenous use	25-JUL-2024 to 25-JUL-2024 1 day	

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EudraCT No: 2023-505993-14-00

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Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	27-JUN-2024 to 27-JUN-2024 1 day	
						Infusion	Intravenous use	29-MAY-2024 to 29-MAY-2024 1 day	
					DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	27-JUN-2024 to 14-AUG-2024 1 month 19 days	
						Injection	6 milligram/kilogram q3w Intravenous use	29-MAY-2024 to 29-MAY-2024 1 day	

Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | TRAMADOL (C) | CLORPHENTERMINE (C) | Acetato de dexametasona (C) | PARACETAMOL (C) | Sodium carboxymethylcellulose (C) | Caffeine (C) | Granisetron (C) | Fluoride (C) | Ranitidine (C) | Dimenhydrinate (C)

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202502GLO017434HU	HUNGARY 74 Years Male	**Thrombocytopenia (Thrombocytopenia)***	Recovered	26-Oct-2024 2 months 21 days	CARBOPLATIN	Infusion	5 milligram q3w Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	Periodic Report Comments. patient exp. event Thrombocytopenia, inv: related to study therapy, CCA: not related to study therapy
						Infusion	5 milligram q3w Intravenous use	10-OCT-2024 to 10-OCT-2024 1 day	
						Infusion	5 milligram q3w Intravenous use	18-SEP-2024 to 18-SEP-2024 1 day	
						Infusion	5 milligram q3w Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
					DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram Intravenous use	30-JAN-2025 to 30-JAN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram Intravenous use	06-AUG-2024 to 09-JAN-2025 5 months 4 days	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	05-NOV-2024 to 05-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-JAN-2025 to 09-JAN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	10-OCT-2024 to 10-OCT-2024 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	18-DEC-2024 to 18-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-SEP-2024 to 18-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-NOV-2024 to 27-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-JAN-2025 to 30-JAN-2025 1 day	

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Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | Bravadin (C) | Bisoprolol sandoz (C) | Apranax (C) | Emozul (C) | Flector (C) | Ondansetron (C) | Trixeo aerosphere (C) | Amalfi (C) | Suprastin (C) | Cerucal (C) | Dexamethasone (C) | Laevolac (C) | Rbc (C) | Granisetron (C) | Contramal (C)									
202508GLO002141CN	CHINA 74 Years Male	**Myelosuppression (Myelosuppression)***	Recovered	19-Dec-2023 3 months 11 days	PEMETREXED	Infusion	500 milligram/sq. meter q3w Intravenous use	09-SEP-2023 to 09-SEP-2023 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	10-NOV-2023 to 10-NOV-2023 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	12-DEC-2023 to 12-DEC-2023 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	20-OCT-2023 to 20-OCT-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	500 milligram/sq. meter q3w Intravenous use	28-SEP-2023 to 28-SEP-2023 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CARBOPLATIN (S) | Esomeprazole (C) | Palonosetron (C) | Denosumab (C) | Fosaprepitant dimeglumine (C)									

SOC:Cardiac disorders

2024A163353	BRAZIL 72.5 Years Female	**Immune-mediated myocarditis (Immune-mediated myocarditis)***	Not Recovered	23-Jul-2024 19 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	05-JUL-2024 to 05-JUL-2024 1 day	periodic report comment. Patient has event : IMMUNE-MEDIATED MYOCARDITIS and Lung infection. For study therapy Action Taken: drug interrupted, drug discontinued. Investigator Causality: not Related, CC: Not Related. Outcome : Recovering and recovered respectively.
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | CARBOPLATIN (S) | | Formoterol fumarate (C) | Metoprolol (C) | Codeine (C) | Piperacilina - tazobactam (C) | Omeprazole gp (C) | Enoxaparin (C) | Levofloxacin (C)									
202504GLO004176CN	CHINA 21 Years Female	**Pericardial effusion (Pericardial effusion)***	Not Recovered	28-Mar-2025 10 months 18 days	PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	11-MAY-2024 to 24-MAR-2025 10 months 14 days	
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | 4g folic (C) | Glutathione (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Endocrine disorders									
202504GLO000761BR	BRAZIL 76 Years Male	**Hypophysitis (Hypophysitis)***	Not Recovered	01-Apr-2025 1 year 2 months 24 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	Patient experienced Hypophysitis related to study therapy durvalumab NOT RELATED to Carboplatin, Datopotamab Deruxtecan CCC: NOT RELATED
						Infusion	1120 milligram q3w Intravenous use	06-MAY-2024 to 06-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	07-MAR-2025 to 07-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-JAN-2025 to 08-JAN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	08-OCT-2024 to 08-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-JAN-2024 to 09-JAN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-MAY-2025 to 09-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	15-APR-2024 to 15-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-SEP-2024 to 17-SEP-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	18-DEC-2024 to 18-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-JUL-2024 to 18-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	19-MAR-2024 to 19-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-MAR-2025 to 26-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	27-FEB-2024 to 27-FEB-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-JUN-2024 to 27-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-MAY-2024 to 27-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-NOV-2024 to 27-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-JAN-2024 to 30-JAN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	30-MAY-2025 to 30-MAY-2025 1 day	

Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | CARBOPLATIN (S) | Atenolol (C) | Simvastatin (C) | Paracetamol (C) | Famotidine (C) | Diphenhydramine (C) | Chlorhexidine (C) | Netupitant (C) | Levothyroxine (C) | Atorvastatin (C) | Clopidogrel (C) | Hyaluronic acid (C) | Netupitant and palonosetron hydrochloride (C)

SOC:Eye disorders

202409GLO009347KR	KOREA, REPUBLIC OF 66.1 Years Female	**Keratitis (Keratitis)***	Recovered	08-Feb-2024 10 months 17 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	23-MAR-2023 to 22-AUG-2024 1 year 5 months	
202505GLO018797PE	PERU 62.7 Years Female	**Keratitis (Keratitis)***	Not Recovered	18-Sep-2024 3 months 14 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	05-JUN-2024 to 28-AUG-2024 2 months 24 days	Periodic Report Comments. patient experienced CTC 3 bilateral keratitis. Investigator causality related company causality unrelated Death details was added.

Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Codeine Phosphate (C) | Muteran (C) | Foichol (C) | Peniramin (C) | Levotuss (C) | Tylenol er (C) | Dexamethasone (C) | Nesbell (C) | Cololo sp (C) | Encover (C) | Foichol (C) | Norzyme (C) | Almax (C) | Cravit (C)

Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Dextromethorphan (C) | Polyvinyl alcohol (C)

SOC:Gastrointestinal disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A228742	INDIA 77.8 Years Male	**Stomatitis (Mucositis oral)***	Recovered	06-Oct-2023 10 days	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	09-NOV-2023 to 09-NOV-2023 1 day	Periodic Report Comment. Patient experienced serious febrile neutropenia related to carboplatin ,Datopotamab Deruxtecan, Durvalumab. CCA- related to Datopotamab Deruxtecan for event oral mucositis;Periodic Report Comments. Patient experienced serious febrile neutropenia related to carboplatin and not related to Datopotamab Deruxtecan, Durvalumab.CCA- related to Datopotamab Deruxtecan for event oral mucositis
						Injection	Intravenous use	19-APR-2024 to 19-APR-2024 1 day	
						Injection	Intravenous use	27-SEP-2023 to 27-SEP-2023 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	02-DEC-2023 to 02-DEC-2023 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	09-FEB-2024 to 09-FEB-2024 1 day	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	4 milligram/kilogram q3w Intravenous use	21-JUN-2024 to 21-JUN-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	22-DEC-2023 to 22-DEC-2023 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	23-MAR-2024 to 23-MAR-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	24-MAY-2024 to 24-MAY-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	29-FEB-2024 to 29-FEB-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	02-DEC-2023 to 02-DEC-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-FEB-2024 to 09-FEB-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-NOV-2023 to 09-NOV-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	19-APR-2024 to 19-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	21-JUN-2024 to 21-JUN-2024 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	22-DEC-2023 to 22-DEC-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	23-MAR-2024 to 23-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	24-MAY-2024 to 24-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-SEP-2023 to 27-SEP-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-FEB-2024 to 29-FEB-2024 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Amaryl m (C) | Minipress xl (C) | Entecavir (C) | Mucoral (C) | Sodabicarb (C) | Dexamethasone (C) | Polyethylene glycol (C) | Metoclopramide (C) | Paracetamol (C) | Pheniramine (C)									
2023A275305	INDIA 68 Years Male	**Stomatitis (Mucositis oral)***	Recovered	10-Nov-2023 10 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	14-DEC-2023 to 17-JUN-2024 6 months 4 days	Periodic Report Comment. The patient experienced ORAL MUCOSITIS. Inv: Related to Datopotamab Deruxtecan, No related to Durvalumab and Carboplatin. CCA: Not related to all study therapy.
						Injection	6 milligram/kilogram q3w Intravenous use	01-NOV-2023 to 23-NOV-2023 23 days	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Oxra (C) | Corex-dx (C) | Dexamethasone (C) | Mucoral (C) | Sodabicarb (C) | Avil (C)									
2023A275680	CHINA 72 Years Male	**Intestinal obstruction (Intestinal obstruction)*** Acute respiratory distress syndrome (ARDS)* Thrombocytopenia (Thrombocytopenia)*	Fatal	19-Nov-2023 3 days	CARBOPLATIN	Infusion	Intravenous use	17-NOV-2023 to 17-NOV-2023 1 day	Periodic Report Comment. The patient Male experienced event: Intestinal obstruction serious related to datopotamab deruxtecan, carboplatin and carboplatin. CCA: Not related to study therapy.;Periodic Report Comments. The patient Male experienced event: Intestinal obstruction, ARDS and thrombocytopenia, serious related datopotamab deruxtecan, carboplatin and carboplatin. CCA: Not related to study therapy.
					DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	17-NOV-2023 to 17-NOV-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	17-NOV-2023 to 17-NOV-2023 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | Ag amlodipine (C) | Indobufen (C) | Ag rosuvastatin calcium (C) | Acetylsalicylic acid (C) | Acetylcysteine (C) | 8-chlortheophylline (C) | Ipratropium bromide (C) | Metoclopramide hydrochloride (C) | Ondansetron hydrochloride (C) | Abtei Vitamin C + Zink (C) | Denosumab (C) | Acetic acid (C) | Clys go (C) | Apo-lactulose (C) | BC diclofenac sodium (C) | (6S)-5-methyltetrahydrofolate (C) | Alverine (C) | 2-Deoxy-d-glucose (C) | Bloxaphte oral care (C) | Anticoagulant citrate dextrose solution (i) (C) | Alfentanyl (C) | Apo-cefuroxime (C) | Albumin human (C) | Berodual inhalation solution (C) | Omeprazole (C) | Burgerstein vitamin b6 (C)									
202411GLO002739BG	BULGARIA 66.8 Years Male	**Vomiting (Vomiting)***	Recovered	04-Nov-2024 1 month 19 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	17-SEP-2024 to 21-NOV-2024 2 months 5 days	Patient experienced Vomiting Inv, related to DATOPOTAMAB DERUXTECAN and DURVALUMAB, CARBOPLATIN, and company causality not related to DATOPOTAMAB DERUXTECAN and DURVALUMAB, CARBOPLATIN
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | CARBOPLATIN (S) | Valtricom (C) | Bisogamma (C) | Jamesi (C) | Neoglim (C) | Oxycodone (C) | Allergen (C) | Chlorhexidine digluconate (C) | Dexamethasone (C) | Ondansetron (C) | Paracetamol (C)									
2024A094996	BRAZIL 73.3 Years Female	**Enterocolitis (Enterocolitis)***	Recovered	18-Apr-2024 16 days	CARBOPLATIN	Infusion	Intravenous use	03-APR-2024 to 03-APR-2024 1 day	Periodic Report Comment. Patient experienced enterocolitis. Inv: related to Datopotamab Deruxtecan, Carboplatin and not related to Durvalumab.Company-Not related.

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EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	07-MAY-2024 to 07-MAY-2024 1 day	
						Infusion	Intravenous use	18-JUN-2024 to 18-JUN-2024 1 day	
						Infusion	Intravenous use	28-MAY-2024 to 28-MAY-2024 1 day	
					DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	07-MAY-2024 to 26-JUN-2025 1 year 1 month 20 days	
						Injection	6 milligram/kilogram q3w Intravenous use	03-APR-2024 to 03-APR-2024 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | Ivabradine 5mg teva (C) | Apo metformin (C) | Aft metoprolol cr (C) | Apo trazodone (C) | Ag quetiapine xr (C) | Adco pantoprazole (C) | Lactated ringers (C) | Apo ondansetron (C) | Sodium bicarbonate (C) | Potassium chloride (C) | Paracetamol (C) | Levothyroxine (C) | Acetylsalicylic acid (C) | Furosemide (C) | Metoprolol (C) | Rosuvastatin (C) | Spironolactone (C) | Valsartan (C) | Trazodone (C) | Quetiapine (C) | Dexamethasone (C) | Diphenhydramine (C)									
2024A187937	INDIA 46.6 Years Male	**Stomatitis (Mucositis oral)***	Recovered	14-Aug-2024 8 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	07-AUG-2024 to 07-AUG-2024 1 day	Periodic Report Comment. the patient experienced grade three mucositisis, related to Datopotamab deruxtecan not related to DURAVALUMAB, Carboplatin. CCA: not related WITH Datopotamab deruxtecan, durvalumab and related with carboplatin
Concomitant Medication(s): | CARBOPLATIN (S) | DURVALUMAB (S) | Furosemide (C) | Spironolactone (C) | Acetylcysteine (C) | Etoricoxib (C) | Dexamethasone (C) | Paracetamol (C) | Tramadol (C) | Doxycycline (C) | Fluconazole (C) | Metronidazole (C) | Cefoperazone (C)									
2024A192258	INDIA 53.6 Years Male	**Stomatitis (Mucositis oral)***	Not Recovered	16-Aug-2024 23 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	16-AUG-2024 to 16-AUG-2024 1 day	Periodic Report Comment. male patient expereinced ORAL MUCOCITIS-serious related to study therapy CCA not related.
						Solution for infusion	200 milligram q3w Intravenous use	25-JUL-2024 to 25-JUL-2024 1 day	
Concomitant Medication(s): | PEMETREXED (S) | CARBOPLATIN (S) | Septran (C) | Meropenem (C) | Voriconazole (C) | Noradrenaline (C) | Amlodipine (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO022430PL	POLAND 76.6 Years Female	**Stomatitis (Inflammation of mouth)***	Not Recovered	21-Aug-2025 1 year 11 months 16 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	01-AUG-2024 to 01-AUG-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	03-JUL-2025 to 03-JUL-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	04-DEC-2024 to 04-DEC-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	06-DEC-2023 to 06-DEC-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	06-FEB-2025 to 06-FEB-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

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						Injection	6 milligram/kilogram q3w Intravenous use	06-SEP-2023 to 06-SEP-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	08-APR-2025 to 08-APR-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	08-MAR-2024 to 08-MAR-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	08-NOV-2023 to 08-NOV-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	09-MAY-2024 to 09-MAY-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	11-JUL-2024 to 11-JUL-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	12-JUN-2025 to 12-JUN-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	12-SEP-2024 to 12-SEP-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	13-NOV-2024 to 13-NOV-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	16-FEB-2024 to 16-FEB-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

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						Injection	6 milligram/kilogram q3w Intravenous use	17-JAN-2025 to 17-JAN-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	18-MAR-2025 to 18-MAR-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	18-OCT-2023 to 18-OCT-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	20-JUN-2024 to 20-JUN-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	21-OCT-2024 to 21-OCT-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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						Injection	6 milligram/kilogram q3w Intravenous use	22-AUG-2024 to 22-AUG-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	22-MAY-2025 to 22-MAY-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	24-JUL-2025 to 14-AUG-2025 22 days	
						Injection	6 milligram/kilogram q3w Intravenous use	26-JAN-2024 to 26-JAN-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	27-DEC-2024 to 27-DEC-2024 1 day	

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						Injection	6 milligram/kilogram q3w Intravenous use	27-FEB-2025 to 27-FEB-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	27-SEP-2023 to 27-SEP-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	28-DEC-2023 to 28-DEC-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	28-MAR-2024 to 28-MAR-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	29-APR-2025 to 29-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

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						Injection	6 milligram/kilogram q3w Intravenous use	29-MAY-2024 to 29-MAY-2024 1 day	

Concomitant Medication(s): CARBOPLATIN (S) | | DURVALUMAB (S) | Diuver (C) | Reltebon (C) | Clemastinum (C) | Dexamethasonum (C) | Famotidinum (C) | Chlorhexidine (C) | Ondansetronum (C) | Paracetamolum (C) | Megestrol acetate (C) | Euthyrox (C) | Erdomed (C) | NaCl (C) | Clatra (C)

SOC:General disorders and administration site conditions

2023A164271	AUSTRIA 74.5 Years Male	**Extravasation (Extravasation)***	Not Recovered	14-Jul-2023 22 days	PACLITAXEL	Infusion	136 milligram/sq. meter q3w Intravenous use	23-JUN-2023 to 25-AUG-2023 2 months 3 days	
						Infusion	141 milligram/sq. meter q3w Intravenous use	25-AUG-2023 to 25-AUG-2023 1 day	
						Infusion	200 milligram/sq. meter q3w Intravenous use	14-JUL-2023 to 14-JUL-2023 1 day	

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						Infusion	200 milligram/sq. meter q3w Intravenous use	23-JUN-2023 to 23-JUN-2023 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CARBOPLATIN (S) | DURVALUMAB (S) | Mirtazapin (C) | Pantoloc (C) | Nebivolol (C) | Folsan (C) | Lixiana (C) | Kytril (C) | Imodium (C) | Resource protein (C) | Acetylcystein hexal (C) | Ceolat (C) | Netupitant | Palonosetron (C) | Epoetin (C) | Amykal (C) | Dexamethason (C) | Dibondrin (C) | Hyaluronidase (C) | Novalgin (C) | Prednisolon (C) | Vitamin d3 (C) | Prednisolone (C) | Zarzio (C) | Lasix (C) | Lonquex (C) | Prednisolone (C) | Hydrocortone (C) | Dermovate (C) | Desloratadin (C) | Amoxillin (C) | Atorvastatin (C) | Azithromycin (C) | Zoledron (C) | Tin fluoride (C)									
2023A205532	CHINA 71.6 Years Male	**Chest discomfort (Chest tightness)***	Not Recovered	23-Aug-2023 nk					
Concomitant Medication(s):									
2024A142127	KOREA, REPUBLIC OF 62.5 Years Female	**Asthenia (Weakness generalized)***	Recovered	17-Jun-2024 nk					
Concomitant Medication(s):									

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Study Design: Not Blinded

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Hepatobiliary disorders									
2023A243650	CHINA 53.8 Years Male	**Hepatic function abnormal (Hepatic impairment)***	Recovered	19-Oct-2023 23 days	CARBOPLATIN	Infusion	Intravenous use	11-DEC-2023 to 11-DEC-2023 1 day	Periodic Report Comment. The Patient experienced Liver impairment AST elevation ALT elevation. Inv causality: related with Carboplatin and Paclitaxel and not related with Pembrolizumab. CCA: not related
						Infusion	Intravenous use	17-NOV-2023 to 17-NOV-2023 1 day	
						Infusion	Intravenous use	27-OCT-2023 to 27-OCT-2023 1 day	
						Infusion	Intravenous use	27-SEP-2023 to 27-SEP-2023 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PACLITAXEL	Infusion	150 milligram/sq. meter q3w Intravenous use	27-OCT-2023 to 27-OCT-2023 1 day	
						Infusion	200 milligram/sq. meter q3w Intravenous use	17-NOV-2023 to 11-DEC-2023 25 days	
						Infusion	200 milligram/sq. meter q3w Intravenous use	27-SEP-2023 to 27-SEP-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

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Concomitant Medication(s): PEMBROLIZUMAB (S) | | PACLITAXEL (S) | Omeprazole sodium (C) | 5 htp with vitamin b6 (C) | Ambroxol hydrochloride (C) | Cefoperazone sodium and sulbactam sodium for injection (2:1) (C) | Levofloxacin (C) | Potassium chloride (C) | Alila multivitamin (C) | Algae polysaccharide extract nos (C) | Promethazine hydrochloride (C) | (6S)-5-methyltetrahydrofolate glucosamine | Acetylcysteine | Betaine | Pyridoxine hydrochloride | Riboflavin | Vitamin b12 nos (C) | Cetirizine hydrochloride (C) | Aprepitant (C) | Codeine Phosphate (C) | Dexamethasone (C) | Dexamethasone sodium phosphate Eipico (C) | Enteral Nutritional Powder (TP) (C) | Lansoprazole (C) | Acetylsalicylate lysine | Metoclopramide hydrochloride (C) | Palonosetron hydrochloride (C) | Acetylcarnitine | Acetylcysteine | Ascorbic acid | Citric acid | Folic acid | Fructose | Levocarnitine fumarate | Selenium | Ubidecarenone | Vitamin e nos | Zinc (C) | Tropisetron hydrochloride (C) | Torasemide (C) | Pegylated recombinant human endostatin (C) | (6S)-5-methyltetrahydrofolate glucosamine | Acetylcarnitine | Amylase | Ascorbic acid | Biotin | Boron glycinate | Calcium pantothenate | Cellulase | Choline bitartrate | Chromium picolinate | Colecalciferol | Equisetum arvense | Herbal nos | Hesperidin | Lipase | Magnesium glyci (C) | Acetylcarnitine | Acetylcysteine | Ascorbic acid | Astaxanthin | Biotin | Calcium | Calcium carbonate | Chromium | Colecalciferol | Copper | Folic acid | Lycopene | Magnesium | Manganese | Mecobalamin | Meso Zeaxanthin | Molybdenum | Nicotinamide | Pantothenic acid | Pyridoxine | Quercetin (C) | Ascorbic acid (C) | Magnesium Isoglycyrrhizinate (C) | Multivitamin formula with minerals tablets (26) (C) | Mucaltin Forte c Vitamini C (C) | Mecobalamin (C) | Granisetron hydrochloride (C) | Metoclopramide dihydrochloride (C) | Diphenhydramine hydrochloride (C) | Ondansetron hydrochloride (C) | Cetirizine (C) | Cefoperazone sodium (C) | Iron Polysaccharide complex (C) | Glutathione (C) | Vitamin b6 (C) | Cefoperazone sodium and sulbactam sodium (C) | Potassium chloride (C) | Multivitamin (C) | Polysaccharide iron (C) | Codeine phosphate (C) | Dexamethasone acetate (C) | Dexamethasone sodium phosphate (C) | Metoclopramide hydrochloride (C) | Tathion (C) | Pegylated recombinant human granulocyte colony stimulating factor (C)									
2023A272280	CHINA 65.9 Years Male	**Drug-induced liver injury (Hy's law case)***	Recovered	16-Nov-2023 2 months 4 days	CARBOPLATIN	Infusion	Intravenous use	13-SEP-2023 to 27-OCT-2023 1 month 15 days	Periodic Report Comment. Patient experienced hy's law. Inv related to study drug. CCA related to study drug.; Patient experienced hy's law. Inv related to study drug. CCA related to study drug.
						Infusion	5 milligram q3w Intravenous use	05-OCT-2023 to 05-OCT-2023 1 day	

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						Infusion	5 milligram q3w Intravenous use	13-SEP-2023 to 13-SEP-2023 1 day	
						Infusion	5 milligram q3w Intravenous use	27-OCT-2023 to 27-OCT-2023 1 day	
					PACLITAXEL	Infusion	200 milligram/sq. meter q3w Intravenous use	05-OCT-2023 to 05-OCT-2023 1 day	
						Infusion	200 milligram/sq. meter q3w Intravenous use	13-SEP-2023 to 13-SEP-2023 1 day	
						Infusion	200 milligram/sq. meter q3w Intravenous use	27-OCT-2023 to 27-OCT-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PACLITAXEL (S) | Aprepitant (C) | Promethazine (C) | Cimetidine (C) | Dexamethasone sodium phosphate (C) | Diphenhydramine (C) | Diyun (C) | Ondansetron (C) | Palonosetron hydrochloride (C) | Tathion (C) | Bicyclol (C) | Glutathione (C) | Compound glycyrrhizin (C) | Reduced Glutathione (C) | Esomeprazole sodium (C) | Esomeprazole sodium (C) | Methylprednisolone sodium succinate (C) | Polyene phosphatidylcholine (C) | Aprepitant (C) | Promethazine (C) | Cimetidine (C) | Dexamethasone sodium phosphate (C) | Diphenhydramine (C) | Esomeprazole sodium (C) | Ondansetron hydrochloride (C) | Palonosetron hydrochloride (C) | Tathion (C) | Bicyclol (C) | Compound glycyrrhizin (C) | Compound glycyrrhizin (C) | Glutathione (C) | Chlorpromazine and promethazine (C) | An shen bu xin (C) | Compound glycyrrhizin (C) | Glutathione (C) | Adenosylmethionine (C) | Methylprednisolone sodium succinate (C) | Polyene phosphatidylcholine (C) | Magnesium (C) | Arginine hydrochloride (C) | Bifen (C) | Compound monoammonium glycyrrhizinate s (C) | Fat soluble vitamins nos (C) | Platelets, human blood (C) | Omeprazole (C) | Potassium chloride (C) | Vitamin C (C)									
2024A061923	CHINA 77.2 Years Male	**Drug-induced liver injury (Hy's law case)***	Recovered	04-Mar-2024 5 months 20 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	20-DEC-2023 to 02-FEB-2024 1 month 14 days	Periodic Report Comment. Patient experienced immune hepatitis. INV; related to Datopotamab deruxtecan, Durvalumab and not related to Carboplatin, Comp: related to study therapy Durvalumab.
						Injection	6 milligram/kilogram q3w Intravenous use	14-SEP-2023 to 16-NOV-2023 2 months 3 days	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	02-FEB-2024 to 02-FEB-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	08-OCT-2023 to 08-OCT-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-SEP-2023 to 14-SEP-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	16-NOV-2023 to 16-NOV-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-DEC-2023 to 20-DEC-2023 1 day	

Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Methylprednisolone sodium succinate (C) | Compound amino acid injection (18aa) (C) | Loratadine (C) | Ondansetron (C) | Cefotaxime sodium (C) | Torasemide (C) | Mosapride citrate (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202501GLO008434GB	UNITED KINGDOM 66 Years Female	**Drug-induced liver injury (Drug-induced hepatitis)***	Recovering	13-Jan-2025 3 months 20 days	CARBOPLATIN	Infusion	Intravenous use	06-NOV-2024 to 06-NOV-2024 1 day	
						Infusion	Intravenous use	16-OCT-2024 to 16-OCT-2024 1 day	
						Infusion	Intravenous use	25-SEP-2024 to 25-SEP-2024 1 day	
						Infusion	Intravenous use	27-NOV-2024 to 27-NOV-2024 1 day	
						Infusion	630 milligram Intravenous use	25-SEP-2024 to 27-NOV-2024 2 months 3 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PEMETREXED (S) | Thiamine (C) | Simvastatin (C) | Folic acid (C) | Paracetamol (C) | Nystatin (C) | Metoclopramide (C) | Atenolol (C) | Hydroxocobalamin (C) | Macrogol (C)									
SOC:Infections and infestations									
2023A192047	BRAZIL 81.6 Years Female	**Gastroenteritis (Gastroenteritis)***	Recovered	09-Aug-2023 nk	CARBOPLATIN	Infusion	Intravenous use	to 08-AUG-2023	Periodic Report Comment. Patient exp. gastroenteritis, pancytopenia. Inv: not related with study therapy w. r.t gastroenteritis. Inv: related with Pemetrexed and Carboplatin, not related with pembrolizumab w.r.t. pancytopenia. CCA: not related with both events.; Periodic Report Comments. Subject has events: gastroenteritis and Pancytopenia, Action taken with Pemetrexed: No change, and Carboplatin and Pembrolizumab: Temporarily withdrawn, and Cisplatin: Not applicable Investigator causality of Pemetrexed, Carboplatin, Pembrolizumab and Cisplatin w.r.t event Pancytopenia: Not related, and gastroenteritis: Not applicable, Company Causality for Pemetrexed, Carboplatin, Pembrolizumab and Cisplatin w.r.t event Pancytopenia and gastroenteritis: Not related
						Infusion	Intravenous use	19-JUL-2023 to 19-JUL-2023 1 day	
					CISPLATIN	Infusion	75 milligram/sq. meter q3w Intravenous use	to	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	01-DEC-2023 to 01-DEC-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	01-FEB-2024 to 01-FEB-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	02-OCT-2023 to 02-OCT-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	03-APR-2024 to 03-APR-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	03-DEC-2024 to 03-DEC-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	03-FEB-2025 to 03-FEB-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	06-JUN-2024 to 06-JUN-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	08-AUG-2023 to 08-AUG-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	09-SEP-2024 to 09-SEP-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	10-JAN-2024 to 10-JAN-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	11-NOV-2024 to 11-NOV-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	12-MAR-2024 to 12-MAR-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	13-JAN-2025 to 13-JAN-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	13-NOV-2023 to 13-NOV-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	13-SEP-2023 to 13-SEP-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	14-MAY-2024 to 14-MAY-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	19-AUG-2024 to 19-AUG-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	19-JUL-2023 to 19-JUL-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	21-FEB-2024 to 21-FEB-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	21-MAR-2025 to 21-MAR-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	21-OCT-2024 to 21-OCT-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	22-APR-2024 to 22-APR-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	22-DEC-2023 to 22-DEC-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	23-DEC-2024 to 23-DEC-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	23-OCT-2023 to 23-OCT-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	27-FEB-2025 to 27-FEB-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	28-JUN-2024 to 28-JUN-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	29-JUL-2024 to 29-JUL-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	30-SEP-2024 to 30-SEP-2024 1 day	
					PEMETREXED	Infusion	500 milligram/sq. meter q3w Intravenous use	08-AUG-2023 to 08-AUG-2023 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	19-JUL-2023 to 19-JUL-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMETREXED (S) | | PEMBROLIZUMAB (S) | CISPLATIN (S) | Losartan (C) | Rosuvastatin (C) | TRIMBOW (C) | Somalgin cardio (C) | Metoprolol (C) | Amitriptyline (C) | NEOZINE (C) | SYSTANE (C) | VIDISIC (C) | Folic acid (C) | Dexamethasone (C) | Ondansetron (C) | ACTIVE KETOPROFEN (C) | DIPYRONE (C) | Bisacodyl (C) | Codeine (C) | Lactulose (C) | TAMARINE (C) | 1,6-FRUCTOSE-DIPHO (C) | VIGADEXA (C) | DRAMAMINE (C) | Prednisone (C) | SEKI (C) | CERUMIN (C) | Levothyroxine (C) | Norfloxacin (C) | ACETYLGLUTAMINE (C) | MESACOL MMX (C) | Vitamin b12 (C)									
2023A221332	CHINA 66.8 Years Male	**Pneumonia (Lung infection)***	Not Recovered	16-Oct-2023 5 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	12-OCT-2023 to 12-OCT-2023 1 day	Periodic Report Comment. Male patient experienced serious events pulmonary infection and bone marrow suppression and obstructive pneumonia and Investigator related to study drug.
Concomitant Medication(s): CARBOPLATIN (S) | PACLITAXEL (S) | | Sodium bicarbonate (C) | Buprenorphine (C) | Protein hydrolysate (C) | Sodium potassium magnesium calcium and glucose (C) | Ambroxol hydrochloride (C)									
2023A227050	POLAND 64 Years Male	**Bacterial sepsis (Gram-negative sepsis)***	Recovered	01-Oct-2023 1 month 11 hrs 10 min	CARBOPLATIN	Infusion	Intravenous use	21-SEP-2023 13:20 to	Periodic Report Comment. Patient experience sepsis caused by other gram-negative bacterie serious and Investigator related to study therapy. CCA: Not related.; Periodic Report Comments. Patient experienced event CTC 3 sepsis caused by other gram-negative bacteria (preferred term: Bacterial sepsis). Investigator states event related to study therapy Carboplatin, Pembrolizumab, Pemetrexed. Company physician considers event unrelated to study therapy Carboplatin, Pembrolizumab, Pemetrexed.
						Infusion	Intravenous use	31-AUG-2023 12:50 to 31-AUG-2023 13:50 1 hr	
					PEMETREXED	Infusion	500 milligram/sq. meter q3w Intravenous use	21-SEP-2023 12:40 to 21-SEP-2023 12:50 10 min	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	500 milligram/sq. meter q3w Intravenous use	31-AUG-2023 12:10 to 31-AUG-2023 12:20 10 min	
						Infusion	500 milligram/sq. meter q3w Intravenous use	31-OCT-2023 12:54 to	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	21-SEP-2023 11:40 to	
						Solution for infusion	200 milligram q3w Intravenous use	31-AUG-2023 11:10 to 31-AUG-2023 11:40 30 min	

Concomitant Medication(s): PEMBROLIZUMAB (S) | | PEMETREXED (S) | CISPLATIN (S) | Acard (C) | Atorvasterol (C) | Metformax (C) | Nedal (C) | Telmisartanum (C) | Oxydolor (C) | Gabapentin (C) | Omeprazol (C) | Pyralgina (C) | Folic acid (C) | Clemastine (C) | Ondansetron (C) | Dexamethasone (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A235815	CHINA 64.8 Years Male	**Pneumonia (Pneumonia)***	Recovered	10-Oct-2023 1 month 5 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	06-SEP-2023 to 25-JAN-2024 4 months 20 days	Periodic Report Comment. Patient experienced Infectious pneumonia. Investigator: related to Datopotamab Deruxtecan, Durvalumab, Carboplatin. CCA : not related.
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Promethazine hydrochloride (C) | Fosaprepitant dimeglumine (C) | Ilaprazole sodium (C) | Palonosetron hydrochloride (C) | Paracetamol (C) | Domperidone (C) | Cefaclor (C) | Bromhexine hydrochloride (C) | Fosfomycin sodium (C) | Methylprednisolone sodium succinate (C) | Acetaminophen (C) | Diprophylline (C)									
2023A246294	HUNGARY 68 Years Male	**Pneumonia (Pneumonia)***	Fatal	29-Oct-2023 25 days					
Concomitant Medication(s):									
2023A281977	CHINA 77 Years Male	**Pneumonia (Lung infection)*** Immune-mediated lung disease (Immune-mediated pneumonitis)*	Fatal	08-Dec-2023 16 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram QIW Intravenous use	23-NOV-2023 to 23-NOV-2023 1 day	Periodic Report Comment. Patient experienced Pulmonary Infection and immunal pneumonitis. Investigator: related with Datopotamab Deruxtecan, Durvalumab, not related with Carboplatin, company physician : not related with study drugs.;Periodic Report Comments. Periodic comment: Patient experience : PULMONARY INFECTION And IMMUNAL PNEUMONITIS Investigator: Related to study therapy. CCA: Not related to Study therapy. The
					DURVALUMAB	Infusion	1120 milligram QIW Intravenous use	23-NOV-2023 to 23-NOV-2023 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
									lab test included BP: On Unknown date BLOOD GAS TEST was 89.51 mg/L, INFLUENZA A Negative, INFLUENZA B Negative, SPO2 98.4%, PARTIAL PRESSURE CO2 33.6 mmHg and PARTIAL PRESSURE Oxygen 110 mmHg.On 20-Dec-2023 CT Showed left upper lobe bronchus was truncated, the left lower lobe bronchus was slightly narrow, most of the left upper lobe was parenchyma attached, the internal density was uneven, the mediastinal lymph nodes were increased and enlarged, and tumor lesions were complicated with obstructive pneumonia. Action taken for All Suspect Drugs was Withdrawn.
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Levoamlodipine besylate (C) | Ambroxol hydrochloride (C) | Compound methoxyphenamine (C) | Famotidine (C) | Ondansetron hydrochloride (C) | Dioxopromethazine hydrochloride (C) | Sodium potassium magnesium calcium and glucose (C) | Ceftazidime (C) | Concentrated sodium chloride (C) | Levofloxacin sodium (C) | Aciclovir and sodium chloride (C) | U Vitamin C (C) | Glucose and sodium chloride (C) | Potassium chloride (C) | Pegylated recombinant human granulocyte colony-stimulating factor (C) | Ambroxol (C) | Compound amino acid injection (14aa) (C) | Piperacillin tazobactam ab (C) | Adco-potassium chloride (C) | Acedoben Sodium (C) | Furosemide (C) | Platelets, human blood (C) | Afrin glycerol (C) | Aceglutamide (C) | Levofloxacin (C) | Ascorbic acid (C) | Potassium chloride (C) | Megestrol acetate (C) | Furosemide sodium (C) | Sodium chloride (C) | Methylprednisolone sodium succinate (C) | Sucralfate (C) | Methylprednisolone sodium succinate (C) | Prednisone acetate (C) | Cefazolin sodium (C) | Silybin meglumine (C) | Pantoprazole (C)									
202410GLO006385US	UNITED STATES 70.8 Years Female	**Sepsis (Sepsis)***	Recovered	03-Oct-2024 2 months 18 days	CARBOPLATIN	Infusion	Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	Periodic Report Comments. The patient recovered with sequelae from the event(s) sepsis after 2 days on 05-OCT-2024. The event was considered serious (Hospitalized). The investigator considered that

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

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Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	16-JUL-2024 to 16-JUL-2024 1 day	there was a reasonable possibility of a causal relationship between the study therapy and the following event(s): sepsis. The company physician did not consider that there was a reasonable possibility of a causal relationship between the study therapy and the event(s).
						Infusion	Intravenous use	19-SEP-2024 to 19-SEP-2024 1 day	
						Infusion	Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PEMETREXED (S) | Amlodipine (C) | Levothyroxine (C) | Lexapro (C) | Metformin HCL (C) | Procrit (C) | B 12 (C) | Neulasta (C) | Rosuvastatin calcium (C) | Olmesartan hctz (C) | Gabapentin (C) | Acetaminophen | Hydrocodone (C) | Ondansetron (C) | Clonazepam (C) | Diclofenac sodium (C) | Folic acid (C) | Mirtazapine (C) | Amlodipine besylate (C) | Hydrochlorothiazide | Olmesartan (C) | Acetaminophen | Hydrocodone (C) | Vitamin b-12 (C)									
202411GLO007579GB	UNITED KINGDOM 69.9 Years Female	**Enterococcal infection (Enterococcus faecalis infection)***	Recovered	09-Nov-2024 8 months 6 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	04-MAR-2024 to 20-FEB-2025 11 months 17 days	Periodic Report Comments. Patient experienced Enterococcus faecalis infection and was related to suspect Datopotamab deruxtecan, not related to durvalumab and carboplatin.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	04-MAR-2024 to 04-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	04-APR-2024 to 04-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-AUG-2024 to 08-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-MAY-2025 to 08-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-JAN-2025 to 09-JAN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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						Infusion	1120 milligram q3w Intravenous use	10-JUL-2025 to 10-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	13-MAR-2025 to 13-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-APR-2025 to 17-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-OCT-2024 to 17-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-JUL-2024 to 18-JUL-2024 1 day	

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						Infusion	1120 milligram q3w Intravenous use	19-DEC-2024 to 19-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	19-JUN-2025 to 19-JUN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-FEB-2025 to 20-FEB-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	23-MAY-2024 to 23-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	25-APR-2024 to 25-APR-2024 1 day	

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						Infusion	1120 milligram q3w Intravenous use	26-SEP-2024 to 26-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-JUN-2024 to 27-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-NOV-2024 to 28-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-AUG-2024 to 29-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-MAY-2025 to 29-MAY-2025 1 day	

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						Infusion	1120 milligram q3w Intravenous use	30-JAN-2025 to 30-JAN-2025 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Mirtazapine (C) | Furosemide (C) | Betamethasone (C) | Eumovate (C) | Hypromellose (C) | Folic acid & iodine complex (C) | Chlorphenamine (C) | Paracetamol (C) | Sodium chloride (C) | Dexamethasone (C) | Ondansetron (C) | Macrogol (C) | Glycerol | Hypromellose | Polihexanide (C)									
202412GLO001962IN	INDIA 54.9 Years Male	**Pneumonia (Pneumonia)***	Fatal	07-Dec-2024 1 year 1 month 10 days 6 hrs	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	01-MAR-2024 18:30 to 01-MAR-2024 19:30 1 hr	Patient experienced Steroid Refractory Interstitial Lung Disease (ILD) Grade -II: event related to DATOPOTAMAB DERUXTECAN , DURVALUMAB , not related to CARBOPLATIN. CCA: event related to DATOPOTAMAB. ;Periodic Report Comments. Patient experienced Steroid Refractory Interstitial Lung Disease (ILD) Grade -II: event related to DATOPOTAMAB DERUXTECAN , DURVALUMAB , not related to CARBOPLATIN. CCA: event related to DATOPOTAMAB
						Infusion	1120 milligram q3w Intravenous use	03-MAY-2024 18:15 to 03-MAY-2024 19:15 1 hr	
						Infusion	1120 milligram q3w Intravenous use	05-JUL-2024 19:00 to 05-JUL-2024 20:00 1 hr	

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						Infusion	1120 milligram q3w Intravenous use	06-SEP-2024 19:00 to 06-SEP-2024 20:00 1 hr	
						Infusion	1120 milligram q3w Intravenous use	08-DEC-2023 16:20 to 08-DEC-2023 17:20 1 hr	
						Infusion	1120 milligram q3w Intravenous use	09-FEB-2024 18:30 to 09-FEB-2024 19:30 1 hr	
						Infusion	1120 milligram q3w Intravenous use	12-APR-2024 18:10 to 12-APR-2024 19:10 1 hr	
						Infusion	1120 milligram q3w Intravenous use	14-JUN-2024 17:00 to 14-JUN-2024 18:00 1 hr	

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						Infusion	1120 milligram q3w Intravenous use	16-AUG-2024 19:00 to 16-AUG-2024 20:00 1 hr	
						Infusion	1120 milligram q3w Intravenous use	16-NOV-2023 18:45 to 16-NOV-2023 19:45 1 hr	
						Infusion	1120 milligram q3w Intravenous use	19-JAN-2024 16:40 to 19-JAN-2024 17:40 1 hr	
						Infusion	1120 milligram q3w Intravenous use	22-MAR-2024 18:00 to 22-MAR-2024 19:00 1 hr	
						Infusion	1120 milligram q3w Intravenous use	24-MAY-2024 14:00 to 24-MAY-2024 15:00 1 hr	

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						Infusion	1120 milligram q3w Intravenous use	26-JUL-2024 19:10 to 26-JUL-2024 20:10 1 hr	
						Infusion	1120 milligram q3w Intravenous use	26-OCT-2023 18:00 to 26-OCT-2023 19:00 1 hr	
						Infusion	1120 milligram q3w Intravenous use	27-SEP-2024 18:00 to 27-SEP-2024 19:00 1 hr	
						Infusion	1120 milligram q3w Intravenous use	29-DEC-2023 15:30 to 29-DEC-2023 16:30 1 hr	
					DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	01-MAR-2024 16:30 to 01-MAR-2024 17:30 1 hr	

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						Injection	6 milligram/kilogram q3w Intravenous use	03-MAY-2024 16:15 to 03-MAY-2024 17:15 1 hr	
						Injection	6 milligram/kilogram q3w Intravenous use	05-JUL-2024 17:00 to 05-JUL-2024 18:00 1 hr	
						Injection	6 milligram/kilogram q3w Intravenous use	06-SEP-2024 17:00 to 06-SEP-2024 18:00 1 hr	
						Injection	6 milligram/kilogram q3w Intravenous use	08-DEC-2023 13:50 to 08-DEC-2023 15:20 1 hr 30 min	
						Injection	6 milligram/kilogram q3w Intravenous use	09-FEB-2024 16:00 to 09-FEB-2024 17:30 1 hr 30 min	

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						Injection	6 milligram/kilogram q3w Intravenous use	12-APR-2024 16:10 to 12-APR-2024 17:10 1 hr	
						Injection	6 milligram/kilogram q3w Intravenous use	14-JUN-2024 15:00 to 14-JUN-2024 16:00 1 hr	
						Injection	6 milligram/kilogram q3w Intravenous use	16-AUG-2024 16:00 to 16-AUG-2024 17:00 1 hr	
						Injection	6 milligram/kilogram q3w Intravenous use	16-NOV-2023 16:15 to 16-NOV-2023 17:45 1 hr 30 min	
						Injection	6 milligram/kilogram q3w Intravenous use	19-JAN-2024 14:10 to 19-JAN-2024 15:40 1 hr 30 min	

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						Injection	6 milligram/kilogram q3w Intravenous use	22-MAR-2024 16:00 to 22-MAR-2024 17:00 1 hr	
						Injection	6 milligram/kilogram q3w Intravenous use	24-MAY-2024 12:00 to 24-MAY-2024 13:00 1 hr	
						Injection	6 milligram/kilogram q3w Intravenous use	26-JUL-2024 17:10 to 26-JUL-2024 18:10 1 hr	
						Injection	6 milligram/kilogram q3w Intravenous use	26-OCT-2023 15:30 to 26-OCT-2023 17:00 1 hr 30 min	
						Injection	6 milligram/kilogram q3w Intravenous use	27-SEP-2024 16:00 to 27-SEP-2024 17:00 1 hr	

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						Injection	6 milligram/kilogram q3w Intravenous use	29-DEC-2023 13:00 to 29-DEC-2023 14:30 1 hr 30 min	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | CARBOPLATIN (S) | Olanzapine (C) | Ultranise (C) | Rantac-D (C) | Beplex forte (C) | Folvite (C) | Cremaffin (C) | Clohex (C) | Gluconorm sr (C) | AB Phylline (C) | Tusq (C) | Ondem Md (C) | Cobadex Czs (C) | Clonazepam (C) | Gluconorm g1 (C) | Wysolone (C) | Refresh (C) | Aprepitant (C) | Albumin (C) | Ceftum (C) | Cefuroxime (C) | Chlorpheniramine (C) | Claribid (C) | Faropenem (C) | Forcan plus (C) | Granisetron (C) | Lantus (C) | Apidra (C) | Mucomix (C) | Ondansetron (C) | Pantocid (C) | Paracetamol (C) | Pegstim (C) | Ranitidine (C) | Septran ds (C) | Tramadol (C) | Udiliv (C) | Potassium chloride (C) | Solumedrol (C) | Ceflen (C) | Duolin (C) | Budecort (C) | Ringer lactate (C) | Infliximab (C) | Dalacin (C) | Oxygen (C)									
202412GLO011699BR	BRAZIL 81 Years Male	**Pneumonia (Lung infection)***	Recovered	12-Dec-2024 3 months 21 days 8 hrs 50 min	PEMETREXED	Infusion	425 milligram/sq. meter q3w Intravenous use	03-OCT-2024 to 03-OCT-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	14-NOV-2024 to 08-MAY-2025 5 months 25 days	
						Infusion	500 milligram/sq. meter q3w Intravenous use	20-AUG-2024 15:10 to 03-OCT-2024 1 month 12 days 8 hrs 50 min	

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EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | CARBOPLATIN (S) | | Secotex (C) | Piron (C) | Pregabalin (C) | Pantoprazole (C) | Panthenol (C) | Dipyrone (C) | Calcium carbonate (C) | Vitamin d (C) | Denosumab (C) | Hyaluronate sodium (C) | Levothyroxine (C) | Tamsulosin hydrochloride (C) | Morphine (C) | Guttalax (C) | Muvinlax (C) | Dexamethasone (C) | Neutrogena (C) | Folic acid (C) | Amiodarone (C) | Bisoprolol (C) | Enoxaparin (C)									
2024A001031	GREECE 74 Years Male	**Pneumonia (Lung infection)** Pyrexia (Fever)*	Recovered	20-Dec-2023 10 days	CARBOPLATIN	Infusion	Intravenous use	09-JAN-2024 to 09-JAN-2024 1 day	Periodic Report Comment. Patient experienced fatique and fever,Inv causality related to Pembrolizumab, Carboplatin and Pemetrexed. Comp causality not related to study therapy.
						Infusion	Intravenous use	11-DEC-2023 to 11-DEC-2023 1 day	
						Infusion	Intravenous use	20-FEB-2024 to 20-FEB-2024 1 day	
						Infusion	Intravenous use	30-JAN-2024 to 30-JAN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

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Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

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		Pneumonia (Lung infection)* Pyrexia (Fever)	Recovered	20-Dec-2023 10 days	PEMETREXED	Infusion	500 milligram/sq. meter q3w Intravenous use	01-APR-2025 to 01-APR-2025 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	01-JUL-2024 to 01-JUL-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	02-APR-2024 to 02-APR-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	02-SEP-2024 to 02-SEP-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	04-NOV-2024 to 04-NOV-2024 1 day	

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

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						Infusion	500 milligram/sq. meter q3w Intravenous use	07-JAN-2025 to 07-JAN-2025 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	07-JUL-2025 to 07-JUL-2025 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	09-JAN-2024 to 09-JAN-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	10-JUN-2024 to 10-JUN-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	11-DEC-2023 to 11-DEC-2023 1 day	

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						Infusion	500 milligram/sq. meter q3w Intravenous use	11-MAR-2025 to 11-MAR-2025 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	12-AUG-2024 to 12-AUG-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	12-MAR-2024 to 12-MAR-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	14-MAY-2024 to 14-MAY-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	14-OCT-2024 to 14-OCT-2024 1 day	

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						Infusion	500 milligram/sq. meter q3w Intravenous use	16-DEC-2024 to 16-DEC-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	16-JUN-2025 to 16-JUN-2025 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	18-FEB-2025 to 18-FEB-2025 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	20-FEB-2024 to 20-FEB-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	22-JUL-2024 to 22-JUL-2024 1 day	

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						Infusion	500 milligram/sq. meter q3w Intravenous use	23-APR-2024 to 23-APR-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	23-SEP-2024 to 23-SEP-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	25-NOV-2024 to 25-NOV-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	26-MAY-2025 to 26-MAY-2025 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	28-JUL-2025 to 28-JUL-2025 1 day	

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						Infusion	500 milligram/sq. meter q3w Intravenous use	30-JAN-2024 to 30-JAN-2024 1 day	
						Infusion	850 milligram/sq. meter Intravenous use	11-DEC-2023 to 18-FEB-2025 1 year 2 months 8 days	
Concomitant Medication(s): | PEMBROLIZUMAB (S) | PEMETREXED (S) | Apixaban (C) | Bisoprolol fumarate (C) | Candesartan cilexetil (C) | Ranolazine (C) | CISPLATIN (S) | Atorvastatin | Ezetimibe (C) | Amlodipin (C) | Chlorhexidine (C)									
2024A046361	INDIA 62 Years Male	**Sepsis (Sepsis)***	Recovered with Sequelae	23-Feb-2024 3 months	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	24-NOV-2023 to 09-FEB-2024 2 months 17 days	Periodic Report Comment. Patient experienced sepsis. Inv: Related to study therapy. CCA: Not related to study therapy.;Periodic Report Comment. Patient experienced SEPSIS, Inves: related to datopotamab deruxtecan, not related Carboplatin, not related to durvalumab, CCA: related to datopotamab deruxtecan, not related Carboplatin, not related to durvalumab
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | A-z (C) | Codeine phosphate (C) | 3 omegas (C) | Aceclofenac and paracetamol (C) | Aloe (C) | Cinchocaine hydrochloride (C) | Empegfilgrastim (C) | Algeldrate (C) | Corofer xt (C) | Biotin (C) | 1/3 Polideks (C) | Pheniramine (C) | 17a-estradiol (C) | Fluconazole (C) | Mucoral (C) | Act pantoprazole (C) | Romiplostim (C) | Codeine (C) | Aloe vera (C) | Netupitant (C)									

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A098465	HUNGARY 50.3 Years Male	**Adrenalitis (Adrenalitis)***	Recovered	22-Apr-2024 9 weeks 4 days					
Concomitant Medication(s):									
2024A113092	KOREA, REPUBLIC OF 67.4 Years Male	**Pneumonia aspiration (Pneumonia aspiration)***	Not Recovered	10-May-2024 1 month	DATOPOTAMAB DERUXTECAN	Injection Injection	4 milligram/kilogram Intravenous use 6 milligram/kilogram q3w Intravenous use	09-MAY-2024 to 09-MAY-2024 1 day 11-APR-2024 to 11-APR-2024 1 day	Periodic Report Comment. Patient experienced pneumonia with aspiration. Inv related to Datopotamab Deruxtecan, not related to Durvalumab and Carboplatin. CCA: not related.

Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Amlodipine (C) | (6S)-5-methyltetrahydrofolate glucosamine (C) | Alverine (C) | GARGARIN (C) | ALPRAZOLAM (C) | Acetylsalicylic acid (C) | MOSAPRIDE (C) | PHAZYME (C) | 1,3,7,9-Tetramethyluric acid (C) | (6S)-5-methyltetrahydrofolate glucosamine (C) | OFLOXACIN (C) | MEGESTROL (C) | ACETAMINOPHEN (C) | APREPITANT (C) | Acetylcysteine (C) | DEXAMETHASONE (C) | PALONOSETRON (C) | BETARGIN (C) | ACETYLCYSTEINE (C) | NYSTATIN (C) | TEGOPRAZAN (C) | CEFEPIME (C) | FILGRASTIM (C) | IBUPROFEN (C) | Aceclofenac (C) | SMOFKABIVEN (C) | ASPLATELET (C) | MEROPENEM (C) | TEICOPLANIN (C) | BENZYDAMINE (C) | Candesartan (C) | Pitavastatin (C) | Folic acid (C) | Oxycodone (C) | Sodium fluoride (C) | Alprazolam (C) | Morphine (C) | Mosapride (C) | Phazyme (C) | Tranexamic (C) | Magnesium hydroxide (C) | Chlorphenamine (C) | Paracetamol (C)

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2024A129089	BRAZIL 64.4 Years Male	**Urosepsis (Urosepsis)***	Not Recovered	01-Jun-2024 9 days	CARBOPLATIN	Infusion	Intravenous use	24-MAY-2024 to 24-MAY-2024 1 day	Periodic Report Comment. The patient experienced SEPSIS WITH URINARY FOCUS. Inv: Realted to Datopotamab deruxtecan and carboplatin,Not Related to Durvalumab. CCA: Not related to study therapy.
						Infusion	5 milligram q3w Intravenous use	24-MAY-2024 to 24-MAY-2024 1 day	
					DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	24-MAY-2024 to 24-MAY-2024 1 day	

Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | Anlo (C) | Acebutolol (C) | Lisinopril dihydrate (C) | Ab-piperacillin (C) | Amlodipine (C) | Hydrochlorothiazide (C) | Rosuvastatin (C) | Dexamethasone (C) | Diphenhydramine (C) | Palonosetron (C) | Paracetamol (C) | Potassium (C) | Phenytoin (C) | Piperacillin (C) | Piperacillin (C) | Tazobactam (C) | Lamotrigine (C) | Fluconazole (C) | Levofloxacin (C) | Meropenem (C) | Vancomycin (C)

2024A169179	BRAZIL 61 Years Male	**Erysipelas (Erysipelas)***	Recovered	23-Jul-2024 11 months 3 days					

Concomitant Medication(s):

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2024A177248	POLAND 63 Years Male	**Conjunctivitis viral (Viral conjunctivitis)***	Not Recovered	12-Apr-2024 7 months 20 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	24-AUG-2023 to 04-JUN-2024 9 months 12 days	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Ondansetron (C) | Argosulfan (C) | Clemastine (C) | Paracetamol (C) | Dexamethasone (C) | Polprazol (C)									
202501GLO005409BR	BRAZIL 68 Years Male	**Pneumonia (Pneumonia)***	Recovered	25-Dec-2024 1 year 12 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	02-JAN-2025 to 02-JAN-2025 1 day	Periodic Report Comments. Male Patient with pneumonia. Investigator: Related to study therapy Durvalumab , Datopotamab deruxtecan. CCA: Not related to Study therapy. Action taken: Dose not Change.
						Injection	6 milligram/kilogram q3w Intravenous use	14-DEC-2023 to 04-DEC-2024 11 months 21 days	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	02-JAN-2025 to 02-JAN-2025 1 day	

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						Infusion	1120 milligram q3w Intravenous use	14-DEC-2023 to 04-DEC-2024 11 months 21 days	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Methylprednisolone (C) | Tiotropium bromide (C) | Formoterol fumarate dihydrate (C) | Salbutamol sulfate (C) | Dexamethasone (C) | Diphenhydramine (C) | Ceftriaxone (C)									
202501GLO008434GB	UNITED KINGDOM 66 Years Female	**Sepsis (Sepsis)** Drug-induced liver injury (Drug-induced hepatitis)*	Recovering	08-Jan-2025 3 months 15 days	PEMETREXED	Infusion	500 milligram/sq. meter q3w Intravenous use	06-NOV-2024 to 06-NOV-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	16-OCT-2024 to 16-OCT-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	25-SEP-2024 to 25-SEP-2024 1 day	

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						Infusion	500 milligram/sq. meter q3w Intravenous use	27-NOV-2024 to 27-NOV-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	30-DEC-2024 to 30-DEC-2024 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | CARBOPLATIN (S) | | Thiamine (C) | Simvastatin (C) | Folic acid (C) | Paracetamol (C) | Nystatin (C) | Metoclopramide (C) | Atenolol (C) | Hydroxocobalamin (C) | Macrogol (C)									
202503GLO018019CN	CHINA 71 Years Male	**Sialoadenitis (Submandibular sialoadenitis)***	Recovered	18-Mar-2025 7 months 23 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	24-JUL-2024 to 27-FEB-2025 7 months 4 days	Periodic report comment. Patient has event : Submandibular gland inflammation. For study therapy Action Taken: drug interrupted, not applicable, not applicable respectively. Investigator Causality: Related, not related, not related respectively. CC: Not Related. Outcome: not Recovered.
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Dexamethasone acetate (C) | Acetaminophen (C) | Dexamethasone sodium phosphate (C) | Epinephrine hydrochloride (C) | Lidocaine hydrochloride (C) | Metoclopramide hydrochloride (C) | Promethazine hydrochloride (C) | Benzalkonium chloride (C) | Metoclopramide dihydrochloride (C) | Diphenhydramine hydrochloride (C) | Esomeprazole sodium (C) | Ondansetron hydrochloride (C) | Palonosetron hydrochloride (C) | Potassium chloride (C) | Glutathione (C) | Magnesium Isoglycyrrhizinate (C) | Polyene phosphatidylcholine (C) | Calcium carbonate (C) | Leucogen (C) | Aprepitant (C) | Methylprednisolone sodium succinate (C) | Paracetamol (C)									

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202505GLO008757FR	FRANCE 60.3 Years Male	**Pneumocystis jirovecii pneumonia (Pneumocystis jirovecii pneumonia)***	Recovered	22-Apr-2025 nk	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	04-SEP-2023 to 14-JAN-2025 1 year 4 months 11 days	
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | Denosumab (C) | Amlodipine (C) | Calcidose (C) | CISPLATIN (S) | Urapidil (C) | Calcidose (C) | Prednisone (C) | Pantoprazole (C) | Lormetazepam (C) | Delursan (C) | Cortancyl (C)									
202507GLO005716BR	BRAZIL 74.5 Years Female	**Pneumonia (Pneumonia)***	Recovered	07-Jul-2025 11 months 20 days	PEMETREXED	Infusion	500 milligram/sq. meter q3w Intravenous use	06-NOV-2024 to 06-NOV-2024 1 day	PRC. Patient experienced Pneumonia. Investigator: related with Pemetrexed and not related with Pembrolizumab, Cisplatin and Carboplatin. Company physician : Not related with study therapy.
						Infusion	500 milligram/sq. meter q3w Intravenous use	08-AUG-2024 to 08-AUG-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	08-MAY-2025 to 08-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	500 milligram/sq. meter q3w Intravenous use	16-APR-2025 to 16-APR-2025 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	16-OCT-2024 to 16-OCT-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	18-JUL-2024 to 18-JUL-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	19-SEP-2024 to 19-SEP-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	22-JUL-2025 to 22-JUL-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	500 milligram/sq. meter q3w Intravenous use	24-JUN-2025 to 24-JUN-2025 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	26-DEC-2024 to 26-DEC-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	27-NOV-2024 to 27-NOV-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	28-AUG-2024 to 28-AUG-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	28-MAY-2025 to 28-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | CARBOPLATIN (S) | | CISPLATIN (S) | Nebivolol hydrochloride (C) | Hydrochlorothiazide (C) | Losartan (C) | Amiodarone (C)									
202509EEA008810FR	FRANCE Unknown	**Meningitis (Meningitis)*** Epilepsy (Epileptic seizure)* Meningioma (Cerebellar meningioma)*	Not Recovered	nk nk	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	to	
					DURVALUMAB	Infusion	Intravenous use	to	
Concomitant Medication(s): DURVALUMAB (S) |									
202509GLO013583KR	KOREA, REPUBLIC OF 74.7 Years Male	**Pneumonia (Pneumonia)***	Not Recovered	16-Sep-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	02-JUL-2025 to 02-JUL-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	02-OCT-2024 to 02-OCT-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	4 milligram/kilogram q3w Intravenous use	02-SEP-2025 to 02-SEP-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	03-DEC-2024 to 03-DEC-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	03-FEB-2025 to 03-FEB-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	08-APR-2025 to 08-APR-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	10-JUN-2025 to 10-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	4 milligram/kilogram q3w Intravenous use	12-AUG-2025 to 12-AUG-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	12-NOV-2024 to 12-NOV-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	14-JAN-2025 to 14-JAN-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	18-MAR-2025 to 18-MAR-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	20-MAY-2025 to 20-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	4 milligram/kilogram q3w Intravenous use	22-JUL-2025 to 22-JUL-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	22-OCT-2024 to 22-OCT-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	24-DEC-2024 to 24-DEC-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	24-FEB-2025 to 24-FEB-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	29-APR-2025 to 29-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	12-SEP-2024 to 12-SEP-2024 1 day	

Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Digosin (C) | Dilatrend (C) | Esperson (C) | Razepam (C) | Anoro (C) | Synatura (C) | Aloxi (C) | Amcillin (C) | Dexamethasone (C) | Emend (C) | Peniramin (C) | Solondo (C) | Tylenol er (C) | Mirabe sr (C) | Monarin (C) | Tamsulosin sr (C) | Lacticare (C) | Dulackhan (C) | Movizolo (C) | Ursa (C) | Xanax (C) | Circadin (C)

SOC:Injury, poisoning and procedural complications

202503GLO022283JP	JAPAN 51 Years Male	**Infusion related reaction (Infusion related reaction)***	Recovered	24-Mar-2025 1 year 1 month 11 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	14-FEB-2024 to 30-SEP-2025 1 year 7 months 17 days	

Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Tramcet (C) | Calonal (C) | Nexium (C) | Januvia (C) | Bezatol (C) | Polaramine (C) | Gaster (C) | Hydrocortone (C) | Oxygen (C)

SOC:Investigations

2023A231303	UNITED STATES 64.7 Years Female	**Platelet count decreased (Platelet count decreased)***	Recovered	25-Sep-2023 nk	PEMETREXED	Infusion	Intravenous use	to	Periodic Report Comment. Patient experienced decreased platelet count, Investigator related to study therapy. Comp causality not related to study therapy.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					CARBOPLATIN	Infusion	Intravenous use	24-JUL-2023 to 25-SEP-2023 2 months 2 days	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	24-JUL-2023 to 25-SEP-2023 2 months 2 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CARBOPLATIN (S) | Amlodipine (C) | Potassium gluconate (C) | VITAMINS D3 (C) | Valsartan (C) | Compazine (C) | Ondansetron (C) | Sodium chloride (C) | Tramadol (C) | B 12 (C) | Vitamin d3 (C) | Polyvinyl alcohol (C) | Acetaminophen (C) | Albuterol (C) | Aluminium | Magnesium hydroxide | Simeticone (C) | Ampicilina sulbactam (C) | Azithromycin (C) | Clonidine HCL (C) | Iohexol (C) | Losartan (C) | Magnesium sulfate (C) | Cefdinir (C) | Romiplostim (C)									
2024A065429	VIET NAM 67.2 Years Male	**Hepatic enzyme increased (Elevated liver enzymes)***	Recovered	14-Mar-2024 6 months 9 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	06-SEP-2023 to 12-JUN-2024 9 months 7 days	Periodic Report Comment. Patient experienced elevated liver enzymes. Inv: related to Datopotamab Deruxtecan, Durvalumab and not related to Carboplatin. CCA: Not related with study therapy.
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Listerine (C) | Sensodyne (C) | Ondanov (C) | Acediasulfonum natricum (C) | Vinxium (C) | Morihepamin (C) | Vinluta (C)									
2024A070279	CHINA 62 Years Female	**Hepatic enzyme increased (Elevated liver enzymes)***	Recovered	05-Nov-2023 3 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	02-FEB-2024 to 02-FEB-2024 1 day	Periodic Report Comments. Patient experienced): elevated liver enzymes. Invest assessed related to Pembrolizumab for both events and Pemetrexed for event elevated liver enzymes. Company physician considered not

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
									related to suspects.
						Solution for infusion	200 milligram q3w Intravenous use	03-NOV-2023 to 03-NOV-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	04-SEP-2025 to 04-SEP-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	05-MAR-2025 to 05-MAR-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	06-DEC-2024 to 06-DEC-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	06-NOV-2024 to 06-NOV-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	08-MAY-2024 to 08-MAY-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	09-MAY-2025 to 09-MAY-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	10-JAN-2024 to 10-JAN-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	11-AUG-2025 to 11-AUG-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	11-FEB-2025 to 11-FEB-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	12-APR-2024 to 12-APR-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	12-OCT-2024 to 12-OCT-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	15-JUL-2024 to 15-JUL-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	17-APR-2025 to 17-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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						Solution for infusion	200 milligram q3w Intravenous use	18-DEC-2023 to 18-DEC-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	18-JUL-2025 to 18-JUL-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	20-JUN-2025 to 20-JUN-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	20-SEP-2024 to 20-SEP-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	21-JUN-2024 to 21-JUN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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						Solution for infusion	200 milligram q3w Intravenous use	21-MAR-2024 to 21-MAR-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	24-NOV-2023 to 24-NOV-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	26-DEC-2024 to 26-DEC-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	26-FEB-2024 to 26-FEB-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	27-MAR-2025 to 27-MAR-2025 1 day	

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Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	29-AUG-2024 to 29-AUG-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	30-MAY-2024 to 30-MAY-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	30-MAY-2025 to 30-MAY-2025 1 day	
					PEMETREXED	Infusion	500 milligram/sq. meter q3w Intravenous use	02-FEB-2024 to 02-FEB-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	03-NOV-2023 to 03-NOV-2023 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	500 milligram/sq. meter q3w Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	06-DEC-2024 to 06-DEC-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	06-NOV-2024 to 06-NOV-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	08-MAY-2024 to 08-MAY-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	10-JAN-2024 to 10-JAN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	500 milligram/sq. meter q3w Intravenous use	11-FEB-2025 to 11-FEB-2025 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	12-APR-2024 to 12-APR-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	12-OCT-2024 to 12-OCT-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	15-JUL-2024 to 15-JUL-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	18-DEC-2023 to 18-DEC-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	500 milligram/sq. meter q3w Intravenous use	20-SEP-2024 to 20-SEP-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	21-JUN-2024 to 21-JUN-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	21-MAR-2024 to 21-MAR-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	24-NOV-2023 to 24-NOV-2023 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	26-DEC-2024 to 26-DEC-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	500 milligram/sq. meter q3w Intravenous use	26-FEB-2024 to 26-FEB-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	29-AUG-2024 to 29-AUG-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	30-MAY-2024 to 30-MAY-2024 1 day	
Concomitant Medication(s): | PEMETREXED (S) | CISPLATIN (S) | Eszol (C) | Tetracycline hydrochloride (C) | Mecobalamine (C) | Abalone shell | Borneol | Calcium carbonate | Mercuriuc sulfide, red | Mercury sulfide | Musk | Realgar (C) | Trazodone (C)									
202504GLO027657CN	CHINA 72.3 Years Female	**Amylase increased (Serum amylase increased)***	Recovered	29-Apr-2025 10 months 16 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	14-JUN-2024 to 08-SEP-2025 1 year 2 months 26 days	periodic report comment. Patient experienced Serum amylase is elevated, investigator: related to DATOPOTAMAB DERUXTECAN, DURVALUMAB, not related to CARBOPLATIN, cca: not related to DATOPOTAMAB DERUXTECAN, DURVALUMAB,

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
									CARBOPLATIN.
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Diclofenac sodium (C) | Multivitamin (C) | Omeprazole sodium (C) | Diphenhydramine hydrochloride (C) | Mecobalamin (C) | Rivaroxaban (C) | Atorvastatin (C) | Dexamethasone (C) | Probiotic (C) | Compound paracetamol (C) | Polyene (C) | Diphenhydramine hydrochloride (C) | Ferrous succinate (C) | Carbamazepine (C) | Atorvastatin calcium (C) | Rivaroxaban (C)									
202507GLO018632BR	BRAZIL 74.6 Years Female	**Ejection fraction decreased (Ejection fraction decreased)***	Recovering	22-Jul-2025 1 year 3 months 20 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	03-JAN-2025 to 03-JAN-2025 1 day	Periodic Report Comments. Patient experienced ejection fraction decreased. Inv: event related to Datopotamab Deruxtecan, Durvalumab and not related to Carboplatin. CCA: not related.
						Injection	4 milligram/kilogram q3w Intravenous use	05-JUN-2025 to 05-JUN-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	4 milligram/kilogram q3w Intravenous use	07-MAY-2024 to 07-MAY-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	08-OCT-2024 to 08-OCT-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	10-DEC-2024 to 10-DEC-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	10-MAR-2025 to 10-MAR-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	15-MAY-2025 to 15-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	4 milligram/kilogram q3w Intravenous use	16-JUL-2024 to 16-JUL-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	17-FEB-2025 to 17-FEB-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	17-SEP-2024 to 17-SEP-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	18-JUN-2024 to 18-JUN-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	19-NOV-2024 to 19-NOV-2024 1 day	

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

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						Injection	4 milligram/kilogram q3w Intravenous use	24-APR-2025 to 24-APR-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	24-JAN-2025 to 24-JAN-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	26-JUN-2025 to 26-JUN-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	28-MAY-2024 to 28-MAY-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

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						Injection	4 milligram/kilogram q3w Intravenous use	29-OCT-2024 to 29-OCT-2024 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	31-MAR-2025 to 31-MAR-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	03-APR-2024 to 03-APR-2024 1 day	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	03-APR-2024 to 03-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	03-JAN-2025 to 03-JAN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

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EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	05-JUN-2025 to 05-JUN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	07-MAY-2024 to 07-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-OCT-2024 to 08-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	10-DEC-2024 to 10-DEC-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505993-14-00

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Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

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						Infusion	1120 milligram q3w Intravenous use	10-MAR-2025 to 10-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	15-MAY-2025 to 15-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	16-JUL-2024 to 16-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-FEB-2025 to 17-FEB-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-SEP-2024 to 17-SEP-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505993-14-00

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						Infusion	1120 milligram q3w Intravenous use	18-JUN-2024 to 18-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	19-NOV-2024 to 19-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	24-APR-2025 to 24-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	24-JAN-2025 to 24-JAN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-JUN-2025 to 26-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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						Infusion	1120 milligram q3w Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-MAY-2024 to 28-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-OCT-2024 to 29-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	31-MAR-2025 to 31-MAR-2025 1 day	

Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Levothyroxine (C) | Acetylsalicylic acid (C) | Furosemide (C) | Ivabradine (C) | Magnesium carbonate (C) | Rosuvastatin (C) | Trazodone (C) | Quetiapine (C) | Ondansetron (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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202510GLO015915US	UNITED STATES 73 Years Male	**Blood bilirubin increased (Blood bilirubin increased)***	Recovered	16-Oct-2025 1 year 6 months 21 days	DURVALUMAB	Infusion	1120 milligram Unknown	26-MAR-2024 to 05-AUG-2025 1 year 4 months 11 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | CARBOPLATIN (S)									
202510GLO021995US	UNITED STATES 74.8 Years Male	**Blood bilirubin increased (Blood bilirubin increased)***	Not Recovered	19-Oct-2025 nk	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	01-APR-2025 to 01-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	03-JUN-2025 to 03-JUN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	04-MAR-2025 to 04-MAR-2025 1 day	

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						Infusion	1120 milligram q3w Intravenous use	05-AUG-2025 to 05-AUG-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-JUN-2024 to 06-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-OCT-2024 to 08-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	10-DEC-2024 to 10-DEC-2024 1 day	

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						Infusion	1120 milligram q3w Intravenous use	11-FEB-2025 to 11-FEB-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	13-MAY-2025 to 13-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	15-JUL-2025 to 15-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	16-JUL-2024 to 16-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-SEP-2024 to 17-SEP-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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						Infusion	1120 milligram q3w Intravenous use	19-NOV-2024 to 19-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	21-JAN-2025 to 21-JAN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	22-APR-2025 to 22-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	23-APR-2024 to 23-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	24-JUN-2025 to 24-JUN-2025 1 day	

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	26-MAR-2024 to 26-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-OCT-2024 to 29-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	31-DEC-2024 to 31-DEC-2024 1 day	

Concomitant Medication(s): CARBOPLATIN (S) | DATOPOTAMAB DERUXTECAN (S) | | Allopurinol (C) | Acetaminophen (C) | Dexamethasone (C) | Diphenhydramine (C) | Famotidine (C) | Miralax (C) | Palonosetron (C) | Senna (C) | Pegfilgrastim (C) | Hydrocortisone (C) | Benzonatate (C) | Atorvastatin (C) | Sacubitril (C) | Bisoprolol (C)

SOC:Metabolism and nutrition disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2023A197425	BULGARIA 54 Years Male	**Type 1 diabetes mellitus (Type 1 diabetes mellitus)***	Not Recovered	27-Aug-2023 1 month 16 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	12-JUL-2023 to 01-JUL-2025 1 year 11 months 20 days	Periodic Report Comment. Patient experienced Diabetes mellitus Type 1 Investigator causality Related to study therapy (datopotamab deruxtecan and durvalumab) and not related to (carboplatin) CCC: NOT RELATED
						Injection	6 milligram/kilogram Intravenous use	22-JUL-2025 to 02-SEP-2025 1 month 12 days	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	01-JUL-2025 to 01-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	02-AUG-2023 to 02-AUG-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	02-MAY-2024 to 02-MAY-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	02-NOV-2023 to 02-NOV-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	02-SEP-2025 to 02-SEP-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	04-JUL-2024 to 04-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	04-OCT-2023 to 04-OCT-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-SEP-2024 to 05-SEP-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	06-DEC-2023 to 06-DEC-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	07-NOV-2024 to 07-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-APR-2025 to 08-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-FEB-2024 to 08-FEB-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-JAN-2025 to 09-JAN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	10-JUN-2025 to 10-JUN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	11-APR-2024 to 11-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	12-AUG-2025 to 12-AUG-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	12-JUL-2023 to 12-JUL-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	13-JUN-2024 to 13-JUN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	15-AUG-2024 to 15-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-OCT-2024 to 17-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-JAN-2024 to 18-JAN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-MAR-2025 to 18-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	19-DEC-2024 to 19-DEC-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	20-MAY-2025 to 20-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	21-MAR-2024 to 21-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	22-JUL-2025 to 22-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	23-MAY-2024 to 23-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	25-FEB-2025 to 25-FEB-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	25-JUL-2024 to 25-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-SEP-2024 to 26-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-DEC-2023 to 28-DEC-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-NOV-2024 to 28-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-APR-2025 to 29-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

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						Infusion	1120 milligram q3w Intravenous use	29-FEB-2024 to 29-FEB-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-JAN-2025 to 30-JAN-2025 1 day	
						Infusion	500 milligram Intravenous use	12-JUL-2023 to 22-JUL-2025 2 years 11 days	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Telmisartan (C) | Sodium valproate (C) | Allergosan (C) | Paracetamol (C) | Zofran (C) | Tolura (C) | Depakine (C) | Xyzal (C) | Ceftriaxone (C) | Furosemide (C) | Insulatard hm (C) | NaCl (C) | Sodium bicarbonate (C) | Actrapid (C) | Ringer (C) | Ondansetron (C)									
2023A256980	CHINA 58.8 Years Female	**Type 1 diabetes mellitus (Type 1 diabetes mellitus)***	Not Recovered	18-Oct-2023 1 month 11 days	CARBOPLATIN	Infusion	Intravenous use	08-SEP-2023 to 08-SEP-2023 1 day	Periodic Report Comment. patient experience serious hyperglycaemia. Inv related to study drug.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	09-NOV-2023 to 09-NOV-2023 1 day	
						Infusion	Intravenous use	20-OCT-2023 to 20-OCT-2023 1 day	
						Infusion	Intravenous use	28-SEP-2023 to 28-SEP-2023 1 day	
						Infusion	5 milligram Intravenous use	08-SEP-2023 to 09-NOV-2023 2 months 2 days	
					PEMETREXED	Infusion	500 milligram/sq. meter q3w Intravenous use	08-SEP-2023 to 08-SEP-2023 1 day	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	500 milligram/sq. meter q3w Intravenous use	07-FEB-2024 to 07-FEB-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	09-NOV-2023 to 09-NOV-2023 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	15-DEC-2023 to 15-DEC-2023 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	18-JAN-2024 to 18-JAN-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	20-OCT-2023 to 20-OCT-2023 1 day	

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						Infusion	500 milligram/sq. meter q3w Intravenous use	27-FEB-2024 to 27-FEB-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	28-SEP-2023 to 28-SEP-2023 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PEMETREXED (S) | Insulin aspart (C) | Levamlodipine besylate (C) | Shen qi (C) | Naphazoline (C)									
2024A124601	CHINA 76.3 Years Female	**Cachexia (Cachexia)***	Recovered	04-May-2024 4 months 16 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	08-APR-2024 to 08-APR-2024 1 day	Periodic Report Comment. Patient experienced total body pain, loss of appetite and vomiting after eating. Inv-related to Pembrolizumab and Pemetrexed and not related with Carboplatin. Company-not related;Periodic Report Comment. Patient experienced total Cachexia Inv-related to Pembrolizumab and Pemetrexed related and with Carboplatin and cisplatin not related. Company for all suspect - not related.; Periodic Report Comments. Patient experienced event Cachexia. Investigator states that, the event related to PEMBROLIZUMAB and
						Solution for infusion	200 milligram q3w Intravenous use	09-JAN-2024 to 09-JAN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

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Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	14-MAR-2024 to 14-MAR-2024 1 day	PEMETREXED and not related with CARBOPLATIN and CISPLATIN. Company physician considers event not related to PEMBROLIZUMAB, PEMETREXED, CARBOPLATIN and CISPLATIN.
						Solution for infusion	200 milligram q3w Intravenous use	19-DEC-2023 to 19-DEC-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	22-FEB-2024 to 22-FEB-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	29-APR-2024 to 29-APR-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	30-JAN-2024 to 30-JAN-2024 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PEMETREXED	Infusion	500 milligram/sq. meter q3w Intravenous use	08-APR-2024 to 08-APR-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	09-JAN-2024 to 09-JAN-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	14-MAR-2024 to 14-MAR-2024 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	19-DEC-2023 to 19-DEC-2023 1 day	
						Infusion	500 milligram/sq. meter q3w Intravenous use	22-FEB-2024 to 22-FEB-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	500 milligram/sq. meter q3w Intravenous use	29-APR-2024 to	
						Infusion	500 milligram/sq. meter q3w Intravenous use	30-JAN-2024 to 30-JAN-2024 1 day	
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | CISPLATIN (S) | Dexamethasone (C) | Abiraterone (C) | Bio good night (C) | Ilaprazole sodium (C) | 2-Deoxy-d-glucose (C) | Toldex (C) | Aloe vera (C) | Promethazine (C) | Ondansetron hydrochloride (C) | Olanzapine (C) | Methylcobalamin (C) | Dexamethasone acetate (C) | Magnesium Isoglycyrrhizinate (C) | Tropisetron hydrochloride (C) | Celecoxib (C) | Mosapride citrate (C) | Aceglutamide and glucose (C) | Pantoprazole sodium (C) | Megestrol acetate (C) | Metoclopramide hydrochloride (C) | Amino acid (C) | Ferrous succinate (C) | Emset (C)									
202507GLO024706CN	CHINA 54.6 Years Male	**Hyperamylasaemia (Hyperamylasemia)***	Recovered	29-Jul-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	01-JUL-2024 to 01-JUL-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	05-NOV-2024 to 05-NOV-2024 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	08-APR-2025 to 08-APR-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	08-JAN-2025 to 08-JAN-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	08-JUN-2024 to 08-JUN-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	09-JUL-2025 to 09-JUL-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	10-AUG-2024 to 10-AUG-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	15-MAR-2025 to 15-MAR-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	16-OCT-2024 to 16-OCT-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	18-JUN-2025 to 18-JUN-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	19-DEC-2024 to 19-DEC-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	19-JUL-2024 to 19-JUL-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	21-FEB-2025 to 21-FEB-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	23-SEP-2024 to 23-SEP-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	24-MAY-2025 to 24-MAY-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	26-JAN-2025 to 26-JAN-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	27-NOV-2024 to 27-NOV-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	29-APR-2025 to 29-APR-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	31-AUG-2024 to 31-AUG-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	31-JUL-2025 to 31-JUL-2025 1 day	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	01-JUL-2024 to 01-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-NOV-2024 to 05-NOV-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	08-APR-2025 to 08-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-JAN-2025 to 08-JAN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-JUN-2024 to 08-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-JUL-2025 to 09-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	10-AUG-2024 to 10-AUG-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	15-MAR-2025 to 15-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	16-OCT-2024 to 16-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-JUN-2025 to 18-JUN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	19-DEC-2024 to 19-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	19-JUL-2024 to 19-JUL-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	21-FEB-2025 to 21-FEB-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	23-SEP-2024 to 23-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	24-MAY-2025 to 24-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-JAN-2025 to 26-JAN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-NOV-2024 to 27-NOV-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	29-APR-2025 to 29-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	31-AUG-2024 to 31-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	31-JUL-2025 to 31-JUL-2025 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S)									

SOC:Musculoskeletal and connective tissue disorders

2023A233612	CHINA 51.7 Years Male	**Osteoarthritis (Osteoarthritis)*** Immune-mediated arthritis (Immune-mediated arthritis)	Recovered	01-Oct-2023 7 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	01-DEC-2023 to 01-DEC-2023 1 day	Periodic Report Comment. Patient experienced osteoarthritis. Inv causality related with Pembrolizumab, CCA-related to Pembrolizumab, not related to Cisplatin and Pemetrexed.;patient experienced CTC 2 osteoarthritis, Inv causality

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	02-FEB-2024 to 02-FEB-2024 1 day	related with Pembrolizumab, not related to Cisplatin and Pemetrexed. CCA- not related to Cisplatin and Pemetrexed, Pembrolizumab..
						Solution for infusion	200 milligram q3w Intravenous use	03-JAN-2025 to 03-JAN-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	04-NOV-2024 to 04-NOV-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	05-JUL-2024 to 05-JUL-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	08-MAY-2025 to 08-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	09-NOV-2023 to 09-NOV-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	09-SEP-2024 to 09-SEP-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	10-APR-2024 to 10-APR-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	10-APR-2025 to 10-APR-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	10-JUL-2025 to 10-JUL-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	12-JAN-2024 to 12-JAN-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	13-JUN-2024 to 13-JUN-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	14-OCT-2024 to 14-OCT-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	16-DEC-2024 to 16-DEC-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	16-SEP-2025 to 16-SEP-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	18-MAR-2024 to 18-MAR-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	18-MAR-2025 to 18-MAR-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	19-JUN-2025 to 19-JUN-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	19-OCT-2023 to 19-OCT-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	20-AUG-2024 to 20-AUG-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505993-14-00

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Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	21-AUG-2025 to 21-AUG-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	22-DEC-2023 to 22-DEC-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	23-FEB-2024 to 23-FEB-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	23-JAN-2025 to 23-JAN-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	23-MAY-2024 to 23-MAY-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

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Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	24-FEB-2025 to 24-FEB-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	25-NOV-2024 to 25-NOV-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	25-SEP-2023 to 25-SEP-2023 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	26-JUL-2024 to 26-JUL-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	29-APR-2024 to 29-APR-2024 1 day	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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						Solution for infusion	200 milligram q3w Intravenous use	29-MAY-2025 to 29-MAY-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	31-JUL-2025 to 31-JUL-2025 1 day	

Concomitant Medication(s): | PEMETREXED (S) | CISPLATIN (S) | Calcium (C) | Denosumab (C) | Flurbiprofen (C) | Flurbiprofen (C) | Diclofenac (C) | Eperizin (C) | Aprepitant (C) | Dexamethasone sodium phosphate (C) | Dexamethasone sodium phosphate (C) | Granisetron hydrochloride (C) | Mecobalamin (C) | Metoclopramide hydrochloride (C) | Torasemide (C) | Diclofenac potassium (C) | Eperisone hydrochloride (C) | Dexamethasone sodium phosphate (C) | Metoclopramide hydrochloride (C) | Ascorbic acid (C) | Vitamins (C) | Calcium (C) | Denosumab (C) | Diclofenac sodium (C) | Aprepitant (C) | Compound glycyrrhizin (C) | Mecobalamin (C) | Metoclopramide hydrochloride (C) | Omeprazole sodium (C) | Torasemide (C) | Ferrous succinate (C) | Vitamin C (C) | Domperidone (C) | Celecoxib (C) | Sodium (C) | Ferrous sulfate (C)

SOC:Neoplasms benign, malignant and unspecified (incl cysts and polyps)

202501GLO013386ES	SPAIN 61.6 Years Female	**Cancer pain (Cancer pain)***	Recovered	07-Aug-2024 nk	CISPLATIN	Infusion	Intravenous use	to	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	to	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | PEMBROLIZUMAB (S) | CARBOPLATIN (S) | PEMETREXED (S) | | PACLITAXEL (S)									
202505GLO013711BR	BRAZIL 75.7 Years Male	**Ocular surface squamous neoplasia (Ocular surface squamous neoplasia)***	Recovered	23-Sep-2024 1 year 2 months 4 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	01-NOV-2023 to 01-NOV-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	04-APR-2024 to 04-APR-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	04-JAN-2024 to 04-JAN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	07-JUN-2024 to 07-JUN-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	08-AUG-2024 to 08-AUG-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	10-AUG-2023 to 10-AUG-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	10-OCT-2023 to 10-OCT-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	14-DEC-2023 to 14-DEC-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	14-MAR-2024 to 14-MAR-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	16-MAY-2024 to 16-MAY-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	18-JUL-2024 to 18-JUL-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	19-SEP-2024 to 19-SEP-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	20-JUL-2023 to 20-JUL-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	21-SEP-2023 to 21-SEP-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	22-FEB-2024 to 22-FEB-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	23-NOV-2023 to 23-NOV-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	25-APR-2024 to 25-APR-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	27-JUN-2024 to 27-JUN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	29-AUG-2024 to 29-AUG-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	31-AUG-2023 to 31-AUG-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	31-JAN-2024 to 31-JAN-2024 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Gliclazide (C) | Metformin (C) | Nesina (C) | Simvastatin (C) | Levothyroxine (C) | Vitamin d (C) | Dipyrone (C) | Ipratropium (C) | Codeine (C) | Belladonna (C)									

SOC:Renal and urinary disorders

202503GLO001896JP	JAPAN 72 Years Male	**Renal impairment (Renal impairment)***	Not Recovered	20-Sep-2024 1 year 1 month 12 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	08-AUG-2025 to 08-AUG-2025 1 day	Periodic Report Comments. Patient experienced renal dysfunction. Inv: event related to Pembrolizumab, Pemetrexed and not related to Carboplatin. CCA: not related.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	09-AUG-2023 to 27-JUN-2025 1 year 10 months 19 days	
						Solution for infusion	200 milligram q3w Intravenous use	18-JUL-2025 to 18-JUL-2025 1 day	
					PEMETREXED	Infusion	400 milligram/sq. meter q3w Intravenous use	14-JUN-2024 to 16-AUG-2024 2 months 3 days	
						Infusion	500 milligram/sq. meter q3w Intravenous use	09-AUG-2023 to 10-MAY-2024 9 months 2 days	

Concomitant Medication(s): | PEMETREXED (S) | CARBOPLATIN (S) | Granisetron (C) | Zoledronic acid (C) | Calonal (C) | Mikeluna (C) | Heparinoid (C) | Magnesium oxide (C) | Takecab (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202503GLO024902CN	CHINA 68 Years Male	**Immune-mediated cystitis (Immune-mediated cystitis)***	Recovered	10-Mar-2025 10 months 1 day	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	10-MAY-2024 to 12-MAR-2025 10 months 3 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | CARBOPLATIN (S) | Leucogen (C) | Mouthwashgum (C)									
202506GLO002617VN	VIET NAM 72.4 Years Male	**Acute kidney injury (Acute kidney injury)***	Recovered	27-May-2025 1 year 5 months	DATOPOTAMAB DERUXTECAN	Injection	232 milligram/kilogram q3w Intravenous use	16-AUG-2024 to 16-AUG-2024 1 day	
						Injection	236 milligram/kilogram q3w Intravenous use	03-MAY-2024 to 24-MAY-2024 22 days	
						Injection	236 milligram/kilogram q3w Intravenous use	05-JUL-2025 to 26-JUL-2025 22 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	236 milligram/kilogram q3w Intravenous use	06-SEP-2024 to 06-SEP-2024 1 day	
						Injection	238 milligram/kilogram q3w Intravenous use	14-JUN-2024 to 14-JUN-2024 1 day	
						Injection	240 milligram/kilogram q3w Intravenous use	14-NOV-2024 to 26-SEP-2025 10 months 13 days	
						Injection	244 milligram/kilogram q3w Intravenous use	27-SEP-2024 to 25-OCT-2024 29 days	
						Injection	342 milligram/kilogram q3w Intravenous use	28-DEC-2023 to 28-FEB-2024 2 months 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	02-JUL-2025 to 02-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	03-MAY-2024 to 03-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-DEC-2024 to 05-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-FEB-2024 to 05-FEB-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-JUL-2024 to 05-JUL-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	05-MAR-2025 to 05-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-FEB-2025 to 06-FEB-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-SEP-2024 to 06-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	07-MAY-2025 to 07-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	10-JUN-2025 to 10-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	14-AUG-2025 to 26-SEP-2025 1 month 13 days	
						Infusion	1120 milligram q3w Intravenous use	14-JUN-2024 to 14-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-NOV-2024 to 14-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	16-APR-2025 to 16-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	16-AUG-2024 to 16-AUG-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	16-JAN-2025 to 16-JAN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-JAN-2024 to 17-JAN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	23-JUL-2025 to 23-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	24-MAY-2024 to 24-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	25-OCT-2024 to 25-OCT-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	26-JUL-2024 to 26-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-MAR-2025 to 26-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-DEC-2024 to 27-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-SEP-2024 to 27-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-DEC-2023 to 28-DEC-2023 1 day	

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EudraCT No: 2023-505993-14-00

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	28-FEB-2024 to 28-FEB-2024 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S)									

SOC:Respiratory, thoracic and mediastinal disorders

2023A267855	CHINA 69.9 Years Male	**Immune-mediated lung disease (Immune-mediated pneumonitis)***	Not Recovered	21-Nov-2023 2 months 23 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	30-AUG-2023 to 02-NOV-2023 2 months 4 days	Periodic Report Comment. The patient exp. pneumonia and pneumonitis (immune-mediated). Inv: pneumonitis (immune-mediated) Related to Datopotamab Deruxtecan, Durvalumab, CCA: Not related to IP. Inv: pneumonia Not related to IP, CCA: Not related to IP.;Periodic Report Comments. The patient exp. pneumonia and pneumonitis (immune-mediated). Inv: pneumonitis (immune-mediated) Related to Datopotamab Deruxtecan, Durvalumab, CCA: Not related to IP. Inv: pneumonia Not related to IP, CCA: Not related to IP.
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	02-NOV-2023 to 02-NOV-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	12-OCT-2023 to 12-OCT-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

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						Infusion	1120 milligram q3w Intravenous use	20-SEP-2023 to 20-SEP-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-AUG-2023 to 30-AUG-2023 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Coenzyme complex (C) | Dexamethasone sodium phosphate (C) | Ilaprazole sodium (C) | Paracetamol (C) | Polyene phosphatidylcholine (C) | Promethazine hydrochloride (C) | Ramosetron hydrochloride (C) | Acetylcysteine (C) | Pfeil (C) | Crescentia cujete (C)									
2023A279002	BRAZIL 64.9 Years Male	**Pneumonitis (Pneumonitis)***	Fatal	20-Nov-2023 2 months 30 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	03-OCT-2023 to 03-OCT-2023 1 day	Periodic Report Comment. The patient had Dyspnea, Dry cough, Chronic obstructive pulmonary disease as concurrent conditions and experienced CTC 5 pneumonitis. Datopotamab Deruxtecan and Durvalumab was permanently discontinued for the event. Investigator assessed event related to Datopotamab Deruxtecan, Durvalumab and not related to Carboplatin. Company physician assessed related to Datopotamab Deruxtecan, not related to Durvalumab, Carboplatin.
						Injection	6 milligram/kilogram q3w Intravenous use	11-SEP-2023 to 11-SEP-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	22-AUG-2023 to 22-AUG-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	23-OCT-2023 to 23-OCT-2023 1 day	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	03-OCT-2023 to 03-OCT-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	11-SEP-2023 to 11-SEP-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	22-AUG-2023 to 22-AUG-2023 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	23-OCT-2023 to 23-OCT-2023 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Losartan potassium (C) | Atorvastatin calcium (C) | Sandoz Beclomethasone Dipropionate (C) | Tiotropium bromide (C) | Amlodipine besylate and Benazepril HCl (C) | Acetylsalicylate calcium (C) | 4-Chlorphenol (C) | Aluminium hydroxide (C) | Ondansetron hydrochloride (C) | Korus sodium hyaluronate (C) | Acetaminophen and codeine phosphate (C) | Berberine chloride hydrate (C) | Ambroxol acefyllinate (C) | Chlorhexidin mybacin mouthwash (C) | Acetylsalicylic acid (C) | Ambroxol (C) | Azithromycin dihydrate (C) | Apo cefepime (C) | Apomine intermittent (C) | Methylprednisolone sodium succinate (C) | Regular insulin novo nordisk (C) | Trimethoprim hydrochloride (C) | Amcal pantoprazole heartburn relief (C) | Tyrothricin (C) | Infliximab (C) | Arrow budesonide (C) | Tiotropium bromide monohydrate (C) | Metformin hydrochloride (C) | Beclomethasone Dipropionate (C) | Amlodipine besylate (C) | Codeine phosphate (C) | Dexamethasone (C) | Famotidine (C) | Sodium hyaluronate (C) | Acetaminophen (C) | Magnesium (C)									
2024A015200	UNITED STATES 66 Years Male	**Acute respiratory failure (Acute hypoxic respiratory failure)***	Recovered	17-Jan-2024 nk	DATOPOTAMAB DERUXTECAN	Injection	Unknown	to	
					DURVALUMAB	Infusion	Unknown	to	
Concomitant Medication(s): DURVALUMAB (S) | | Asprin (C) | Oxygen (C)									

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A029092	CHINA 64 Years Male	**Pulmonary embolism (Pulmonary embolism)***	Not Recovered	01-Feb-2024 4 months 27 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	05-JAN-2024 to 05-JAN-2024 1 day	Periodic Report Comment. the patient experienced grade four pulmonary embolism, not related to Datopotamab Deruxtecan, related to Durvalumab. Com causality not related
						Infusion	1120 milligram q3w Intravenous use	06-SEP-2023 to 06-SEP-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-NOV-2023 to 08-NOV-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-DEC-2023 to 14-DEC-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-OCT-2023 to 18-OCT-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	25-JAN-2024 to 25-JAN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-SEP-2023 to 26-SEP-2023 1 day	
Concomitant Medication(s): | DATOPOTAMAB DERUXTECAN (S) | CARBOPLATIN (S) | Pantoprazole (C) | Rivaroxaban (C) | Palonosetron (C) | Paracetamol (C) | Fosaprepitant (C)									
2024A033017	CHINA 73 Years Male	**Immune-mediated lung disease (Immune-mediated pneumonitis)***	Recovering	01-Feb-2024 2 months 23 days	DURVALUMAB	Infusion	1120 milligram Intravenous use	10-NOV-2023 to 12-JAN-2024 2 months 3 days	Periodic Report Comment. Patient experience serious pneumonitis (immune pneumonia). Inv related to Durvalumab and not related to Carboplatin, Datopotamab Deruxtecan. CCA related to Durvalumab.;Periodic Report Comments. Patient experience serious pneumonitis (immune pneumonia). Inv related to Durvalumab and not related to Carboplatin, Datopotamab Deruxtecan. CCA related to Durvalumab.
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | CARBOPLATIN (S) | Amlodipine (C) | Losartan potassium and hydrochlorothiazide (C) | Metoprolol (C) | Centrum (C) | Acetaminophen (C) | Dexamethasone sodium phosphate (C) | Omeprazole (C) | Palonosetron hydrochloride (C) | Promethazine hydrochloride (C) | 5 htp with vitamin b6 (C) | Doxycycline (C) | Compound megestrol acetate (C) | Metoclopramide hydrochloride (C) | Mosapride citrate (C) | Metformin | Saxagliptin (C) | Dextromethorphan (C) | Losartan potassium and hydrochlorothiazide (C) | Vitamin b6 (C) | Megestrol acetate (C) | Doxycycline hydrochloride (C) | Nemonoxacin malate (C) | Acetylcysteine (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

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Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A148901	CHINA 62 Years Male	**Interstitial lung disease (Interstitial lung disease)***	Not Recovered	20-Jun-2024 8 months 9 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	12-OCT-2023 to 13-JUN-2024 8 months 2 days	
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | CISPLATIN (S) | Adrenal cortical extract (C) | Acetazolamide (C) | Gentamcin sulfate and procaine hydrochloride and vitaminb12 (C) | Lidocaine hydrochloride (C) | Dexamethasone sodium phosphate (C) | Esomeprazole sodium (C) | Ondansetron hydrochloride (C) | A.s.a. compound with codeine (C) | Human erythropoietin (C) | Polysaccharide iron (C) | Compound methoxyphenamine (C) | Ilaprazole sodium (C) | Sodium bicarbonate (C) | Vitamin b12 (C) | Polyethylene glycol (C) | Ferrous succinate (C) | Ondansetron hydrochloride (C) | Dolasetron mesylate (C) | Compound cefaclor (C) | Cefoperazone sodium and sulbactam sodium (C) | Folic acid (C)									
2024A160705	CHINA 68.5 Years Male	**Immune-mediated lung disease (Immune-mediated lung disease)***	Not Recovered	11-Jul-2024 9 months 4 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	08-OCT-2023 to 25-JUN-2024 8 months 18 days	Periodic Report Comment. Patient experienced immune Pneumonitis ,Inv, related to Datopotamab Deruxtecan, Durvalumab, not related to Carboplatin, CCA : related to Datopotamab Deruxtecan, Durvalumab, not related to Carboplatin
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	08-OCT-2023 to 08-OCT-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	03-APR-2024 to 03-APR-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	04-JUN-2024 to 04-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-JAN-2024 to 05-JAN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	13-DEC-2023 to 13-DEC-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	13-MAR-2024 to 13-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-MAY-2024 to 14-MAY-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	21-FEB-2024 to 21-FEB-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	22-NOV-2023 to 22-NOV-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	24-APR-2024 to 24-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	25-JUN-2024 to 25-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-JAN-2024 to 29-JAN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	31-OCT-2023 to 31-OCT-2023 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Stoma (C) | Bisoprolol fumarate (C) | Sulfamethoxazole (C) | Sodium bicarbonate (C)									
2024A197780	JAPAN 65.7 Years Male	**Pneumonitis (Pneumonitis)***	Fatal	28-Aug-2024 6 months 1 day	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	28-FEB-2024 to 14-AUG-2024 5 months 18 days	Periodic Report Comment. Patient experienced pneumonitis. Inv: event related to Datopotamab Deruxtecan and Durvalumab, not related to Carboplatin; Comp: not related to study therapy.
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	01-MAY-2024 to 01-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	03-JUL-2024 to 03-JUL-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	10-APR-2024 to 10-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	12-JUN-2024 to 12-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-AUG-2024 to 14-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	19-MAR-2024 to 19-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	22-MAY-2024 to 22-MAY-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	24-JUL-2024 to 24-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-FEB-2024 to 28-FEB-2024 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | CANAGLIFLOZIN (C) | Glimepiride (C) | Metformin hydrochloride (C) | Ag rosuvastatin calcium (C) | Semaglutide (C) | Voglibose (C) | Lansoprazole (C) | Thiamazole (C) | Sinil loxoprofen sodium hydrate (C) | Pirenoxine (C) | Acetaminophen (C) | Misoprostol (C) | Oxycodone hydrochloride (C) | Ascorbic acid (C) | Insulin glargine bs (C) | Insulin human (C) | Methylprednisolone sodium succinate (C) | Morphine hydrochloride (C) | COROXYGEN (C) | Haloperidol (C) | Prednisolone (C) | Ambroxol hydrochloride (C) | Rosuvastatin calcium (C) | Loxoprofen sodium hydrate (C) | Calcium polystyrene sulfonate (C) | Ursodeoxycholic acid (C) | Chlorpheniramine maleate (C) | Dexamethasone sodium phosphate (C) | Palonosetron hydrochloride (C) | Insulin glargine (C) | Oxygen (C) | Hydroxyzine hydrochloride (C)									
2024A203896	CANADA 71.4 Years Male	**Pulmonary toxicity (Pulmonary toxicity)***	Recovered	11-Jun-2024 8 months 16 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	25-OCT-2023 to 22-MAY-2024 6 months 28 days	Periodic Report Comment. The patient experienced Pulmonary toxicity. Investigator: related to Datopotamab Deruxtecan, Durvalumab, not related to Carboplatin. CCA not related.
						Injection	6 milligram/kilogram q3w Intravenous use	27-SEP-2023 to 27-SEP-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	01-MAY-2024 to 01-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-DEC-2023 to 06-DEC-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	07-FEB-2024 to 07-FEB-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	10-APR-2024 to 10-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	15-NOV-2023 to 15-NOV-2023 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	17-JAN-2024 to 17-JAN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-MAR-2024 to 20-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	22-MAY-2024 to 22-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	25-OCT-2023 to 25-OCT-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-FEB-2024 to 27-FEB-2024 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	27-SEP-2023 to 27-SEP-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-DEC-2023 to 28-DEC-2023 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Acetylsalicylic acid (C) | Atorvastatin (C) | Coenzyme q10 (C) | Nitroglycerin (C) | Restoralax (C) | Allopurinol (C) | Zoledronic acid (C) | Prednisone (C) | Listerine (C) | Akynzeo (C)									
202501GLO006640VN	VIET NAM 71 Years Male	**Immune-mediated lung disease (Immune-mediated pneumonitis)*** Stomatitis (Inflammation of mouth)*	Fatal	08-Jan-2025 1 year 3 months 14 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	26-SEP-2023 to 30-DEC-2024 1 year 3 months 5 days	Patient experienced immunotherapy-induced pneumonitis. Investigator: not related. Company: related. Patient experienced inflammation of the oral mucosa. Investigator: related to Datopotamab Deruxtecan, Durvalumab, not related to Carboplatin. Company: not related;Periodic Report Comments. Patient has event : immunotherapy-induced pneumonitis, inflammation of the oral mucosa. For study therapy Action Taken: Not applicable, Investigator Causality: Related, related, not related respectively. CC: Not Related. Outcome: Fatal,
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	02-APR-2024 to 02-APR-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
									recovering respective with adverse events reported.
						Infusion	1120 milligram q3w Intravenous use	04-JUN-2024 to 04-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	07-NOV-2023 to 07-NOV-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-AUG-2024 to 08-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-JAN-2024 to 09-JAN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	10-DEC-2024 to 10-DEC-2024 1 day	

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						Infusion	1120 milligram q3w Intravenous use	10-OCT-2024 to 10-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	12-MAR-2024 to 12-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	13-DEC-2023 to 13-DEC-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-MAY-2024 to 14-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-JUL-2024 to 17-JUL-2024 1 day	

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						Infusion	1120 milligram q3w Intravenous use	17-OCT-2023 to 17-OCT-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	19-SEP-2024 to 19-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-FEB-2024 to 20-FEB-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-NOV-2024 to 20-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	23-APR-2024 to 23-APR-2024 1 day	

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Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	26-JUN-2024 to 26-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-SEP-2023 to 26-SEP-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-AUG-2024 to 29-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-DEC-2024 to 30-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-JAN-2024 to 30-JAN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	31-OCT-2024 to 31-OCT-2024 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Listerine (C) | Sensodyne (C) | Sendatron (C) | Omevin (C) | Dimedrol (C) | Omeprazole normon (C) | Ondanov (C) | Paracetamol (C) | Eprex (C) | Aminoplasmal (C) | Nerusyn (C) | Ciprobay (C) | Kabiven (C) | Listerine (C) | Sensodyne (C)									
202506GLO021301CN	CHINA 21 Years Female	**Pleural effusion (Bilateral pleural effusion)***	Not Recovered	28-Mar-2025 10 months 18 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	11-MAY-2024 to 24-MAR-2025 10 months 14 days	patient experienced CTC 4 bilateral pleural effusion, Investigator Causality related to Pembrolizumab and Not related to Carboplatin, Pemetrexed Company causality was not related
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | Folic acid (C) | Levothyroxine sodium (C) | Omeprazole (C) | Prednisone acetate (C) | Ondansetron hydrochloride (C)									
202509GLO008823PE	PERU 71.7 Years Female	**Respiratory failure (Respiratory failure)***	Fatal	04-Sep-2025 1 year 1 month 19 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	07-AUG-2024 to 07-AUG-2024 1 day	Patient experienced Respiratory failure due to pneumonia Investigator causality: RELATED to Pembrolizumab NOT RELATED to Carboplatin, Pemetrexed CCA: NOT RELATED
						Solution for infusion	200 milligram q3w Intravenous use	17-JUL-2024 to 17-JUL-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	20-SEP-2024 to 20-SEP-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	28-AUG-2024 to 28-AUG-2024 1 day	
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | Folic acid (C) | Lactulose (C) | Ipratropium bromide (C) | Salmeterol (C)									
202509GLO022089BR	BRAZIL 70.7 Years Male	**Immune-mediated lung disease (Immune-mediated pneumonitis)***	Recovering	19-Aug-2025 2 years 18 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	01-APR-2025 to 01-APR-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	02-AUG-2023 to 02-AUG-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	04-OCT-2023 to 04-OCT-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	05-NOV-2024 to 05-NOV-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	06-DEC-2023 to 06-DEC-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	07-FEB-2024 to 07-FEB-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	07-JAN-2025 to 07-JAN-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	08-JUL-2025 to 08-JUL-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	08-OCT-2024 to 08-OCT-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	09-APR-2024 to 09-APR-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	10-DEC-2024 to 10-DEC-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	10-JUN-2024 to 10-JUN-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	11-MAR-2025 to 11-MAR-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	13-MAY-2025 to 13-MAY-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	13-SEP-2023 to 13-SEP-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	16-NOV-2023 to 16-NOV-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

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						Injection	6 milligram/kilogram q3w Intravenous use	17-JAN-2024 to 17-JAN-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	17-JUN-2025 to 17-JUN-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	17-SEP-2024 to 17-SEP-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	18-FEB-2025 to 18-FEB-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	19-MAR-2024 to 19-MAR-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505993-14-00

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						Injection	6 milligram/kilogram q3w Intravenous use	21-MAY-2024 to 21-MAY-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	22-APR-2025 to 22-APR-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	23-AUG-2023 to 23-AUG-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	25-OCT-2023 to 25-OCT-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	

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						Injection	6 milligram/kilogram q3w Intravenous use	27-DEC-2023 to 27-DEC-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	27-FEB-2024 to 27-FEB-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	28-JAN-2025 to 28-JAN-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	29-JUL-2025 to 29-JUL-2025 1 day	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	01-APR-2025 to 01-APR-2025 1 day	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

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						Infusion	1120 milligram q3w Intravenous use	02-AUG-2023 to 02-AUG-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	04-OCT-2023 to 04-OCT-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-NOV-2024 to 05-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-DEC-2023 to 06-DEC-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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						Infusion	1120 milligram q3w Intravenous use	07-FEB-2024 to 07-FEB-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	07-JAN-2025 to 07-JAN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-JUL-2025 to 08-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-OCT-2024 to 08-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-APR-2024 to 09-APR-2024 1 day	

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						Infusion	1120 milligram q3w Intravenous use	10-JUN-2024 to 10-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	11-MAR-2025 to 11-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	13-MAY-2025 to 13-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	13-SEP-2023 to 13-SEP-2023 1 day	

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						Infusion	1120 milligram q3w Intravenous use	16-NOV-2023 to 16-NOV-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-JAN-2024 to 17-JAN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-JUN-2025 to 17-JUN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-SEP-2024 to 17-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-FEB-2025 to 18-FEB-2025 1 day	

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						Infusion	1120 milligram q3w Intravenous use	19-MAR-2024 to 19-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	21-MAY-2024 to 21-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	22-APR-2025 to 22-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	23-AUG-2023 to 23-AUG-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	25-OCT-2023 to 25-OCT-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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						Infusion	1120 milligram q3w Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-DEC-2023 to 27-DEC-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-FEB-2024 to 27-FEB-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-JAN-2025 to 28-JAN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-JUL-2025 to 29-JUL-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Dipyrone (C) | Bisacodyl (C) | Calcium carbonate (C)									
202510GLO023831BR	BRAZIL 81 Years Male	**Pleural effusion (Bilateral pleural effusion)***	Not Recovered	29-Apr-2025 8 months 8 days 10 hrs 10 min	PEMBROLIZUMAB	Solution for infusion		20-AUG-2024 13: 50 to	
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | Tamsulosin hydrochloride (C) | Folic acid (C) | Bisoprolol (C) | Calcium carbonate (C) | Hyaluronate sodium (C) | Levothyroxine (C) | Budesonide and Formoterol (C) | Domperidone (C) | Vitamin b12 (C) | Famotidine (C) | Bactrim (C) | Codeine (C)									

SOC:Vascular disorders

2023A267875	CHINA 66.9 Years Female	**Pelvic venous thrombosis (Iliac vein thrombosis)***	Recovering	19-Nov-2023 17 days	PEMETREXED	Infusion	500 milligram/sq. meter q3w Intravenous use	03-NOV-2023 to 03-NOV-2023 1 day	Periodic Report Comment. Patient experience lower extremity venous thrombosis. iliac venous thrombosis. Investigator causality related to Pembrolizumab, Pemetrexed and Carboplatin. CCA-Unrelated.;Periodic Report Comment. Patient experienced LOWER EXTREMITY VENOUS THROMBOSIS. ILIAC VENOUS THROMBOSIS : related to study therapy Pembrolizumab, Carboplatin and Pemetrexed.
						Infusion	500 milligram/sq. meter q3w Intravenous use	29-NOV-2023 to 29-NOV-2023 1 day	

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EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	750 milligram/sq. meter Intravenous use	03-NOV-2023 to 29-NOV-2023 27 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | CARBOPLATIN (S) | | Cisplatin (S) | Dexamethasone (C) | Interferon (unspecified) (C) | Aprepitant (C) | Compound glycyrrhizin (C) | Furosemide (C) | Invert sugar (C) | Mecobalamine (C) | Metoclopramide hydrochloride (C) | Omeprazole sodium (C) | Tropisetron hydrochloride (C) | Vitamin b6 (C) | Leucogen (C) | Mai ling da (C) | Diosmin (C) | Edoxaban tosilate (C) | Folic acid (C) | Ferrous succinate (C)									
2024A141357	BRAZIL 77.4 Years Male	**Hypotension (Hypotension)***	Recovered	23-May-2024 4 months 15 days	DATOPOTAMAB DERUXTECAN	Injection	3 milligram/kilogram q3w Intravenous use	27-NOV-2024 to 30-MAY-2025 6 months 4 days	Periodic Report Comment. Patient experienced VOMITING and HYPOTENSION. Inv: Related to DATOPOTAMAB DERUXTECAN. CCA: Not related to study therapy.
						Injection	4 milligram/kilogram q3w Intravenous use	27-JUN-2024 to 08-OCT-2024 3 months 12 days	
						Injection	6 milligram/kilogram q3w Intravenous use	09-JAN-2024 to 27-MAY-2024 4 months 19 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	06-AUG-2024 to 06-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-MAY-2024 to 06-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	07-MAR-2025 to 07-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-JAN-2025 to 08-JAN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-OCT-2024 to 08-OCT-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	09-JAN-2024 to 09-JAN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-MAY-2025 to 09-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	15-APR-2024 to 15-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-SEP-2024 to 17-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-DEC-2024 to 18-DEC-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	18-JUL-2024 to 18-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	19-MAR-2024 to 19-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-MAR-2025 to 26-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-FEB-2024 to 27-FEB-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	27-JUN-2024 to 27-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-MAY-2024 to 27-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-NOV-2024 to 27-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-JAN-2024 to 30-JAN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-MAY-2025 to 30-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Atenolol (C) | Simvastatin (C) | Chlorhexidine (C) | Paracetamol (C) | Famotidine (C) | Netupitant | Palonosetron (C) | Diphenhydramine (C) | Coldamaris prophylactic (C) | 8-chlortheophylline (C) | Antasida plus famotidine (C) | 1,3-butandiol (C) | Aspen Ondansetron (C) | Levothyroxine (C) | Dexamethasone (C) | Clopidogrel (C) | Ondasetron (C) | Netupitant and palonosetron hydrochloride (C)									
2024A179573	JAPAN 70.6 Years Female	**Hypotension (Hypotension)*** Pneumonitis (Pneumonitis)	Recovered	09-Aug-2024 6 months 7 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	04-JUN-2024 to 16-JUL-2024 1 month 13 days	Periodic Report Comment. the patient experienced suspected pneumonitis and hypotension, related to Datopotamab Deruxtecan, Durvalumab and not related to Carboplatin. CCA: not related.;Periodic Report Comments. the patient experienced suspected pneumonitis and hypotension, related to Datopotamab Deruxtecan, Durvalumab and not related to Carboplatin. CCA: not related.
						Injection	6 milligram/kilogram q3w Intravenous use	03-FEB-2024 to 01-MAY-2024 2 months 29 days	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	01-MAY-2024 to 01-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	03-FEB-2024 to 03-FEB-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	04-JUN-2024 to 04-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	10-APR-2024 to 10-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	16-JUL-2024 to 16-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	25-JUN-2024 to 25-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-FEB-2024 to 26-FEB-2024 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926N

Study ID: D926NC00001

EudraCT No: 2023-505993-14-00

Study Design: Not Blinded

Study Description: D926NC00001 Ph 3 Dato-DXd + Imfinzi 1L NSCLC - A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination with Durvalumab and Carboplatin Versus Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Locally Advanced or Metastatic NSCLC without Actionable Genomic Alterations (D926NC00001; AVANZAR)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Loxoprofen (C) | Brotizolam doc (C) | Symproic (C) | Magmitt (C) | Dexart (C) | Takecab (C) | LInzess (C) | Geninax (C) | Bfluid (C) | Predonine (C) | Ms contin (C) | Opso (C) | Sodium hyaluronate (C) | Mouth wash (C) | Calonal (C) | Polaramine (C) | Palonosetron (C) | Tarlige (C) | Mosapride citrate (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
202410GLO013025IN	INDIA 40 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	14-Oct-2024 5 months 5 days	PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	10-MAY-2024 to 15-JUL-2025 1 year 2 months 6 days	
Concomitant Medication(s): | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Multivitamin (C) | Cremaffin (C) | Betadine (C) | Palonosetron (C) | Perinorm (C) | Ranitidine (C) | Granisetron (C) | Domperidone (C) | Filgrastim (C)									
202411GLO007621TH	THAILAND 40 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	28-Oct-2024 29 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	30-SEP-2024 to 03-DEC-2024 2 months 4 days	Periodic Report Comment. The patient experienced Febrile neutropenia: related to PEMBROLIZUMAB, PACLITAXEL and not related to CARBOPLATIN, DOXORUBICN HYDROCHLORIDE, CYCLOPHOSPHAMIDE. CCA: not related.;Periodic Report Comments. The patient experienced Febrile neutropenia: related to PEMBROLIZUMAB, PACLITAXEL and not related to CARBOPLATIN, DOXORUBICN HYDROCHLORIDE, CYCLOPHOSPHAMIDE. CCA: not related.
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	02-JUL-2024 to 02-SEP-2024 2 months 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	30-SEP-2024 to 23-JUL-2025 9 months 24 days	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | CARBOPLATIN (S) | PACLITAXEL (S) | Akynzeo (C) | Dexamethasone (C) | Chlorpheniramine (C) | Famotidine (C) | Lorazepam (C)									
202411GLO024770FR	FRANCE 33 Years Female	**Febrile bone marrow aplasia (Febrile aplasia)***	Recovered	26-Nov-2024 2 months 11 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	16-SEP-2024 to 18-NOV-2024 2 months 3 days	
					EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	16-SEP-2024 to 18-NOV-2024 2 months 3 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Tranxene (C) | Laroxyl (C) | Zoloft (C) | Inexium (C) | Xylocaine (C) | Zelitrex (C)									
202411GLO024778VN	VIET NAM 42 Years Female	**Anaemia (Anemia)***	Recovered	28-Nov-2024 3 months 21 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter Intravenous use	08-AUG-2024 to 02-DEC-2024 3 months 25 days	Periodic Report Comments. Patient experienced Anemia Inv causality Related: Pembrolizumab, Doxorubicin, Cyclo-phosphamide Not related: Paclitaxel, Carboplatin CCA: Not related
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | CAPECITABINE (S) | Levocetirizin (C) | Aescin (C) | Esomeprazole (C) | Bilastin (C) | Dexamethason (C) | Vismed multi (C) | Bbm cough (C) | Methylprednisolone (C) | Glockner (C) | Raciper (C)									
202412GLO020163AU	AUSTRALIA 59 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	22-Dec-2024 14 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram q3w Intravenous use	09-DEC-2024 to 22-JAN-2025 1 month 14 days	Periodic report comment. Patient has event : febrile neutropenia For study therapy Action Taken: no change, dose reduce and not applicable respectively Investigator Causality: not Related, related CC: Not

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram q3w Intravenous use	09-DEC-2024 to 22-JAN-2025 1 month 14 days	Related. Outcome: Recovered
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Crestor (C) | Melobic (C) | Naltrexone (C) | Ondansetron (C) | Metoclopramide (C) | Enoxaparin (C)									
202501GLO013350TR	TURKEY 38 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	16-Jan-2025 2 months 11 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	06-NOV-2024 to 06-NOV-2024 1 day	The patient experienced febrile neutropenia. Investigator: Related to Doxorubicin Hydrochloride, Cyclophosphamide. Not related to Pembrolizumab, Carboplatin, Paclitaxel. Company: Not related; Periodic Report Comments.
						Infusion	60 milligram/sq. meter q3w Intravenous use	08-JAN-2025 to 08-JAN-2025 1 day	The patient experienced febrile neutropenia. Investigator: Related to Doxorubicin Hydrochloride, Cyclophosphamide. Not related to Pembrolizumab, Carboplatin, Paclitaxel. Company: Not related
						Infusion	60 milligram/sq. meter q3w Intravenous use	18-DEC-2024 to 18-DEC-2024 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	60 milligram/sq. meter q3w Intravenous use	27-NOV-2024 to 27-NOV-2024 1 day	
					CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	06-NOV-2024 to 06-NOV-2024 1 day	
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	08-JAN-2025 to 08-JAN-2025 1 day	
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	18-DEC-2024 to 08-JAN-2025 22 days	
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	27-NOV-2024 to 27-NOV-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Hyonat (C) | Granisetron (C) | Dekort (C) | Avil (C) | Emend (C) | Benexol (C) | Minoset (C) | Lotebra (C) | Ofnol (C) | Dexamethasone (C) | Fraven (C) | Folbiol (C) | Lomotil (C) | Zarzio (C) | Augmentin (C) | Parol (C) | Leucostim (C) | Sodium chloride (C) | Apikobal (C) | Mucinac (C) | Oralac (C) | Pulcet (C) | Tazilix (C) | Tylol (C) | Venavit (C) | Vancotek (C) | Fix (C) | Fentanyl (C) | Progas (C) | Revafen (C) | Tramosel (C) | Aksef (C) | Arveles (C) | Lansor (C) | Iburamin cold (C) | Klamoks (C)									
202501GLO025831ES	SPAIN 43 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	29-Jan-2025 13 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	17-JAN-2025 to 14-MAR-2025 1 month 26 days	Periodic Report Comments. Patient experienced febrile neutropenia Inv causality: RELATED to Pembrolizumab, Doxorubicin and Cyclophosphamide CCA: NOT RELATES
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Ibuprofen (C) | Dexamethasone (C) | Olanzapine (C) | Ondansetron (C)									
202502GLO000871IN	INDIA 46 Years Female	**Neutropenia (Neutropenia)***	Not Recovered	31-Jan-2025 3 months 7 days	CARBOPLATIN	Infusion	Intravenous use	25-OCT-2024 to 16-JAN-2025 2 months 23 days	The patient experienced neutropenia. Investigator: related to Pembrolizumab, Doxorubicin Hydrochloride, Cyclophosphamide. Not related to Carboplatin, Paclitaxel. Company: Related.;Periodic Report Comments. The patient experienced neutropenia. Investigator: related to Pembrolizumab, Doxorubicin Hydrochloride, Cyclophosphamide. Not related to Carboplatin, Paclitaxel. Company: Related.;Patient experienced Neutropenia Inv. Causality : Related, CCA: Related.
					PACLITAXEL	Infusion	80 milligram/sq. meter qw Intravenous use	25-OCT-2024 to 16-JAN-2025 2 months 23 days	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	25-OCT-2024 to 02-APR-2025 5 months 9 days	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	700 milligram/sq. meter q3w Intravenous use	15-FEB-2025 to 02-APR-2025 1 month 19 days	
						Powder for solution for injection/infusion	860 milligram/sq. meter q3w Intravenous use	24-JAN-2025 to 24-JAN-2025 1 day	
					DOXORUBICIN HYDROCHLORIDE	Infusion	70 milligram/sq. meter q3w Intravenous use	02-FEB-2025 to 02-APR-2025 2 months 1 day	
						Infusion	86 milligram/sq. meter q3w Intravenous use	24-JAN-2025 to 24-JAN-2025 1 day	

Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | | Thyroxine (C) | Levothyroxine (C) | Thyrox (C) | Gargle (C) | Metoclopramide (C) | Ondansetron (C) | Pantoprazole (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

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EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202502GLO012434SG	SINGAPORE 39 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	14-Feb-2025 11 days	DOXORUBICIN HYDROCHLORIDE	Infusion	51 milligram/sq. meter q3w Intravenous use	05-MAR-2025 to 16-APR-2025 1 month 12 days	The patient experienced febrile neutropenia. Investigator: related to Doxorubicin Hydrochloride, Cyclophosphamide; not related to Pembrolizumab, Carboplatin, Paclitaxel. Company: related to Cyclophosphamide; not related to Pembrolizumab, Carboplatin, Paclitaxel, Doxorubicin Hydrochloride.
						Infusion	60 milligram/sq. meter q3w Intravenous use	04-FEB-2025 to 04-FEB-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Dexamethasone (C) | Akynzeo (C) | Sennosides (C) | Lactulose (C) | Metoclopramide HCL (C)									
202502GLO014665IT	ITALY 56 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	11-Feb-2025 14 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	29-JAN-2025 to 10-APR-2025 2 months 13 days	
					EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	29-JAN-2025 to 10-APR-2025 2 months 13 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Ondansetron (C) | Desametasone (C) | Clorfenamina (C) | Tachipirina (C) | Bentelan (C) | Fosaprepitant (C) | Famotidina (C) | Tiobec (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202502GLO020543DE	GERMANY 29 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	21-Feb-2025 3 months 8 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	14-NOV-2024 to 17-APR-2025 5 months 4 days	
					CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	06-MAR-2025 to 17-APR-2025 1 month 12 days	
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	13-FEB-2025 to 13-FEB-2025 1 day	
					EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	06-MAR-2025 to 17-APR-2025 1 month 12 days	
						Infusion	90 milligram/sq. meter q3w Intravenous use	13-FEB-2025 to 13-FEB-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Granisetron (C) | Zoladex (C) | Pantoprazol (C) | Unacid (C)									
202503GLO005118CN	CHINA 36 Years Female	**Anaemia (Anemia aggravated)***	Not Recovered	03-Jul-2024 1 month 9 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	04-JUL-2024 to 04-JUL-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	04-SEP-2024 to 04-SEP-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	14-JUN-2024 to 14-JUN-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	15-AUG-2024 to 15-AUG-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	17-OCT-2024 to 17-OCT-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	25-JUL-2024 to 25-JUL-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	25-MAY-2024 to 25-MAY-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	26-SEP-2024 to 26-SEP-2024 1 day	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	14-MAY-2025 to 27-JUN-2025 1 month 14 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	25-MAY-2024 to 22-APR-2025 10 months 29 days	
Concomitant Medication(s): | DURVALUMAB (S) | PACLITAXEL (S) | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | CARBOPLATIN (S) | Rivaroxaban (C) | Loratadine (C) | Triamcinolone (C) | Dexamethasone (C) | Heparin sodium (C) | Ondansetron hydrochloride (C) | Paracetamol (C) | Promethazine hydrochloride (C) | Omeprazole sodium (C) | Vitamin b6 (C) | Levofloxacin (C) | Netupitant and palonosetron hydrochloride (C) | Mecobalamine (C) | Netupitant (C) | Sodium hyaluronate (C) | Iron dextran (C) | Dexamethasone sodium phosphate (C) | Acetaminophen (C) | Dexamethasone sodium phosphate (C) | Chlorpromazine hydrochloride (C)									
202503GLO005673ES	SPAIN 51 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	05-Mar-2025 7 days	DOXORUBICIN HYDROCHLORIDE	Infusion	Intravenous use	11-APR-2025 to 02-MAY-2025 22 days	
						Infusion	Intravenous use	27-FEB-2025 to 21-MAR-2025 23 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | CYCLOPHOSPHAMIDE (S) | Losartan (C) | Hydrochlorothiazide (C) | Diazepam (C) | Melatonin (C) | Lormetazepam (C) | Paracetamol (C)									
202503GLO019010US	UNITED STATES 71 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Not Recovered	20-Mar-2025 1 month 21 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter Intravenous use	30-JAN-2025 to 03-APR-2025 2 months 5 days	Patient has Febrile Neutropenia. Action taken with study therapy was No change. Investigator Causality: Related, CC: Not Related for cyclophosphamide, doxorubicin hydrochloride

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | CYCLOPHOSPHAMIDE (S) | | CARBOPLATIN (S) | Metformin (C) | Colace (C) | Prednisone (C) | PACLITAXEL (S)									
202504GLO022184US	UNITED STATES 53 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	23-Apr-2025 14 days	DOXORUBICIN HYDROCHLORIDE	Infusion	Intravenous use	10-APR-2025 to 12-JUN-2025 2 months 3 days	Periodic Report Comments. the patient experienced anemia (preferred term: Anaemia) and febrile neutropenia related to CYCLOPHOSPHAMIDE and not related to PEMBROLIZUMAB and paclitaxel;Periodic Report Comments. Patient experienced event Febrile neutropenia. Investigator states event Febrile neutropenia related to Cyclophosphamide and Doxorubicin and not related to Pembrolizumab, Paclitaxel and Carboplatin. Company physician considers event Febrile neutropeniarelated not related to Cyclophosphamide, Doxorubicin, Pembrolizumab, Paclitaxel and Carboplatin.
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Tylenol (C) | Lipitor (C) | Zyrtec (C) | Afrin (C) | Trazodone (C) | Centrum silver (C) | Valacyclovir (C) | Dulcolax (C)									
202504GLO023366DE	GERMANY 29 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	25-Apr-2025 2 months 13 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	13-FEB-2025 to 17-APR-2025 2 months 5 days	PRC Comment. Female patient with event: Febrile neutropenia Inv causality: related to Pembrolizumab, Cyclophosphamide, Epirubicin and not related to Paclitaxel, Carboplatin CCA: not related.

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Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					EPIRUBICIN	Infusion	90 milligram/sq. meter q3w	06-MAR-2025 to 06-MAR-2025 1 day	
						Infusion	90 milligram/sq. meter q3w	13-FEB-2025 to 13-FEB-2025 1 day	
						Infusion	90 milligram/sq. meter q3w	17-APR-2025 to 17-APR-2025 1 day	
						Infusion	90 milligram/sq. meter q3w	27-MAR-2025 to 27-MAR-2025 1 day	
					PEMBROLIZUMAB	Solution for infusion	200 milligram	17-APR-2025 to 17-APR-2025 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

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EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram	27-MAR-2025 to 27-MAR-2025	
						Solution for infusion	200 milligram q3w	05-DEC-2024 to 05-DEC-2024 1 day	
						Solution for infusion	200 milligram q3w	06-MAR-2025 to 06-MAR-2025 1 day	
						Solution for infusion	200 milligram q3w	13-FEB-2025 to 13-FEB-2025 1 day	
						Solution for infusion	200 milligram q3w	14-NOV-2024 to 14-NOV-2024 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w	16-JAN-2025 to 16-JAN-2025 1 day	
						Solution for infusion	200 milligram q3w	27-DEC-2024 to 27-DEC-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	14-NOV-2024 to 17-APR-2025 5 months 4 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Zoladex (C) | Pantoprazol (C) | Vitamin d3 (C) | Dexamethason (C) | Granisetron (C) | Amoxiclav (C) | Ciprofloxacin (C) | Panotile cipro (C) | Akynzeo (C) | Unacid (C) | Filgrastim (C) | Neulasta (C) | Macrogol (C) | Paracetamol (C) | Neupogen (C) | Piperacillin/tazobactam (C)									
202505GLO011825VN	VIET NAM 36 Years Female	**Anaemia (Anemia)***	Recovered	26-Nov-2024 nk	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter Intravenous use	18-FEB-2025 to 22-APR-2025 2 months 5 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Dimedrol (C) | Lorytec (C) | Ondanov (C) | Grafeel (C) | Ficocyte (C) | Dexamethasone (C) | Neutromax (C) | Itamegrani (C)									

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202505GLO016853CA	CANADA 54 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	18-May-2025 10 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter Intravenous use	09-MAY-2025 to 09-MAY-2025 1 day	periodic report comment. Patient experienced febrile neutropenia, inv: related to CYCLOPHOSPHAMIDE, DOXORUBICIN HYDROCHLORIDE, not related to PACLITAXEL, PEMBROLIZUMAB, CARBOPLATIN, cca: not related to CYCLOPHOSPHAMIDE, DOXORUBICIN HYDROCHLORIDE, PACLITAXEL, PEMBROLIZUMAB, CARBOPLATIN.
Concomitant Medication(s): | CARBOPLATIN (S) | PACLITAXEL (S) | CYCLOPHOSPHAMIDE (S) | PEMBROLIZUMAB (S) | Lorazepam (C) | Secaris (C) | Sinus rinse (C) | Rivaroxaban (C)									
202505GLO018471IN	INDIA 57 Years Female	**Pancytopenia (Pancytopenia)***	Recovered	21-May-2025 3 months 3 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	19-FEB-2025 to 14-MAY-2025 2 months 26 days	The patient experienced Neutropenia. Investigator: related to pembrolizumab, epirubicin, cyclophosphamide. and not related to paclitaxel and carboplatin. Company: not related.
					CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	14-MAY-2025 to 14-MAY-2025 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	14-MAY-2025 to 14-MAY-2025 1 day	
Concomitant Medication(s): | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Telma AM (C) | Cremaffin plus (C) | Emeset (C) | Mucaine (C) | Pan D (C) | Paracetamol (C) | Lomotil (C) | Thyrox (C) | Domstal (C) | Augmentin (C) | Bifilac (C) | Filgrastim (C)									
202505GLO021200BR	BRAZIL 54 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	22-May-2025 10 days	DOXORUBICIN HYDROCHLORIDE	Infusion	Intravenous use	13-MAY-2025 to 03-JUN-2025 22 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Losartan (C) | Gliclazide (C) | Dexamethasone (C) | Ondansetron (C) | Diphenhydramine (C)									
202505GLO023509ES	SPAIN 29 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	26-May-2025 11 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	450 milligram/sq. meter q3w Intravenous use	10-JUN-2025 to 05-AUG-2025 1 month 27 days	
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	16-MAY-2025 to 16-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DOXORUBICIN HYDROCHLORIDE	Infusion	45 milligram/sq. meter q3w Intravenous use	10-JUN-2025 to 05-AUG-2025 1 month 27 days	
						Infusion	60 milligram/sq. meter q3w Intravenous use	16-MAY-2025 to 16-MAY-2025 1 day	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	05-FEB-2025 to 09-APR-2025 2 months 5 days	
						Solution for infusion	200 milligram q3w Intravenous use	10-JUN-2025 to 10-JUN-2025 1 day	

Concomitant Medication(s): PEMBROLIZUMAB (S) | CARBOPLATIN (S) | PACLITAXEL (S) | DOXORUBICIN HYDROCHLORIDE (S) | | Dexamethasone (C) | Famotidine (C) | Paracetamol (C) | Anso (C) | Granisetron Teva Italia (C) | Retinol (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202505GLO028841US	UNITED STATES 61 Years Female	**Anaemia (Symptomatic anemia)***	Recovered	03-Jun-2025 14 days	DOXORUBICIN HYDROCHLORIDE	Infusion	48 milligram/sq. meter qw Intravenous use	02-JUL-2025 to 02-JUL-2025 1 day	Periodic Report Comment. Patient experienced acute symptomatic anemia, investigator: related to PEMBROLIZUMAB, PACLITAXEL, CARBOPLATIN, DOXORUBICIN HYDROCHLORIDE, CYCLOPHOSPHAMIDE. CCA: not related.
						Infusion	48 milligram/sq. meter qw Intravenous use	12-JUN-2025 to 12-JUN-2025 1 day	
						Infusion	60 milligram/sq. meter qw Intravenous use	21-MAY-2025 to 21-MAY-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Albuterol Hfa (C) | Aspirin (C) | Atorvastatin (C) | Evolocumab (C) | Montelukast (C)									
202506GLO005311DE	GERMANY 55 Years Female	**Pancytopenia (Pancytopenia)***	Recovered	04-Jun-2025 8 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	28-MAY-2025 to 28-MAY-2025 1 day	Patient experienced Pancytopenia: event related to Epirubicin Cyclophosphamide and not related to Pembrolizumab, Paclitaxel, Carboplatin. CCA: event related to Epirubicin Cyclophosphamide and not related to Pembrolizumab, Paclitaxel, Carboplatin.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	28-MAY-2025 to 28-MAY-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | EPIRUBICIN (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Fortecortin (C) | Granisetron (C) | Tavegil (C)									
202506GLO006408TR	TURKEY 60 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	09-Jun-2025 1 day	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	09-JUN-2025 to 07-AUG-2025 1 month 30 days	
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	29-MAY-2025 to 07-AUG-2025 2 months 10 days	
					CARBOPLATIN	Infusion	Intravenous use	04-FEB-2025 to 25-APR-2025 2 months 22 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PACLITAXEL	Infusion	80 milligram/sq. meter q3w Intravenous use	04-FEB-2025 to 08-MAY-2025 3 months 5 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Delix (C) | Galvus met (C) | Esomeprazole (C)									
202506GLO011133TR	TURKEY 61 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	13-Jun-2025 1 month 5 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter Intravenous use	09-MAY-2025 to 03-JUN-2025 26 days	
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter Intravenous use	09-MAY-2025 to 03-JUN-2025 26 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S)									
202506GLO017787US	UNITED STATES 38 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	20-Jun-2025 3 months 7 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	11-JUL-2025 to 11-JUL-2025 1 day	Periodic Report Comments. Patient experienced febrile neutropenia investigator causality related to pembrolizumab, not related to carboplatin, paclitaxel, cyclophosphamide, doxorubicin, CCA not related.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	13-JUN-2025 to 13-JUN-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	14-MAR-2025 to 25-APR-2025 1 month 12 days	
						Solution for infusion	200 milligram q3w Intravenous use	23-MAY-2025 to 25-MAY-2025 3 days	
Concomitant Medication(s): | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Ondansetron (C) | Claritin (C) | Imodium (C) | Alpha lipoic acid (C)									
202506GLO024200BR	BRAZIL 47 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	25-Jun-2025 nk	DOXORUBICIN HYDROCHLORIDE	Infusion Intravenous use		to	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	13-MAR-2025 to 30-APR-2025 1 month 18 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Propranolol (C) | Lithium (C) | Aripiprazole (C) | Escitalopram (C)									
202507GLO005673BR	BRAZIL 43 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	07-Jul-2025 14 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	24-JUN-2025 to 26-AUG-2025 2 months 3 days	The patient experienced Febrile neutropenia. Pembrolizumab, Cyclophosphamide, Doxorubicin Hydrochloride, Paclitaxel, Carboplatin were continued with respect to the event. Investigator assessed as not related to Pembrolizumab, Paclitaxel, Carboplatin, related to Cyclophosphamide, Doxorubicin Hydrochloride. Company physician assessed as not related to Pembrolizumab, Cyclophosphamide, Doxorubicin Hydrochloride, Paclitaxel, Carboplatin.
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	24-JUN-2025 to 26-AUG-2025 2 months 3 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Codeine (C) | Dexamethasone (C) | Diphenhydramine (C) | Netupitant (C) | Bisacodyl (C) | Dipyrone (C)									
202507GLO006976CN	CHINA 43 Years Female	**Anaemia (Anemia)** White blood cell count decreased (White blood cell count decreased)* Neutrophil count decreased	Recovering	06-May-2025 nk	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	01-JUL-2025 to 01-JUL-2025 1 day	Periodic Report Comments. Patient experienced Anemia, neutrophil count decreased, platelet count decreased and white blood cell count decreased, Inv. related to IP, CCA not related to IP

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
		(Neutrophil count decreased) Platelet count decreased (Platelet count decreased)*				Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	12-AUG-2025 to 12-AUG-2025 1 day	
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	22-JUL-2025 to 22-JUL-2025 1 day	
		Anaemia (Anemia)* White blood cell count decreased (White blood cell count decreased)* Neutrophil count decreased (Neutrophil count decreased)* Platelet count decreased (Platelet count decreased)*	Recovering	06-May-2025 nk	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	01-JUL-2025 to 01-JUL-2025 1 day	
						Infusion	60 milligram/sq. meter q3w Intravenous use	12-AUG-2025 to 12-AUG-2025 1 day	
						Infusion	60 milligram/sq. meter q3w Intravenous use	22-JUL-2025 to 22-JUL-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Bicyclol (C) | Recombinant Human Erythropoietin (C) | Recombinant human thrombopoietin (C) | Iron Polysaccharide complex (C) | Diclofenac (C)									
202507GLO011014CN	CHINA 41 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	12-Jul-2025 8 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	05-JUL-2025 to 09-SEP-2025 2 months 5 days	
					EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	05-JUL-2025 to 09-SEP-2025 2 months 5 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | PACLITAXEL (S) | | CARBOPLATIN (S) | Olanzapine (C)									
202507GLO019129TR	TURKEY 32 Years Female	**Neutropenia (Neutropenia)***	Recovered	21-Jul-2025 2 months 9 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter Intravenous use	13-MAY-2025 to 14-AUG-2025 3 months 2 days	
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter Intravenous use	13-MAY-2025 to 14-AUG-2025 3 months 2 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | CARBOPLATIN (S) | PACLITAXEL (S) | Kordexa (C) | Fullfresh (C) | Dekort (C) | Avil (C) | Kytril (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO021614PL	POLAND 50 Years Female	**Febrile neutropenia (Neutropenic fever)***	Recovered	23-Jul-2025 14 days	DOXORUBICIN HYDROCHLORIDE	Infusion	Intravenous use	10-JUL-2025 to 17-SEP-2025 2 months 8 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Euthyrox (C)									
202507GLO022422VN	VIET NAM 65 Years Female	**Pancytopenia (Pancytopenia)*** Pneumonitis (Pneumonitis)* Abdominal pain (Abdominal pain)	Recovering	23-Jul-2025 8 days	DOXORUBICIN	Infusion	60 milligram/sq. meter q3w Intravenous use	16-JUL-2025 to 16-JUL-2025 1 day	Periodic Report Comments. Patient has event Pancytopenia, Pneumonia potential and Unexplaned abdominal pain Action taken with PEMBROLIZUMAB, DOXORUBICIN, CYCLOPHOSPHAMIDE was no change and with PACLITAXEL and CARPeriodic Report CommentsBOPLATIN was not applicable. For Investigator Causality: with respective to PEMBROLIZUMAB, DOXORUBICIN, CYCLOPHOSPHAMIDE was related and with PACLITAXEL and CARBOPLATIN was not related. Company causality: not related for events.
		Pancytopenia (Pancytopenia)* Pneumonitis (Pneumonitis) Abdominal pain (Abdominal pain)	Recovering	23-Jul-2025 3 months 1 day	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	04-JUN-2025 to 04-JUN-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	14-MAY-2025 to 14-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	16-JUL-2025 to 16-JUL-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	23-APR-2025 to 23-APR-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	25-JUN-2025 to 25-JUN-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Levothyroxine (C) | Atorvastatin (C) | Candesartan (C) | Aloxi (C) | Dexamethasone (C) | Dimedrol (C) | Natri clorid (C)									
202507GLO022737JP	JAPAN 51 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovering	26-Jul-2025 13 days	DOXORUBICIN HYDROCHLORIDE	Infusion	Intravenous use	14-JUL-2025 to 25-AUG-2025 1 month 12 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | CARBOPLATIN (S) | | CYCLOPHOSPHAMIDE (S) | Cortril (C) | Arokaris (C) | Loxoprofen (C) | Renivace (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO007587IT	ITALY 58 Years Female	**Pancytopenia (Pancytopenia)***	Recovering	11-Aug-2025 nk	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	to	
					EPIRUBICIN	Infusion	Intravenous use	to	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	09-MAY-2025 to 10-JUL-2025 2 months 2 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | CARBOPLATIN (S) | EPIRUBICIN (S) | | Flutiform (C) | Pantoprazole (C) | Dexamethasone (C) | Chlorphenamine (C) | Tazocin (C) | Paracetamol aft (C)									
202508GLO010901DE	GERMANY 37 Years Female	**Neutropenia (Neutropenia)***	Recovered	11-Aug-2025 7 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter Intravenous use	05-AUG-2025 to 05-AUG-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					EPIRUBICIN	Infusion	90 milligram/sq. meter Intravenous use	05-AUG-2025 to 05-AUG-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | CARBOPLATIN (S) | EPIRUBICIN (S) | | Bepanthen (C)									
202508GLO012556TR	TURKEY 41 Years Female	**Neutropenia (Neutropenia)***	Recovered	14-Aug-2025 1 month 1 day	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	14-JUL-2025 to 05-AUG-2025 23 days	
					EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	14-JUL-2025 to 05-AUG-2025 23 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Pantoprazole (C) | Dexamethasone (C)									
202508GLO013732CH	SWITZERLAND 70 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	14-Aug-2025 3 months 3 days	PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	02-JUN-2025 to 02-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram Intravenous use	04-AUG-2025 to 25-AUG-2025 22 days	
						Solution for infusion	200 milligram Intravenous use	12-MAY-2025 to 12-MAY-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	14-JUL-2025 to 14-JUL-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	23-JUN-2025 to 23-JUN-2025 1 day	

Concomitant Medication(s): | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | CARBOPLATIN (S) | PACLITAXEL (S) | Actonel (C) | Cortison (C) | Movicol (C) | Paspertin (C) | Zyprexa Velotab (C) | Daptomycin (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO014774CN	CHINA Female	**Myelosuppression (Bone marrow suppression)***	Recovered	16-Aug-2025 3 months 2 days	PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	15-MAY-2025 to 18-SEP-2025 4 months 4 days	
Concomitant Medication(s): | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Cimetidine (C) | Dexamethasone (C) | Diphenhydramine (C) | Ilaprazole sodium (C) | Netupitant and palonosetron hydrochloride (C) | Ambroxol hydrochloride (C) | Montmorillonite (C) | Leucogen (C) | Polyene phosphatidylcholine (C) | Bicyclol (C) | Levofloxacin (C) | Omeprazole sodium (C) | Tiopronin (C)									
202508GLO016287US	UNITED STATES 57 Years Female	**Febrile neutropenia (Febrile neutropenia)** Sepsis (Sepsis)* Colitis (Typhlitis)*	Recovering	19-Aug-2025 1 month 11 days	CARBOPLATIN	Infusion	Intravenous use	09-JUL-2025 to 17-SEP-2025 2 months 9 days	Periodic Report Comments. Patient has event Neutropenia, Febrile Neutropenia, Colitis and Sepsis Action taken all drug drug was no change. Investigator Causality related for PACLITAXEL, CARBOPLATIN and not related for PEMBROLIZUMAB and Company causality: not related.
		Febrile neutropenia (Febrile neutropenia) Sepsis (Sepsis) Colitis (Typhlitis)*	Recovering	19-Aug-2025 1 month 11 days	PACLITAXEL	Infusion	80 milligram/sq. meter qw Intravenous use	09-JUL-2025 to 17-SEP-2025 2 months 9 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | Metformin (C) | Losartan (C) | Atorvastatin (C)									
202508GLO020433US	UNITED STATES 71 Years Female	**Febrile neutropenia (Neutropenic fever)***	Recovered	23-Aug-2025 nk	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	09-MAY-2025 to 09-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	27-JUN-2025 to 27-JUN-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	30-MAY-2025 to 30-MAY-2025 1 day	
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	15-AUG-2025 to 15-AUG-2025 1 day	
Concomitant Medication(s): | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | CARBOPLATIN (S) | PACLITAXEL (S) | Lovastatin (C) | Asprin (C) | Furosemide (C) | Lisinopril (C) | Metoprolol (C) | Vitamin d3 (C) | Dexamethasone (C) | Famotidine (C) | Diphenhydramine (C) | Granisetron (C) | Compazine (C) | Hydrocortisone (C) | Gabapentin (C) | Vancomycin (C)									
202508GLO022599AT	AUSTRIA 40 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	24-Aug-2025 1 year 11 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	480 milligram/sq. meter Intravenous use	05-SEP-2025 to 05-SEP-2025 1 day	Patient experienced Febrile Neutropenia Inv causality: RELATED with Epirubicin and Cyclo-phosphamide NOT RELATED with Durvalumab and Dato-DXd

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for injection/infusion	590 milligram/sq. meter Intravenous use	14-AUG-2024 to 14-AUG-2024 1 day	
					EPIRUBICIN	Infusion	72 milligram/sq. meter Intravenous use	05-SEP-2025 to 05-SEP-2025 1 day	
						Infusion	89 milligram/sq. meter Intravenous use	14-AUG-2024 to 14-AUG-2024 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | EPIRUBICIN (S) |									
202509GLO003090AT	AUSTRIA 40 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	24-Aug-2025 11 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	590 milligram/sq. meter q3w Intravenous use	14-AUG-2025 to	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					EPIRUBICIN	Infusion	89 milligram/sq. meter q3w Intravenous use	14-AUG-2025 to	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | EPIRUBICIN (S) | | Dexamethasone (C) | Goserelin (C)									
202509GLO006528BR	BRAZIL 62 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	08-Sep-2025 13 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	27-AUG-2025 to 17-SEP-2025 22 days	Periodic Report Comments. Patient experienced Febrile neutropenia, Investigator assessed the event to be related with Cyclophosphamide, Doxorubicin Hydrochloride and not related with Carboplatin, Paclitaxel, Pembrolizumab. CCA: not related.
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | CARBOPLATIN (S) | PACLITAXEL (S)									
202509GLO007284BR	BRAZIL 62 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	06-Sep-2025 11 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	15-OCT-2025 12:40 to 15-OCT-2025 13:10 30 min	
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	24-SEP-2025 13:28 to 24-SEP-2025 13:58 30 min	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	27-AUG-2025 to 27-AUG-2025 1 day	
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	15-OCT-2025 12:24 to 15-OCT-2025 12:39 15 min	
						Infusion	60 milligram/sq. meter q3w Intravenous use	24-SEP-2025 13:10 to 24-SEP-2025 13:25 15 min	
						Infusion	60 milligram/sq. meter q3w Intravenous use	27-AUG-2025 to 27-AUG-2025 1 day	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	06-JUN-2025 to 27-AUG-2025 2 months 22 days	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	15-OCT-2025 11:18 to 15-OCT-2025 12:18 1 hr	
						Solution for infusion	200 milligram q3w Intravenous use	24-SEP-2025 to 24-SEP-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Acetylsalicylic acid (C) | Enalapril (C) | Hydrochlorothiazide (C) | Clonazepam (C) | Metformin (C) | Nph insulin (C) | Simvastatin (C) | Sertraline (C) | Amlodipine (C) | Amiodarone (C) | Potassium chloride (C) | Hydralazine (C) | Pantoprazole (C)									
202509GLO007715US	UNITED STATES 53 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	08-Sep-2025 11 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	29-AUG-2025 to 29-AUG-2025 1 day	Periodic Report Comments. Patient experienced febrile neutropenia. Inv: event related to Cyclophosphamide, Doxorubicin Hydrochloride, not related to Carboplatin, Paclitaxel, Pembrolizumab. CCA: not related.
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter Intravenous use	29-AUG-2025 to 29-AUG-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Levothyroxine (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202509GLO008764US	UNITED STATES 66 Years Female	**Febrile neutropenia (Neutropenic fever)***	Recovered	09-Sep-2025 1 month 26 days	PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	05-AUG-2025 to 05-AUG-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	15-JUL-2025 to 15-JUL-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	26-AUG-2025 to 23-SEP-2025 29 days	
Concomitant Medication(s): | PACLITAXEL (S) | CARBOPLATIN (S) | Esomeprazole magnesium delayed release (C) | Iron (C)									
202509GLO012429DE	GERMANY 34 Years Female	**Neutropenia (Neutropenia)***	Recovered	09-Sep-2025 nk	PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	05-JUN-2025 to 16-OCT-2025 4 months 12 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	28-AUG-2025 to 16-OCT-2025 1 month 19 days	
					EPIRUBICIN	Infusion	Intravenous use	28-AUG-2025 to 16-OCT-2025 1 month 19 days	
Concomitant Medication(s): | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Sinupret (C) | Dexamethason (C) | Granisetron (C) | Akynzeo (C) | Cefuroxim (C)									
202509GLO016198BG	BULGARIA 46 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	18-Sep-2025 30 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	20-AUG-2025 to 10-SEP-2025 22 days	
						Powder for solution for injection/infusion	Intravenous use	20-AUG-2025 to 20-AUG-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DOXORUBICIN HYDROCHLORIDE	Infusion	Intravenous use	10-SEP-2025 to 10-SEP-2025 1 day	
						Infusion	Intravenous use	20-AUG-2025 to 20-AUG-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S)									
202509GLO018950CN	CHINA 48 Years Female	**Myelosuppression (Bone marrow suppression)***	Not Recovered	21-Sep-2025 10 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter Intravenous use	12-SEP-2025 to	
					EPIRUBICIN	Infusion	150 milligram/sq. meter Intravenous use	12-SEP-2025 to	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202510GLO000914CA	CANADA 46 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Fatal	29-Sep-2025 nk	CARBOPLATIN	Infusion	1.5	04-SEP-2025 to 18-SEP-2025	
						Infusion	1.5	14-AUG-2025 to 14-AUG-2025	
						Infusion	1.5	21-AUG-2025 to 21-AUG-2025	
						Infusion	1.5	28-AUG-2025 to 28-AUG-2025 1 day	
						Infusion	1.5 Intravenous use	07-AUG-2025 to 07-AUG-2025	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PACLITAXEL	Infusion	80 milligram/sq. meter	04-SEP-2025 to 18-SEP-2025 15 days	
						Infusion	80 milligram/sq. meter qw	14-AUG-2025 to 14-AUG-2025 1 day	
						Infusion	80 milligram/sq. meter qw	21-AUG-2025 to 21-AUG-2025 1 day	
						Infusion	80 milligram/sq. meter qw	28-AUG-2025 to 28-AUG-2025 1 day	
						Infusion	80 milligram/sq. meter qw Intravenous use	07-AUG-2025 to 07-AUG-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PACLITAXEL (S) | Vitamin C (C) | Benadryl (C) | Famotidine (C) | Olanzapine (C) | Ondansetron (C)									
202510GLO001743FR	FRANCE 52 Years Female	**Anaemia (Anemia)***	Not Recovered	07-Apr-2025 15 days	CARBOPLATIN	Infusion	Intravenous use	24-MAR-2025 to 29-JUL-2025 4 months 6 days	Periodic Report Comments. Patient experienced the event "ANEMIA" . INV causality not related for PEMBROLIZUMAB & EPIRUBICIN & CYCLOPHOSPHAMIDE, related for PACLITAXEL & CARBOPLATIN. Company causality not related for all drugs.
					PACLITAXEL	Infusion	Intravenous use	24-MAR-2025 to 24-JUN-2025 3 months 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | | Escitalopram (C) | Gabapentine (C) | Relvar (C) | Ventilastin (C) | Pegfilgrastim (C) | Diosmectite (C) | Tiorfan (C) | Bactrim forte (C) | Prednisone (C)									
202510GLO001773US	UNITED STATES 57 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Not Recovered	02-Oct-2025 8 months	DURVALUMAB	Infusion	1120 milligram Unknown	03-FEB-2025 to 29-JUL-2025 5 months 27 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) |									
202510GLO001913US	UNITED STATES 57 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Not Recovered	02-Oct-2025 8 months	DURVALUMAB	Infusion	1120 milligram	03-FEB-2025 to 29-JUL-2025 5 months 27 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) |									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202510GLO016465VN	VIET NAM Female	**Febrile neutropenia (Febrile neutropenia)***	Recovering	17-Oct-2025 2 months 11 hrs	DOXORUBICIN HYDROCHLORIDE	Infusion	Intravenous use	17-AUG-2025 13:00 to 08-OCT-2025 13:00 1 month 21 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | CYCLOPHOSPHAMIDE (S) | Dexamethasone (C) | Sanlein (C)									
202510GLO022749BR	BRAZIL 29 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	24-Jul-2025 1 month 22 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	03-JUN-2025 to	
Concomitant Medication(s): | CYCLOPHOSPHAMIDE (S) | PEMBROLIZUMAB (S) | CARBOPLATIN (S) | PACLITAXEL (S) | Clobetasol (C) | Symbicort (C) | Fluoxetine (C) | Akynzeo (C) | Dexamethasone (C) | Diphenhydramine (C) | Pantoprazole (C) | Bisacodyl (C) | Ondansetron (C) | Desonide (C) | Doxycycline (C) | Benzoyl peroxide (C) | Hamamelis (C) | Amoxicillin (C) | Dipirone (C) | Bromopride (C) | Cefepima (C) | Clonazepam (C) | Dipyrone (C) | Enoxaparin (C) | Omeprazole (C) | Oxacillin (C) | Vancomycin (C) | Epinephrine (C) | Fentanyl (C) | Ketoprofen (C) | Lidocaine (C) | Midazolam (C) | Propofol (C) | Bromoprida (C) | Heparin (C) | Potassium chloride (C) | Sulfamethoxazole (C) | Trimethoprim (C) | Fluconazole (C) | Metronidazole (C) | Miconazole nitrate (C) | Fexofenadine (C) | Hydroxyzine (C) | Tetracaine (C) | Triamcinolone (C) | Influenza vaccine (C) | Desvenlafaxine (C) | Loperamide (C) | Nystatin (C) | Saline (C) | Scopolamine (C) | Tramadol (C) | Tocopherol (C) | Formoterol (C) | Desloratadine (C) | Hydrocortisone (C) | Prednisone (C)									

SOC:Endocrine disorders

202504GLO028915CA	CANADA 66 Years Female	**Hypophysitis (Hypophysitis)***	Not Recovered	07-May-2025 2 months 18 days	CARBOPLATIN	Infusion	Intravenous use	20-FEB-2025 to 24-APR-2025 2 months 5 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | CYCLOPHOSPHAMIDE (S) | DOXORUBICIN HYDROCHLORIDE (S) | Betaderm (C) | Dexamethasone (C) | Diphenhydramine (C) | Ondansetron (C) | Ranitidine (C) | Secaris (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202509GLO006062DE	GERMANY 52 Years Female	**Hypopituitarism (Hypopituitarism)***	Not Recovered	05-Sep-2025 2 months 12 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	25-JUN-2025 to 16-JUL-2025 22 days	Periodic Report Comments. The patient experienced Hypopituitarism. Investigator causality related to Pembrolizumab, Epirubicin and Cyclo-phosphamide. CCA not related.
					EPIRUBICIN	Infusion	Intravenous use	25-JUN-2025 to 16-JUL-2025 22 days	

Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Neupogen (C) | Advantan (C)

SOC:Gastrointestinal disorders

202410GLO022072TR	TURKEY 66 Years Female	**Stomatitis (Mucositis oral)***	Recovered	16-May-2024 8 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	14-OCT-2024 to 14-OCT-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	09-MAY-2024 to 23-SEP-2024 4 months 15 days	

Concomitant Medication(s): | DURVALUMAB (S) | Olmetec (C) | Duskonal (C) | Lipitor (C) | Euthyrox (C) | Mikostatin (C) | Redoxon (C) | Zofer (C) | Flucan (C) | Piraldyne (C) | Desefin (C) | Pheniramine (C) | Pantoprazole (C) | Granisetron (C) | PARACETAMOL (C) | Listerine cool mint (C) | Majezik (C) | Kenacort-a (C) | Dekort (C) | Antepsin (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202412GLO006742JP	JAPAN 43 Years Female	**Nausea (Nausea)***	Recovered	07-Dec-2024 3 days	DATOPOTAMAB DERUXTECAN	Injection	Unknown	05-DEC-2024 to 28-MAY-2025 5 months 24 days	
					DURVALUMAB	Infusion	Unknown	05-DEC-2024 to 16-SEP-2025 9 months 12 days	
Concomitant Medication(s): | DURVALUMAB (S) | Hyaluronate na (C) | Restamin (C) | Dexart (C)									
2024A168270	JAPAN 42 Years Female	**Immune-mediated enterocolitis (Immune-mediated colitis)***	Recovered	08-Jul-2024 1 month 2 days	CARBOPLATIN	Infusion	Intravenous use	07-JUN-2024 to 12-SEP-2024 3 months 6 days	Periodic Report Comment. Patient experienced immuno related colitis. Inv: related to Pembrolizumab, Paclitaxel, Carboplatin and Study procedure. CCA: not related to Pembrolizumab, Paclitaxel, Carboplatin and Study procedure.;PRC. Patient experienced immuno related colitis INV: related to pembrolizumab, paclitaxel and carboplatin and not related to cyclophosphamide and epirubicin. CCA: not related to paclitaxel and carboplatin. Related to pembrolizumab.
					PACLITAXEL	Infusion	80 milligram/sq. meter Intravenous use	07-JUN-2024 to 12-SEP-2024 3 months 6 days	
Concomitant Medication(s): EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PEMBROLIZUMAB (S) | PACLITAXEL (S) | | Loxoprofen (C) | Rebamipide (C) | Diphenhydramine (C) | Decadron phosphate (C) | Gaster (C) | Granisetron (C) | Heparinoid (C) | Methaderm (C) | Miya-bm (C) | Restamin (C)									

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A170621	TURKEY 56 Years Female	**Nausea (Nausea)** Neutropenia (Neutropenia) Pancytopenia (Pancytopenia)*	Recovered	25-Jul-2024 4 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter Intravenous use	22-JUL-2024 to 01-OCT-2024 2 months 10 days	prc comment. patient experienced CTC 3 Nausea, CTC 4 Pancytopenia and CTC 4 Neutropenia. Pembrolizumab: neutropenia: inv. Causality: related, Nausea& Pancytopenia: not related Doxorubicin & cyclophosphamide: Inv. Causa: related. Paclitaxel & Carboplatin: nausea: inv. Causality: related, neutropenia & Pancytopenia: not related CCA: not related.
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Neruda (C) | Emofix (C) | Fraven (C) | Conyza canadensis (C) | Metpamid (C) | Gadexon (C) | Granisetron (C) | Pheniramine (C) | Ondansetron (C)									
202502GLO007052MY	MALAYSIA 42 Years Female	**Vomiting (Vomiting)***	Recovered	09-Feb-2025 4 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	04-JUL-2025 to	PERIODIC REPORT COMMENT. The patient experienced vomit. Investigator Causality: Related, CC: Not Related.; Periodic Report Comments. Subject has event: vomit, Action taken with study drug: No change, Investigator causality: related, Company Causality: Not related
						Infusion	1120 milligram q3w Intravenous use	06-FEB-2025 to 06-FEB-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	09-APR-2025 to 09-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	12-JUN-2025 to 12-JUN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-MAY-2025 to 20-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-FEB-2025 to 27-FEB-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-APR-2025 to 30-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505928-59-00

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Slow k (C) | Urea (C) | Cetirizine (C) | Lactulose (C)									
202503GLO011111CA	CANADA 53 Years Female	**Immune-mediated enterocolitis (Immune-mediated colitis)***	Recovered	11-Mar-2025 1 year 3 months 12 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram q3w Intravenous use	02-FEB-2024 to 02-FEB-2024 1 day	Periodic Report Comments. Patient experienced immune checkpoint colitis. Inv: event Related to DURVALUMAB, DATOPOTAMAB DERUXTECAN. CCA : Not Related to DURVALUMAB and DATOPOTAMAB DERUXTECAN.
						Injection	6 milligram q3w Intravenous use	05-APR-2024 to 05-APR-2024 1 day	
						Injection	6 milligram q3w Intravenous use	12-JAN-2024 to 12-JAN-2024 1 day	
						Injection	6 milligram q3w Intravenous use	12-MAR-2024 to 12-MAR-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505928-59-00

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram q3w Intravenous use	22-DEC-2023 to 22-DEC-2023 1 day	
						Injection	6 milligram q3w Intravenous use	23-FEB-2024 to 23-FEB-2024 1 day	
						Injection	6 milligram q3w Intravenous use	26-APR-2024 to 26-APR-2024 1 day	
						Injection	6 milligram q3w Intravenous use	30-NOV-2023 to 30-NOV-2023 1 day	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	02-FEB-2024 to 02-FEB-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	04-SEP-2024 to 04-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-APR-2024 to 05-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-JUL-2024 to 05-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	06-NOV-2024 to 06-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	12-JAN-2024 to 12-JAN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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						Infusion	1120 milligram q3w Intravenous use	12-MAR-2024 to 12-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-AUG-2024 to 14-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	16-OCT-2024 to 16-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-DEC-2024 to 18-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	22-DEC-2023 to 22-DEC-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	23-FEB-2024 to 23-FEB-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	24-JUL-2024 to 24-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	25-SEP-2024 to 25-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-APR-2024 to 26-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-NOV-2024 to 27-NOV-2024 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	30-NOV-2023 to 30-NOV-2023 1 day	
Concomitant Medication(s): DURVALUMAB (S) | | Lorazepam (C) | Mometasone furoate (C) | Zenhale (C) | Amlodipine (C) | Advil (C)									
202504GLO000935DE	GERMANY 36 Years Female	**Colitis (Colitis)***	Recovered	12-Mar-2025 nk	CARBOPLATIN	Infusion	Intravenous use	27-MAR-2025 to	Periodic Report Comments. patient experienced colitis: investigator causality: related to DATOPOTAMAB DERUXTECAN, DURVALUMAB, CARBOPLATIN, PACLITAXEL, company causality: not related to DATOPOTAMAB DERUXTECAN, DURVALUMAB, CARBOPLATIN, PACLITAXEL.
					PACLITAXEL	Infusion	80 milligram/sq. meter q3w Intravenous use	27-MAR-2025 to	
					DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	27-NOV-2024 to 21-FEB-2025 2 months 26 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | PACLITAXEL (S) | Escitalopram (C) | Paracetamol (C) | Aprepitant (C) | Granisetrone (C) | Tavegil (C) | Cetirizine (C) | Fortecortin (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202504GLO014537US	UNITED STATES 44 Years Female	**Gastric haemorrhage (Gastric hemorrhage)***	Recovered	16-Apr-2025 3 months 25 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	12-FEB-2025 to 25-MAR-2025 1 month 14 days	
						Injection	6 milligram/kilogram q3w Intravenous use	23-DEC-2024 to 13-JAN-2025 22 days	
Concomitant Medication(s): | DURVALUMAB (S) | Ativan (C) | Enoxaparin (C) | Systane (C) | Sucralfate (C) | Tylenol (C) | Compazine (C) | Aloxi (C) | Benadryl (C) | Pepcid (C) | Solumedrol (C) | Zofran (C) | Prilosec otc (C) | Carafate (C) | Aprepitant (C) | Decadron (C) | Diphenhydramine (C) | Famotidine (C) | Ferric derisomaltose (C) | Palonosetron (C) | Melatonin (C) | Mupirocin (C) | Nicoderm (C) | Oxycodone (C) | Pantoprazole (C) | Acetaminophen (C) | Morphine (C) | Potassium chloride (C)									
202504GLO018028AT	AUSTRIA 40 Years Female	**Stomatitis (Stomatitis)***	Recovered	16-Apr-2025 3 months 21 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	22-MAY-2025 to 22-MAY-2025 1 day	Periodic Report Comments. Patient experienced Stomatitis oral. Investigator causality related to Datopotamab Deruxtecan, Investigator causality not related to Durvalumab. CCA not related.
						Injection	6 milligram/kilogram q3w Intravenous use	17-JAN-2025 to 10-APR-2025 2 months 25 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	27-DEC-2024 to 27-DEC-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	30-APR-2025 to 30-APR-2025 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | Monodex (C) | Paracetamol (C)									
202504GLO019326ES	SPAIN 49 Years Female	**Stomatitis (Mucositis oral)***	Recovered	16-Apr-2025 2 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram Intravenous use	16-JUN-2025 to 07-JUL-2025 22 days	Periodic Report Comments. The patient experienced Oral Mucositis. Action Taken: No Change. For Study therapy: Investigator causality: Related to DATOPOTAMAB DERUXTECAN and not related to DURVALUMAB. Company causality: Related to DATOPOTAMAB DERUXTECAN and not related to DURVALUMAB. Outcome: Recovering.
						Injection	4 milligram/kilogram Intravenous use	27-MAY-2025 to 27-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram Intravenous use	15-APR-2025 to 15-APR-2025 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | Enantyum (C) | Omeprazol al (C) | Isoplasmal g (C) | Dexamethasone (C) | Metamizol (C) | Lorazepam vir (C)									
202505GLO004803CN	CHINA 64 Years Female	**Vomiting (Vomiting)***	Recovered	03-May-2025 1 month 14 days	DURVALUMAB	Infusion	1120 milligram Intravenous use	03-JUL-2025 to 03-JUL-2025 1 day	Periodic Report Comments. Patient has event : Vomiting. For study therapy Action Taken: Dose not changed , Investigator Causality: Related, CC: Not Related. Outcome: Recovered.
						Infusion	1120 milligram Intravenous use	10-APR-2025 to 10-APR-2025 1 day	
						Infusion	1120 milligram Intravenous use	12-JUN-2025 to 12-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram Intravenous use	20-MAR-2025 to 20-MAR-2025 1 day	
						Infusion	1120 milligram Intravenous use	22-MAY-2025 to 22-MAY-2025 1 day	
						Infusion	1120 milligram Intravenous use	29-APR-2025 to 29-APR-2025 1 day	
Concomitant Medication(s): | DATOPOTAMAB DERUXTECAN (S) | Dexamethasone (C) | Sodium hyaluronate (C)									
202505GLO011590US	UNITED STATES 49 Years Female	**Nausea (Nausea)***	Recovered	13-May-2025 26 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	02-JUN-2025 to 11-JUL-2025 1 month 10 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	18-APR-2025 to 09-MAY-2025 22 days	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	18-APR-2025 to 11-JUL-2025 2 months 24 days	
Concomitant Medication(s): | DURVALUMAB (S) | Omeprazole (C) | Pravastatin (C) | Loratadine (C) | Acetaminophen (C) | Lovenox (C) | Zofran (C) | Famotidine (C)									
202505GLO014284US	UNITED STATES 49 Years Female	**Nausea (Nausea)***	Recovered	13-May-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	01-AUG-2025 to 01-AUG-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	02-JUN-2025 to 12-SEP-2025 3 months 11 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	4 milligram/kilogram q3w Intravenous use	11-JUL-2025 to 11-JUL-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	12-SEP-2025 to 12-SEP-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	20-JUN-2025 to 20-JUN-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	22-AUG-2025 to 22-AUG-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	09-MAY-2025 to 09-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	18-APR-2025 to 18-APR-2025 1 day	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	01-AUG-2025 to 01-AUG-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	02-JUN-2025 to 12-SEP-2025 3 months 11 days	
						Infusion	1120 milligram q3w Intravenous use	09-MAY-2025 to 09-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	11-JUL-2025 to 11-JUL-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	12-SEP-2025 to 12-SEP-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-APR-2025 to 18-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-JUN-2025 to 20-JUN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	22-AUG-2025 to 22-AUG-2025 1 day	

Concomitant Medication(s): | DURVALUMAB (S) | Acetaminophen (C) | Omeprazole (C) | Loratadine (C) | Pravastatin (C) | Lovenox (C) | Zofran (C) | Famotidine (C) | Decadron (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202506GLO002827GB	UNITED KINGDOM 49 Years Female	**Stomatitis (Stomatitis)***	Not Recovered	03-Jun-2025 7 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	28-MAY-2025 to 09-JUL-2025 1 month 12 days	
Concomitant Medication(s): | DURVALUMAB (S) | Dexamethasone (C) | Cetirizine hydrochloride (C) | Paracetamol (C) | Chlorphenamine (C)									
202506GLO005249DE	GERMANY 36 Years Female	**Stomatitis (Mucositis oral)***	Recovered	06-Jun-2025 8 days 11 hrs 45 min	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	10-JUL-2025 11:21 to 23-OCT-2025 13:40 3 months 13 days 2 hrs 19 min	Periodic Report Comments. Patient experienced mucositis: event not reported to datopotamab deruxtecan and durvalumab. CCA: Not related.
						Injection	6 milligram/kilogram q3w Intravenous use	28-MAY-2025 12:15 to 18-JUN-2025 12:27 21 days 12 min	
Concomitant Medication(s): DURVALUMAB (S) | | Paracetamol (C) | Dexamethason (C) | Histakut (C) | Elmex (C) | Dectaflur (C) | Novamin (C) | Ibuprofen (C) | Laxoberal (C) | Macrogol (C) | Lidocaine (C)									
202506GLO009926CA	CANADA 42 Years Female	**Anal fissure (Anal fissure)***	Not Recovered	23-May-2025 3 months 4 days	PACLITAXEL	Infusion	Intravenous use	20-FEB-2025 to 22-MAY-2025 3 months 3 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | | CARBOPLATIN (S) | Citalopram (C) | Nifedipine (C) | Dilaudid (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202506GLO025641US	UNITED STATES 55 Years Female	**Vomiting (Vomiting)***	Recovered	30-Jun-2025 4 months 12 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	19-FEB-2025 to	Periodic Report Comment. Patient experienced Intractable Nausea and Vomiting, Inv: related to study therapy, CCA: not related to study therapy.
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) |									
202507GLO005800HU	HUNGARY Female	**Stomatitis (Stomatitis)***	Recovered	26-Jun-2025 4 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	23-JUN-2025 to 23-JUN-2025 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | Acetaminophen (C) | Quamatel (C) | Algopyrin (C) | Nystatin (C)									
202507GLO009188GB	UNITED KINGDOM 27 Years Female	**Oesophagitis (Oesophagitis)***	Recovered	10-Jul-2025 1 month 1 day	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	10-JUL-2025 to 10-JUL-2025 1 day	
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	10-JUN-2025 to 10-JUL-2025 1 month 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	29-JUL-2025 to 29-JUL-2025 1 day	
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	01-JUL-2025 to 01-JUL-2025 1 day	
						Infusion	60 milligram/sq. meter q3w Intravenous use	10-JUN-2025 to 10-JUN-2025 1 day	
						Infusion	60 milligram/sq. meter q3w Intravenous use	29-JUL-2025 to 29-JUL-2025 1 day	

Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Chlorphenamine (C) | Dexamethasone (C) | Dexamethasone (C) | Domperidone (C) | Ondansetron (C) | Enoxaparin (C) | Cetraben (C) | Cetrizine (C) | Dermol (C) | Senna (C) | Fexofenadine (C) | Prednisolone (C) | Ondansetron (C) | Metoclopramide (C) | Pantoprazole (C) | Paracetamol (C) | Codeine (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO009258FR	FRANCE 42 Years Female	**Stomatitis (Mucositis oral)***	Recovered	04-Jul-2025 3 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	02-JUL-2025 to 30-JUL-2025 29 days	Periodic Report Comments. Patient experienced Oral mucositis Related to Datopotamab Deruxtecan and Durvalumab. Company causality assessment is not related.
					DURVALUMAB	Infusion	1120 milligram Intravenous use	02-JUL-2025 to 02-JUL-2025 1 day	
						Infusion	1120 milligram Intravenous use	30-JUL-2025 to 30-JUL-2025 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | Betamethasone (C)									
202507GLO012076CN	CHINA 50 Years Female	**Vomiting (Vomiting)***	Recovered	26-Jun-2025 1 month 13 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	14-MAY-2025 to 16-JUL-2025 2 months 3 days	Periodic Report Comments. Female Patient with vomiting and upper respiratory infection. Investigator: Related to study therapy Datopotamab deruxtecan to the event vomiting but not related to upper respiratory infection. CCA: Not Related to Study therapy Datopotamab deruxtecan, durvalumab. Action taken: No change
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Flupentixol (C) | Escitalopram oxalate (C) | Dexamethasone (C) | Sodium hyaluronate (C)									

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO017707IN	INDIA 59 Years Female	**Stomatitis (Mucositis oral)***	Recovered	20-Jun-2025 23 days	DATOPOTAMAB DERUXTECAN	Injection	294 milligram Intravenous use	29-MAY-2025 to 10-JUL-2025 1 month 12 days	Periodic Report Comments. Patient experienced mucositis. Investigator did not assess causality for study therapy. CCA: not related
						Injection	294 milligram Intravenous use	31-JUL-2025 to 03-SEP-2025 1 month 4 days	
Concomitant Medication(s): | DURVALUMAB (S) | Lactulose (C) | Dexamethasone (C)									
202507GLO021162JP	JAPAN Female	**Stomatitis (Mucositis oral)***	Unknown	nk nk	DATOPOTAMAB DERUXTECAN	Injection			
Concomitant Medication(s):									
202507GLO022881CN	CHINA 42 Years Female	**Vomiting (Vomited)***	Recovered	25-Jul-2025 3 months 15 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	11-APR-2025 to 25-JUL-2025 3 months 15 days	Periodic Report Comments. Patient experienced Vomit Investigator causality: RELATED Company causality was RELATED with Dato-DXd and NOT RELATED with DURVALUMAB.
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Sodium hyaluronate (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO009864DE	GERMANY 62 Years Female	**Diarrhoea (Diarrhea)***	Recovered	12-Aug-2025 1 month 3 days	EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	10-JUL-2025 to 11-SEP-2025 2 months 2 days	
					CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	10-JUL-2005 to 11-SEP-2025 20 years 2 months 2 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Tantum verde (C) | Dexamethason (C)									
202508GLO011881CN	CHINA 47 Years Female	**Vomiting (Vomiting)***	Recovered	19-Jul-2025 2 months 25 days	DURVALUMAB	Infusion	Unknown	19-SEP-2025 to 19-SEP-2025 1 day	
						Infusion	q3w Unknown	29-AUG-2025 to 29-AUG-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w	06-JUN-2025 to 06-JUN-2025 1 day	
						Infusion	1120 milligram q3w	08-AUG-2025 to 08-AUG-2025 1 day	
						Infusion	1120 milligram q3w	16-MAY-2025 to 16-MAY-2025 1 day	
						Infusion	1120 milligram q3w	18-JUL-2025 to 18-JUL-2025 1 day	
						Infusion	1120 milligram q3w	27-JUN-2025 to 27-JUN-2025 1 day	

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Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	25-APR-2025 to 25-APR-2025 1 day	
Concomitant Medication(s): | DATOPOTAMAB DERUXTECAN (S) | Acetaminophen (C) | Benzhydramine hydrochloride (C) | Dexamethasone phosphate (C) | Ondansetron (C) | Magnesium Isoglycyrrhizinate (C) | Omeprazole (C) | Ibuprofen (C) | Compound Guaifenesine Pentoxyverine Citrate and Chlorphenamine Maleate (C) | Dexamethasone sodium phosphate (C) | Diphenhydramine (C) | Paracetamol (C) | Tropisetron hydrochloride (C) | Ibuprofen (C) | Celecoxib (C) | Arbidol (C)									
202509GLO003534CN	CHINA 50 Years Female	**Vomiting (Vomiting)***	Recovered	17-Jul-2025 2 months 4 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	14-MAY-2025 to 16-JUL-2025 2 months 3 days	Periodic Report Comments. The patient experienced Vomiting. Investigator causality related to Datopotamab Deruxtecan and Durvalumab. CCA related to Datopotamab Deruxtecan and not related to Durvalumab.
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Flupentixol (C) | Escitalopram (C)									
202509GLO027150DE	GERMANY 54 Years Female	**Stomatitis (Mucositis oral)***	Recovered	16-Feb-2025 3 months 13 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram Unknown	04-NOV-2024 to 17-MAR-2025 4 months 14 days	
Concomitant Medication(s): | DURVALUMAB (S)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202510GLO023791CN	CHINA Female	**Vomiting (Vomiting)***	Recovered	26-Jun-2025 1 month 13 days	DURVALUMAB	Infusion	Unknown	04-JUN-2025 to 04-JUN-2025 1 day	
						Infusion	Unknown	14-MAY-2025 to 14-MAY-2025 1 day	
						Infusion	1120 milligram Unknown	06-AUG-2025 to 06-AUG-2025 1 day	
						Infusion	1120 milligram Unknown	09-OCT-2025 to 09-OCT-2025 1 day	
						Infusion	1120 milligram Unknown	16-JUL-2025 to 16-JUL-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram Unknown	17-SEP-2025 to 17-SEP-2025 1 day	
						Infusion	1120 milligram Unknown	25-JUN-2025 to 25-JUN-2025 1 day	
						Infusion	1120 milligram Unknown	27-AUG-2025 to 27-AUG-2025 1 day	

Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Escitalopram oxalate (C) | Flupentixol (C) | Acetaminophen (C) | Diphenhydramine hydrochloride (C) | Netupitant and palonosetron hydrochloride (C) | Dexamethasone (C) | Amino acid (C) | Famotidine (C) | Ondansetron hydrochloride (C) | Vitamin b6 (C) | Vitamin C (C) | Dolasetron mesylate (C) | Levofloxacin and Sodium Chloride (C) | Lysine acetylsalicylate (C) | Bicyclol (C) | Cimetidine (C) | Magnesium Isoglycyrrhizinate (C) | Tropisetron (C) | Aprepitant (C) | Omeprazole (C) | Azintamide (C) | Mosapride citrate (C) | Sodium hyaluronate (C) | Dexamethasone sodium phosphate (C) | Diphenhydramine (C) | Compound azintamide (C)

SOC:General disorders and administration site conditions

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A175830	GERMANY 71 Years Female	**Pain (General body pain)***	Recovered	31-Jul-2024 2 months 16 days	CARBOPLATIN	Infusion	Intravenous use	16-MAY-2024 to 08-AUG-2024 2 months 24 days	Periodic Report Comment. Patient expereninced General body pain. Inv: related to Pembrolizumab, Carboplatin, Paclitaxel and Cyclophosphamide, not related to Epirubicin. CCA not related.
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	16-MAY-2024 to 25-JUL-2024 2 months 10 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PACLITAXEL (S) | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | Ursodeoxycholic acid (C) | ACETYLSALICYLSAEURE (C) | SITAGLIPTIN (C) | OMEPRAZOL (C) | VALSARTAN (C) | SIMVASTATIN (C) | DAPAGLIFLOZIN (C) | DAPAGLIFLOZIN (C) | CELECOXIB (C) | CELECOXIB (C)									
2024A179534	GERMANY 71 Years Female	**General physical health deterioration (General physical health deterioration)***	Recovered	06-Aug-2024 2 months 22 days	CARBOPLATIN	Infusion	Intravenous use	16-MAY-2024 to 08-AUG-2024 2 months 24 days	Periodic Report Comment. Patient experienced General physical health deterioration. to carboplatin, pembrolizumab and pemetrexed .Inv: not related to study therapy.
					PACLITAXEL	Infusion	80 milligram Intravenous use	16-MAY-2024 to 25-JUL-2024 2 months 10 days	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	16-MAY-2024 to 25-JUL-2024 2 months 10 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PACLITAXEL (S) | Ursodeoxycholic acid (C) | Acetylsalicylsaeure (C) | Sitagliptin (C) | Omeprazol (C) | Valsartan (C) | Simvastatin (C) | Insulin aspart (C) | Amlodipin (C) | Insulin human isophane (C) | Celecoxib (C) | Movicol (C) | Vitamin d (C) | Magnesium (C) | Olaflur (C)									
202505GLO019783BR	BRAZIL 39 Years Female	**Hyperthermia malignant (Malignant hyperthermia)***	Recovered	21-May-2025 nk	CARBOPLATIN	Infusion	Intravenous use	16-APR-2025 to 16-APR-2025 1 day	Patient experienced malignant hyperthermia. Investigator causality not reported to pembrolizumab, carboplatin and paclitaxel. CCA not related.
						Infusion	Intravenous use	23-APR-2025 to 21-MAY-2025 29 days	
					PACLITAXEL	Infusion	80 milligram/sq. meter qw Intravenous use	16-APR-2025 to 16-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	80 milligram/sq. meter qw Intravenous use	23-APR-2025 to 21-MAY-2025 29 days	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	16-APR-2025 to 23-JUL-2025 3 months 8 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | CYCLOPHOSPHAMIDE (S) | DOXORUBICIN HYDROCHLORIDE (S) | Cimetidine (C) | Decadron (C) | Dexamethasone (C) | Diphenhydramine (C) | Omeprazole (C) | Ondansetron (C)									
202506GLO015840DE	GERMANY 29 Years Female	**General physical health deterioration (General physical health deterioration)***	Recovered	18-Jun-2025 7 months 5 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	14-NOV-2024 to 17-APR-2025 5 months 4 days	Periodic Report Comments. Patient experienced Deterioration in general condition with weight loss Related to Pembrolizumab and not related to Epirubicin, Cyclophosphamide, Paclitaxel and Carboplatin. Company causality assessment is not related.
Concomitant Medication(s): | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Dexamethason (C) | Granisetron (C) | Zoladex (C) | Vitamin d3 (C) | Pantoprazol (C) | Akynzeo (C) | Propranolol hydrochloride (C) | Thiamazol (C) | Certoparin sodium (C) | Piperacillin+tazobactam (C) | Paracetamol (C) | Hydrocortison (C) | Amoxiclav (C) | Blood transfusion, auxiliary products (C) | Panotile cipro (C) | Unacid (C) | Ciprofloxacin (C) | L-thyroxin (C) | Filgrastim (C) | Neulasta (C) | Macrogol (C) | Neupogen (C) | Cetirizin (C) | Jonosteril (C) | Ibuprofen (C) | Methocarbamol (C) | Linezolid (C) | Vagisan (C) | Fungizid (C) | Oxycodon (C) | Cefazolin (C) | Metamizol (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO007069CN	CHINA 58 Years Female	**Fatigue (Fatigue)** Urinary tract infection (Urinary tract infection)* Cystitis (Cystitis)*	Recovered	07-Jul-2025 3 months 6 days	CARBOPLATIN	Infusion	Intravenous use	02-APR-2025 to 03-JUL-2025 3 months 2 days	
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	02-APR-2025 to 20-JUN-2025 2 months 19 days	
		Fatigue (Fatigue) Urinary tract infection (Urinary tract infection) Cystitis (Cystitis)*	Recovered	07-Jul-2025 3 months 6 days	PACLITAXEL	Infusion	73 milligram/sq. meter Intravenous use	13-JUN-2025 to 03-JUL-2025 21 days	
						Infusion	80 milligram/sq. meter Intravenous use	02-APR-2025 to 06-JUN-2025 2 months 5 days	

Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | Ora (C) | Minocycline hydrochloride (C)

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO020193BR	BRAZIL 29 Years Female	**General physical health deterioration (General physical health deterioration)***	Recovered	22-Jul-2025 1 month 20 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	03-JUN-2025 to 15-JUL-2025 1 month 13 days	
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	03-JUN-2025 to 15-JUL-2025 1 month 13 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Clobetasol (C) | Fluoxetine (C) | Akynzeo (C) | Dexamethasone (C) | Diphenhydramine (C) | Pantoprazole (C) | Bisacodyl (C)									
202507GLO025491JP	JAPAN 61 Years Female	**Pyrexia (Pyrexia)***	Recovered	21-Jul-2025 20 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	02-JUL-2025 to 02-JUL-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S)									
202508GLO000962MY	MALAYSIA 34 Years Female	**Pyrexia (Fever)*** Pneumonia (Bronchial pneumonia)*	Not Recovered	31-Jul-2025 5 months 8 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	13-MAY-2025 to 14-JUL-2025 2 months 2 days	Periodic Report Comments. Patient has event Worsening of Fever Action taken with DATOPOTAMAB DERUXTECAN and DURVALUMAB was unknown. Investigator Causality: not reported. Company causality: not related.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	24-FEB-2025 to 14-APR-2025 1 month 22 days	
Concomitant Medication(s): | DURVALUMAB (S) | Emend (C) | Dexamethasone (C)									
202508GLO001818FR	FRANCE 44 Years Female	**Hyperthermia (Hyperthermia)***	Recovered	31-Jul-2025 nk	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	10-JUL-2025 to 21-AUG-2025 1 month 12 days	
						Solution for infusion	200 milligram q3w Intravenous use	12-JUN-2025 to 12-JUN-2025 1 day	
Concomitant Medication(s): PACLITAXEL (S) | | CARBOPLATIN (S)									
202508GLO002930FR	FRANCE 46 Years Female	**Hyperthermia (Hyperthermia)***	Recovered	28-Jul-2025 27 days	CARBOPLATIN	Infusion	Intravenous use	02-JUL-2025 to 04-AUG-2025 1 month 3 days	Periodic Report Comments. Patient experienced hyperthermia. Investigator Causality: not related to PEMBROLIZUMAB, PACLITAXEL and Related to CARBOPLATIN Company causality: not related.
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | Thealose (C) | Alprazolam (C)									

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EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202509GLO007229CN	CHINA 56 Years Female	**Malaise (Malaise)***	Recovering	05-Sep-2025 9 months 26 days	PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	11-NOV-2024 to 09-APR-2025 4 months 30 days	
Concomitant Medication(s): CARBOPLATIN (S) | PACLITAXEL (S) | CYCLOPHOSPHAMIDE (S) | EPIRUBICIN (S) | | Paracetamol (C) | Potassium chloride (C) | Leucogen (C) | Rivaroxaban (C) | Sodium hyaluronate (C) | Dexamethasone sodium phosphate (C) | Glutathione (C) | Omeprazole sodium (C) | Palonosetron hydrochloride (C) | Promethazine hydrochloride (C) | Ondansetron hydrochloride (C) | Ondansetron (C) | Ertapenem (C) | Estazolam (C) | Flunarizine hydrochloride (C) | Indomethacin (C) | Ketorolac tromethamine (C) | Pantoprazole sodium (C) | Vitamin b6 (C) | Vitamin C (C) | Budesonide (C) | Spironolactone (C) | Ipratropium bromide (C) | Bifonazole (C) | Granisetron hydrochloride (C) | Hydrochlorothiazide (C) | Megestrol acetate (C) | Triamcinolone acetonide (C) | Astragalus polysaccharide (C) | Enteral (C) | Essentiale (C) | Glycerin (C) | Iron Polysaccharide complex (C)									
202509GLO007675DE	GERMANY 40 Years Female	**General physical health deterioration (Reduced general condition)***	Recovered	09-Sep-2025 3 months 8 days	CARBOPLATIN	Infusion	Intravenous use	02-JUN-2025 to 13-AUG-2025 2 months 12 days	Periodic Report Comments. Patient experienced reduced general condition. Inv: related paclitaxel and carboplatin and not related to pembrolizumab. CCA- not related
					PACLITAXEL	Infusion	80 milligram/sq. meter q3w Intravenous use	02-JUN-2025 to 14-AUG-2025 2 months 13 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | PACLITAXEL (S) | | Ampho moronal (C) | Pantoprazol (C) | Paracetamol (C) | Famotidin (C) | Dexamethason (C) | Granisetron (C) | Loperamid (C) | Tramal (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202509GLO019973BR	BRAZIL 62 Years Female	**Asthenia (Asthenia)***	Not Recovered	28-Aug-2025 2 days	DOXORUBICIN HYDROCHLORIDE	Infusion	45 milligram/sq. meter q3w Intravenous use	15-OCT-2025 11:59 to 15-OCT-2025 12:14 15 min	Periodic Report Comments. Patient experienced Asthenia, Investigator causality: related to Pembrolizumab, Doxorubicin Hydrochloride, Cyclophosphamide and not related to Paclitaxel and Carboplatin, company causality: not related to study therapy.
						Infusion	60 milligram/sq. meter q3w Intravenous use	27-AUG-2025 to 17-SEP-2025 22 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Clopidogrel (C) | Amlodipine (C) | Rosuvastatin (C) | Dexamethasone (C) | Famotidine (C) | Dexchlorpheniramine (C) | Omeprazole (C) | Atenolol (C)									
202509GLO023864CN	CHINA 55 Years Female	**Death (Unknown cause of death)***	Fatal	25-Sep-2025 2 months 30 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	07-AUG-2025 to 07-AUG-2025 1 day	Source Document. Action Taken: Not Applicable Investigator Causality: Related CC: Not Related
						Injection	6 milligram/kilogram q3w Intravenous use	17-JUL-2025 to 17-JUL-2025 1 day	

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EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	18-SEP-2025 to 18-SEP-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	27-JUN-2025 to 27-JUN-2025 1 day	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	07-AUG-2025 to 07-AUG-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-JUL-2025 to 17-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-SEP-2025 to 18-SEP-2025 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	27-JUN-2025 to 27-JUN-2025 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | Amlodipine (C) | Atorvastatin (C) | Acetaminophen (C) | Dexamethasone (C) | Diphenhydramine (C) | Esomeprazole (C) | Ondansetron (C) | Polyethylene glycol (C) | Ebastine (C) | Paracetamol (C) | Famotidine (C) | Lactulose (C) | Cefuroxime (C) | Ornidazole (C) | Sodium chloride (C) | Epinephrine (C)									
202509GLO024347PL	POLAND 78 Years Female	**Death (Death)***	Fatal	24-Sep-2025 4 months 10 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	15-MAY-2025 to 18-SEP-2025 4 months 4 days	
					DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	15-MAY-2025 to 18-SEP-2025 4 months 4 days	
Concomitant Medication(s): | DURVALUMAB (S)									
202510GLO013333BE	BELGIUM 38 Years Female	**Pyrexia (Fever)***	Not Recovered	14-Oct-2025 1 year 1 month 12 days	DURVALUMAB	Infusion		03-SEP-2024 to 22-SEP-2025 1 year 20 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | PACLITAXEL (S) | CARBOPLATIN (S)									

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202510GLO016535FR	FRANCE 54 Years Female	**Pyrexia (Fever)***	Not Recovered	11-Oct-2025 10 months 27 days	DURVALUMAB	Infusion	1120 milligram Intravenous use	15-NOV-2024 to 26-SEP-2025 10 months 12 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Vismed (C) | Solupred (C)									

SOC:Hepatobiliary disorders

202411GLO014169JP	JAPAN 53 Years Female	**Hepatic function abnormal (Hepatic function disorder)***	Recovering	18-Nov-2024 2 months 22 days	CARBOPLATIN	Infusion	Intravenous use	04-DEC-2024 to 04-DEC-2024 1 day	Periodic Report Comments. Patient experienced adrenal insufficiency and hepatic function disorder. INV: Carboplatin, Cyclophosphamide, Epirubicin, Paclitaxel not related to event adrenal insufficiency and hepatic function disorder. Paclitaxel, Pembrolizumab and the related to adrenal insufficiency and hepatic function disorder and hepatic function disorder. CCA: Carboplatin, Cyclophosphamide, Epirubicin and Paclitaxel not related to event adrenal insufficiency and hepatic function disorder. Paclitaxel and Pembrolizumab related to events adrenal insufficiency and hepatic function disorder.
						Infusion	Intravenous use	28-AUG-2024 to 13-NOV-2024 2 months 17 days	
					PACLITAXEL	Infusion	80 milligram/sq. meter qw Intravenous use	28-AUG-2024 to 04-DEC-2024 3 months 7 days	

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EudraCT No: 2023-505928-59-00

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
		Hepatic function abnormal (Hepatic function disorder)* Adrenal insufficiency (Adrenal insufficiency)	Recovering	18-Nov-2024 2 months 22 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	28-AUG-2024 to 06-NOV-2024 2 months 10 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | | Ibuprofen (C) | Dexart (C) | Famotidine (C) | Palonosetron (C) | Metoclopramide (C) | Fexofenadine hydrochloride (C) | Antebate (C) | Polaramin (C) | Fexofenadin (C) | Heparinoid (C) | L-Cysteine (C) | Metoclopramide hydrochloride (C) | Solacet d (C) | Solacet f (C) | Pyridoxine hydrochloride (C) | Betamethasone (C)									
2024A075714	UNITED KINGDOM 74 Years Female	**Drug-induced liver injury (Drug-induced hepatitis)***	Recovered	28-Mar-2024 25 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	08-APR-2024 to 08-APR-2024 1 day	Periodic Report Comment. The patient experienced DRUG INDUCED HEPATITIS. Investigator: not related to Datopotamab Deruxtean, related to Durvalumab. NOT RELATED to Cyclophosphamide and Epirubicin CCA: related to Datopotamab Deruxtean, Durvalumab NOT APPLICABLE to Cyclophosphamide and Epirubicin
						Injection	6 milligram/kilogram q3w Intravenous use	04-MAR-2024 to 04-MAR-2024 1 day	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	04-MAR-2024 to 04-MAR-2024 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | Losartan (C) | Atorvastatin (C) | Calcium carbonate | Colecalciferol (C) | Paracetamol (C) | Loratadine (C) | Hydrocortisone (C) | Metoclopramide (C) | Dexamethasone (C) | Aprepitant (C) | Chlorphenamine (C) | Ondansetron (C) | Hypromellose (C) | Risedronate sodium (C)									

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A096083	KOREA, REPUBLIC OF 55 Years Female	**Hepatitis (Hepatitis)***	Recovered	15-Apr-2024 2 months 8 days	PACLITAXEL	Infusion	80 milligram/sq. meter q3w Intravenous use	08-FEB-2024 to 14-MAY-2024 3 months 7 days	Periodic Report Comment. Patient experienced hepatitis serious and Inv. related to Pembrolizumab, Doxorubicin, Cyclophosphamide, Paclitaxel not related to Carboplatin CCA: Not related to Carboplatin, Doxorubicin,Paclitaxel related to Pembrolizumab, Cyclophosphamide;Patient experienced hepatitis serious and Inv. related to Pembrolizumab, Paclitaxel not related to Carboplatin, Doxorubicin, Cyclophosphamide, CCA: Not related to Pembrolizumab, Paclitaxel not related to Carboplatin, not applicable to cyclophosphamide and doxorubicin.
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | | CARBOPLATIN (S) | Ursa (C) | Gabapentin (C) | Phenil (C) | Dexamethasone (C) | Akynzeo (C) | Solondo (C)									
2024A188411	CHINA 50 Years Female	**Drug-induced liver injury (Drug-induced liver injury)***	Recovered	15-Aug-2024 2 months 25 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	08-OCT-2024 to 10-DEC-2024 2 months 3 days	Periodic Report Comment. the patient experienced grade three liver failure: drug induced liver disease, related to Durvalumab and not related to Datopotamab Deruxtecan. Com causality not related.

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						Injection	4 milligram/kilogram q3w Intravenous use	14-SEP-2024 to 14-SEP-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	22-MAY-2024 to 29-JUL-2024 2 months 8 days	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	22-MAY-2024 to 31-JUL-2025 1 year 2 months 10 days	
Concomitant Medication(s): | DURVALUMAB (S) | Levothyroxine sodium (C) | Bicyclol (C) | Loratadine (C) | Paracetamol (C) | Dexamethasone (C) | Ondansetron hydrochloride (C) | Heparin sodium (C) | Vitamin B1 (C) | Methimazole (C) | Rivaroxaban (C) | Vitamin b6 (C) | Magnesium Isoglycyrrhizinate (C) | Glutathione (C) | Vitamin C (C) | Promethazine hydrochloride (C)									
2024A190646	JAPAN 56 Years Female	**Drug-induced liver injury (Drug-induced liver injury)***	Recovering	20-Aug-2024 2 months 3 days	CARBOPLATIN	Infusion	Intravenous use	18-JUN-2024 to 24-SEP-2024 3 months 7 days	Periodic Report Comment. The patient experienced CTC grade four suspected drug-induced liver injury, Invest related to Pembrolizumab, CCA not related.

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					PACLITAXEL	Infusion	80 milligram/sq. meter qw Intravenous use	18-JUN-2024 to 24-SEP-2024 3 months 7 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PACLITAXEL (S) | CYCLOPHOSPHAMIDE (S) | EPIRUBICIN (S) | BAYASPIRIN (C) | TAKECAB (C) | REZALTAS (C) | AZUNOL (C) | LOXONIN (C) | Atorvastatin (C) | Cilostazol (C) | Bayaspirin (C) | Takecab (C) | Rezaltas (C) | Azunol (C) | Dexart (C) | Famotidine (C) | Palonosetron (C) | Polaramine (C) | Loxonin (C) | Mucosta (C) | Ursodeoxycholic acid (C) | Olmesartan (C) | Dexamethasone sodium phosphate (C) | Fosnetupitant chloride hydrochloride (C) | Palonosetron hydrochloride (C)									
202502GLO003172CN	CHINA 41 Years Female	**Hepatic function abnormal (Function liver abnormal)***	Recovered	04-Feb-2025 26 days	CARBOPLATIN	Infusion	Intravenous use	10-FEB-2025 to 26-MAR-2025 1 month 17 days	Periodic Report Comment. Patient experienced abnormal liver function Inv, related to Pembrolizumab, CCA: related to Pembrolizumab, Inv, Not related to Epirubicin, CCA: Not related to Epirubicin, Inv, Not related to Cyclophosphamide, CCA: Not related to Cyclophosphamide, Inv, related to Paclitaxel, CCA: related to Paclitaxel, Inv, related to Carboplatin, CCA: related to Carboplatin.
						Infusion	Intravenous use	10-JAN-2025 to 10-JAN-2025 1 day	
					PACLITAXEL	Infusion	80 milligram/sq. meter Intravenous use	10-FEB-2025 to 25-FEB-2025 16 days	

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						Infusion	80 milligram/sq. meter Intravenous use	10-JAN-2025 to 10-JAN-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	17-JAN-2025 to 17-JAN-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	25-JAN-2025 to 25-JAN-2025 1 day	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	10-FEB-2025 to 04-JUL-2025 4 months 25 days	
						Solution for infusion	200 milligram q3w Intravenous use	10-JAN-2025 to 10-JAN-2025 1 day	

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Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | Dexamethasone sodium phosphate (C) | Diphenhydramine hydrochloride (C) | Vitamin b6 (C) | Ranitidine hydrochloride (C) | Netupitant and palonosetron hydrochloride (C)									
202503GLO007019DE	GERMANY 35 Years Female	**Hepatitis (Hepatitis)***	Recovered	10-Mar-2025 3 months 6 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	05-DEC-2024 to 18-FEB-2025 2 months 14 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Elmex (C) | Ibuprofen (C) | Dexamethason (C)									
202503GLO019009IT	ITALY 46 Years Female	**Drug-induced liver injury (Drug-induced liver injury)***	Recovered	18-Mar-2025 1 month 8 days	CARBOPLATIN	Infusion	Intravenous use	11-FEB-2025 to 12-MAR-2025 1 month 2 days	Periodic Report Comments. Pt exp. event Drug-induced liver injury, Investigator causality: not related to study therapy, CCA : Related to study therapy
						Infusion	Intravenous use	26-MAR-2025 to 07-MAY-2025 1 month 12 days	
					PACLITAXEL	Infusion	80 milligram/sq. meter q3w Intravenous use	11-FEB-2025 to 12-MAR-2025 1 month 2 days	

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Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	80 milligram/sq. meter q3w Intravenous use	26-MAR-2025 to 07-MAY-2025 1 month 12 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PACLITAXEL (S) | Nebivolol (C) | Paroxetine (C) | Reaptan (C) | Ondansetron (C) | Pantoprazole (C) | Trimeton (C) | Deltacortene (C)									
202505GLO022303VN	VIET NAM 64 Years Female	**Suspected drug-induced liver injury (Suspected drug-induced liver injury)***	Recovering	26-May-2025 1 month 11 days	CAPECITABINE	Tablet	1250 milligram/sq. meter Oral use	06-MAY-2025 to 20-MAY-2025 15 days	periodic report comment. Patient experienced Acute liver injury suspected caused by IP (DILI), investigator: related to Durvalumab, Capecitabine, not related to Datopotamab Deruxtecan, cca: not related to Durvalumab, Capecitabine, Datopotamab Deruxtecan.
						Tablet	1250 milligram/sq. meter Oral use	16-APR-2025 to 29-APR-2025 14 days	
					DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	04-JUN-2024 to 03-DEC-2024 6 months	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	04-JUN-2024 to 06-MAY-2025 11 months 3 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | Stadfovir (C) | Meyervir af (C)									
202507GLO020496US	UNITED STATES 39 Years Female	**Hypertransaminasaemia (Transaminitis)***	Recovered	22-Jul-2025 1 month 5 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	09-JUL-2025 to 09-JUL-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	18-JUN-2025 to 18-JUN-2025 1 day	
Concomitant Medication(s): | PACLITAXEL (S) | CARBOPLATIN (S) | Magnesium complex (C) | Famotidine (C) | Diphenhydramine (C) | Methylprednisolone sodium succinate (C)									
202508GLO000525US	UNITED STATES 39 Years Female	**Hypertransaminasaemia (Transaminitis)***	Recovering	29-Jul-2025 1 month 12 days	PACLITAXEL	Infusion	80 milligram/sq. meter qw Intravenous use	02-JUL-2025 to 02-JUL-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	80 milligram/sq. meter qw Intravenous use	09-JUL-2025 to 09-JUL-2025 1 day	
						Infusion	80 milligram/sq. meter qw Intravenous use	18-JUN-2025 to 18-JUN-2025 1 day	
						Infusion	80 milligram/sq. meter qw Intravenous use	25-JUN-2025 to 25-JUN-2025 1 day	
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	18-JUN-2025 to 18-JUN-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	09-JUL-2025 to 09-JUL-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

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Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CARBOPLATIN (S) | Motrin (C) | Magnesium complex (C) | Famotidine an (C) | Palonosetron (C)									
202508GLO000934IN	INDIA 59 Years Female	**Hypertransaminasaemia (Transaminitis)***	Recovered with Sequelae	19-Jul-2025 1 year 1 month 29 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	11-FEB-2025 to 11-FEB-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	11-JAN-2025 to 11-JAN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	15-MAR-2025 to 20-AUG-2025 5 months 6 days	
						Infusion	1120 milligram q3w Intravenous use	21-MAY-2024 to 20-AUG-2025 1 year 3 months	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | OLAPARIB (S) | Ondansetron (C) | Metoclopramide (C) | Dexamethasone (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO011251FR	FRANCE 49 Years Female	**Cholestasis (Cholestasis)***	Fatal	13-Aug-2025 6 months 21 days	PEMBROLIZUMAB	Solution for infusion	200 milligram	21-FEB-2025 to 21-FEB-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	04-JUL-2025 to 04-JUL-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	05-JUN-2025 to 05-JUN-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	05-MAY-2025 to 05-MAY-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	10-APR-2025 to 10-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram Intravenous use	20-MAR-2025 to 20-MAR-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	24-JAN-2025 to 24-JAN-2025 1 day	
Concomitant Medication(s): | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S)									
202508GLO011254CN	CHINA 51 Years Female	**Liver injury (Liver injury)***	Recovered	11-Aug-2025 2 months 2 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram q3w Intravenous use	10-JUN-2025 to 22-JUL-2025 1 month 13 days	
						Injection	6 milligram q3w Intravenous use	18-SEP-2025 to 18-SEP-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	01-JUL-2025 to 01-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	10-JUN-2025 to 10-JUN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-SEP-2025 to 18-SEP-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	22-JUL-2025 to 22-JUL-2025 1 day	

Concomitant Medication(s): | DURVALUMAB (S) | Fenofibrate (C) | Acetaminophen (C) | Dexamethasone (C) | Diphenhydramine hydrochloride (C) | Estazolam (C) | Glutathione (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO016359JP	JAPAN 67 Years Female	**Hepatic function abnormal (Hepatic dysfunction NOS)***	Recovered	20-Aug-2025 3 months 14 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	07-MAY-2025 to 09-JUL-2025 2 months 3 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Valsartan (C) | Daiphen (C) | Meropenem (C)									
202509GLO000597FR	FRANCE 46 Years Female	**Hepatitis (Hepatitis)***	Not Recovered	10-Aug-2025 1 month 9 days	CARBOPLATIN	Infusion	Intravenous use	02-JUL-2025 to 04-AUG-2025 1 month 3 days	
					PACLITAXEL	Infusion	80 milligram/sq. meter Intravenous use	02-JUL-2025 to 18-AUG-2025 1 month 17 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | Thealose (C) | Alprazolam (C) | Augmentin (C) | Doliprane (C) | Metoclopramide (C)									
202509GLO003463VN	VIET NAM 64 Years Female	**Drug-induced liver injury (Drug-induced liver injury)***	Recovering	26-May-2025 1 month 12 days	CAPECITABINE	Tablet	Oral use	15-APR-2025 to 20-MAY-2025 1 month 6 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	04-JUN-2024 to 03-DEC-2024 6 months	
					DURVALUMAB	Infusion	Intravenous use	04-JUN-2024 to 06-MAY-2025 11 months 3 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | Amvifeta (C) | Bromhexin (C) | Tunadimet (C) | Raciper (C) | Dimedrol (C)									
202509GLO004586US	UNITED STATES 69 Years Female	**Hepatic failure (Hepatic failure)** *	Not Recovered	04-Sep-2025 3 months 13 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	02-JUL-2025 to 02-JUL-2025 1 day	Periodic Report Comments. Patient experienced Hepatic failure Related to Pembrolizumab, Paclitaxel, Carboplatin, Doxorubicin Hydrochloride, Cyclophosphamide and Tylenol. Company causality assessment is not related.
						Infusion	60 milligram/sq. meter q3w Intravenous use	11-JUN-2025 to 11-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	60 milligram/sq. meter q3w Intravenous use	23-JUL-2025 to 23-JUL-2025 1 day	
						Infusion	60 milligram/sq. meter q3w Intravenous use	23-MAY-2025 to 23-MAY-2025 1 day	
					CARBOPLATIN	Infusion	Intravenous use	05-MAR-2025 to 05-MAR-2025 1 day	
						Infusion	Intravenous use	12-FEB-2025 to 12-FEB-2025 1 day	
						Infusion	Intravenous use	23-APR-2025 to 23-APR-2025 1 day	

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EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	25-MAR-2025 to 25-MAR-2025 1 day	
					PACLITAXEL	Infusion	80 milligram/sq. meter Intravenous use	02-APR-2025 to 02-APR-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	05-MAR-2025 to 05-MAR-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	07-MAY-2025 to 07-MAY-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	09-APR-2025 to 09-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	80 milligram/sq. meter Intravenous use	12-FEB-2025 to 12-FEB-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	12-MAR-2025 to 12-MAR-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	19-FEB-2025 to 19-FEB-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	19-MAR-2025 to 19-MAR-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	23-APR-2025 to 23-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505928-59-00

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	80 milligram/sq. meter Intravenous use	25-MAR-2025 to 25-MAR-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	26-FEB-2025 to 26-FEB-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	30-APR-2025 to 30-APR-2025 1 day	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	02-JUL-2025 to 02-JUL-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	05-MAR-2025 to 05-MAR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	11-JUN-2025 to 11-JUN-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	12-FEB-2025 to 12-FEB-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	23-APR-2025 to 23-APR-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	23-JUL-2025 to 23-JUL-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	23-MAY-2025 to 23-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	26-MAR-2025 to 26-MAR-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Acetaminophen (S) | Tylenol (C) | Vit d3 (C) | Vitamin b complex (C) | Atorvastatin (C) | Cholecalciferol (C) | Magnesium oxide (C) | Bisoprolol fumarate (C) | Macrobid (C) | Coq-10 (C) | Dexamethasone (C) | Lidocaine (C) | Aloxi (C) | Benadryl (C) | Decadron (C) | Fosaprepitant (C) | Normal saline (C) | Pepcid (C) | L-Glutamine (C) | Filgrastim (C) | Loratadine (C) | Famotidine (C) | Omeprazole (C) | Nystatin (C)									
202510GLO013497CN	CHINA 60 Years Female	**Suspected drug-induced liver injury (Suspected Hy's law case)***	Not Recovered	28-Sep-2025 1 year 1 month 7 days	CARBOPLATIN	Infusion	Unknown	22-AUG-2024 to 04-NOV-2024 2 months 14 days	
					PACLITAXEL	Infusion	Unknown	22-AUG-2024 to 19-NOV-2024 2 months 29 days	
					PEMBROLIZUMAB	Solution for infusion	Unknown	22-AUG-2024 to 15-JUL-2025 10 months 24 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Unknown	27-NOV-2024 to 06-FEB-2025 2 months 11 days	
					EPIRUBICIN	Infusion	Unknown	27-NOV-2024 to 06-FEB-2025 2 months 11 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) |									
202510GLO015919FR	FRANCE	**Hepatic cytolysis (Hepatic cytolysis)***	Not Recovered	05-Jun-2025 4 months 13 days	CARBOPLATIN	Infusion	Intravenous use	24-JAN-2025 to 17-APR-2025 2 months 25 days	
					PACLITAXEL	Infusion	80 milligram/sq. meter Intravenous use	24-JAN-2025 to 17-APR-2025 2 months 25 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	24-JAN-2025 to 04-JUL-2025 5 months 11 days	
Concomitant Medication(s): EPIRUBICIN (S) | PEMBROLIZUMAB (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) |									
202510GLO021053FR	FRANCE Female	**Hepatic cytolysis (Hepatic cytolysis)***	Not Recovered	05-Jun-2025 nk	CARBOPLATIN	Infusion Infusion Infusion	Intravenous use Intravenous use Intravenous use	to 04-APR-2025 to 04-APR-2025 1 day 07-MAR-2025 to 07-MAR-2025 1 day	Periodic Report Comments. The investigator considered that there was a reasonable possibility of a causal relationship between the study therapy Carboplatin, Paclitaxel, Pembrolizumab and the following event(s): hepatic cytolysis. The investigator did not consider that there was a reasonable possibility of a causal relationship between the study therapy Cyclophosphamide, Epirubicin and the following event(s): hepatic cytolysis. The company physician considered that there was a reasonable possibility of a causal relationship between the study therapy Carboplatin, Paclitaxel and Pembrolizumab and the following event(s): hepatic cytolysis. The company physician did not consider that there was a reasonable possibility of a causal relationship between the

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	10-APR-2025 to 10-APR-2025 1 day	study therapy Cyclophosphamide and Epirubicin and the following event(s):hepatic cytolysis.
						Infusion	Intravenous use	14-FEB-2025 to 14-FEB-2025 1 day	
						Infusion	Intravenous use	17-APR-2025 to	
						Infusion	Intravenous use	20-MAR-2025 to 20-MAR-2025 1 day	
						Infusion	Intravenous use	21-FEB-2025 to 21-FEB-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	24-JAN-2025 to 24-JAN-2025 1 day	
						Infusion	Intravenous use	28-FEB-2025 to 28-FEB-2025 1 day	
						Infusion	Intravenous use	28-MAR-2025 to 28-MAR-2025 1 day	
						Infusion	Intravenous use	31-JAN-2025 to 31-JAN-2025 1 day	
					PACLITAXEL	Infusion	Intravenous use	to	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	64 milligram/sq. meter Intravenous use	17-APR-2025 to 17-APR-2025 1 day	
						Infusion	80 milligram/sq. meter	28-MAR-2025 to 28-MAR-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	04-APR-2025 to 04-APR-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	07-MAR-2025 to 07-MAR-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	10-APR-2025 to 10-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	80 milligram/sq. meter Intravenous use	14-FEB-2025 to 14-FEB-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	20-MAR-2025 to 20-MAR-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	21-FEB-2025 to 21-FEB-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	24-JAN-2025 to 24-JAN-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	28-FEB-2025 to 28-FEB-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	80 milligram/sq. meter Intravenous use	31-JAN-2025 to 31-JAN-2025	
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	04-JUL-2025 to 04-JUL-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	05-JUN-2025 to 05-JUN-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	05-MAY-2025 to 05-MAY-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	10-APR-2025 to 10-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram Intravenous use	20-MAR-2025 to 20-MAR-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	21-FEB-2025 to 21-FEB-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	24-JAN-2025 to 24-JAN-2025 1 day	

Concomitant Medication(s): PEMBROLIZUMAB (S) | | PACLITAXEL (S) | CYCLOPHOSPHAMIDE (S) | EPIRUBICIN (S) | Omeprazole (C) | Doliprane (C) | Paroxetine (C) | Quetiapine (C) | Filgrastim (C) | Paracetamol (C) | Prednisone (C) | Cellcept (C) | Tacrolimus (C)

SOC:Immune system disorders

2024A176928	JAPAN 40 Years Female	**Anaphylactic reaction (Anaphylaxis)***	Recovered	02-Aug-2024 1 month 6 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	28-JUN-2024 to 02-AUG-2024 1 month 6 days	Periodic Report Comment. Patient expereinced Anaphylaxis. Inv: related to Dato-dxd and not related to Durvalumab. CCA not related.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | DURVALUMAB (S) | RESTAMIN KOWA (C) | Azunol gargle liquid (C) | Decadron (C) | Dexart (C) | Palonosetron (C) | Acetaminophen (C) | Famotidine (C) | Predonine (C) | White petrolatum (C) | Locoid (C)									
2024A191298	SWITZERLAND 38 Years Female	**Drug hypersensitivity (Drug allergy)***	Recovered	21-Aug-2024 2 months 4 days	EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	09-JUL-2024 to 09-JUL-2024 1 day	Periodic Report Comment. Patient experienced drug allergy. Inv: related to Pembrolizumab, Epirubicin and Cyclophosphamide, not related to Paclitaxel, Carboplatin. Com causality not related.
						Infusion	90 milligram/sq. meter q3w Intravenous use	18-JUN-2024 to 18-JUN-2024 1 day	
						Infusion	90 milligram/sq. meter q3w Intravenous use	20-AUG-2024 to 20-AUG-2024 1 day	
						Infusion	90 milligram/sq. meter q3w Intravenous use	30-JUL-2024 to 30-JUL-2024 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Movicol (C) | Gelo (C) | Sidroga (C) | Bepanthen (C) | Magnesium (C) | Bexin (C) | Vitamin b12 (C) | Zarzio (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A203366	JAPAN 49 Years Female	**Anaphylactic reaction (Anaphylaxis)***	Recovered	05-Sep-2024 2 months 24 days	CARBOPLATIN	Infusion	Intravenous use	13-JUN-2024 to 05-SEP-2024 2 months 24 days	Periodic Report Comment. The patient experienced anaphlaxis .serious Inv-related to Carboplatin.CCA: Not related.;Patient experienced grade one Anaphlaxis, Investigator related, and company Not related.
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | | Dexamethasone sodium phosphate (C) | Famotidine (C) | Granisetron hydrochloride (C) | (+)-alfa-tocopherolum (C) | Magnesium oxide (C) | Oxarol (C) | Bilanoa (C) | Antebate (C) | Heparinoid (C) | Acetaminophen (C) | Tarlige (C) | Potassium iodide (C) | Adrenaline (C)									
202503GLO005466VN	VIET NAM 39 Years Female	**Drug hypersensitivity (Drug allergy)***	Recovered	07-Mar-2025 4 months 7 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	01-NOV-2024 to 14-FEB-2025 3 months 14 days	The patient experienced Medicine allergy. Investigator: related to Durvalumab, not related to Datopotamab Deruxtecan. Company: not related.
						Infusion	1120 milligram q3w Intravenous use	07-MAR-2025 to 07-MAR-2025 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | CYCLOPHOSPHAMIDE (S) | DOXORUBICIN HYDROCHLORIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Dexamethasone (C) | Hyaluronate sodium (C) | Urgo grietas filmogel (C)									
202503GLO018120MY	MALAYSIA 28 Years Female	**Drug hypersensitivity (Allergic reaction to drug)***	Recovered	19-Mar-2025 8 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	04-APR-2025 to 04-APR-2025 1 day	Periodic Report Comments. Female patient with event: Pruritic Inv causality: not reported, CCA: not related

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	05-JUN-2025 to 05-JUN-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	07-AUG-2025 to 07-AUG-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	12-MAR-2025 to 12-MAR-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	15-MAY-2025 to 15-MAY-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	17-JUL-2025 to 17-JUL-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	24-APR-2025 to 24-APR-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	26-JUN-2025 to 26-JUN-2025 1 day	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	04-APR-2025 to 04-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-JUN-2025 to 05-JUN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	07-AUG-2025 to 07-AUG-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	12-MAR-2025 to 12-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	15-MAY-2025 to 15-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-JUL-2025 to 17-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	24-APR-2025 to 24-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	26-JUN-2025 to 26-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | DURVALUMAB (S) | Kytril (C) | Ranitidine (C) | Piriton (C) | Eyemo (C) | Dexamethasone (C) | Steroids (C) | Methylprednisolone (C) | Prednisolone (C) | Aprepitant (C) | Hydrocortisone (C) | Akynzeo (C)									
202504GLO002675JP	JAPAN 26 Years Female	**Anaphylactic reaction (Anaphylactic reaction)***	Recovered	03-Apr-2025 22 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	02-APR-2025 to 02-APR-2025 1 day	Initial. Female patient with event: Infusion Reaction Inv causality: related to Dato-DXd, CCA: not related;PRC. The patient experienced infusion reaction. Investigator: related to datopotamab deruxtecan and not related to durvalumab company physician: related to datopotamab deruxtecan and not related to durvalumab.
						Injection	6 milligram/kilogram q3w Intravenous use	13-MAR-2025 to 13-MAR-2025 1 day	
Concomitant Medication(s): | DURVALUMAB (S)									
202505GLO019672ES	SPAIN 79 Years Female	**Anaphylactic reaction (Anaphylaxis)***	Recovered	21-May-2025 3 months 2 days	CARBOPLATIN	Infusion	Intravenous use	07-MAY-2025 to 07-MAY-2025 1 day	Patient experienced anaphylaxis Investigator causality RELATED with Carboplatin NOT RELATED with Pembrolizumab and Paclitaxel Company causality RELATED with Carboplatin NOT RELATED with Pembrolizumab and Paclitaxel
						Infusion	Intravenous use	14-MAY-2025 to 21-MAY-2025 8 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	20-FEB-2025 to 16-APR-2025 1 month 28 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | Simvastatina (C) | Enalapril (C) | Eutirox (C)									
202506GLO005278JP	JAPAN 62 Years Female	**Anaphylactic reaction (Anaphylaxis)***	Recovered	06-Jun-2025 2 months 24 days	CARBOPLATIN	Infusion	Intravenous use	14-MAR-2025 to 06-JUN-2025 2 months 24 days	
					PACLITAXEL	Infusion	70 milligram/sq. meter Intravenous use	06-JUN-2025 to 06-JUN-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	14-MAR-2025 to 30-MAY-2025 2 months 17 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PACLITAXEL (S) | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | Bilanoa (C) | Hachiazule (C)									

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202506GLO024097JP	JAPAN 52 Years Female	**Hypersensitivity (Allergic reaction)***	Recovered	26-Jun-2025 2 months 10 days	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	17-APR-2025 to 26-JUN-2025 2 months 10 days	Periodic Report Comments. Patient experienced Allergic reaction, Investigator: related to DATOPOTAMAB DERUXTECAN, company: not related to DATOPOTAMAB DERUXTECAN. Patient experienced Allergic reaction, Investigator: not related to DURVALUMAB, company: not related to DURVALUMAB.
Concomitant Medication(s): | DURVALUMAB (S) | Dienogest (C) | Azunol (C)									
202506GLO025729HK	HONG KONG 61 Years Female	**Anaphylactic reaction (Anaphylaxis)***	Recovered	27-Jun-2025 2 months 18 days	CARBOPLATIN	Infusion	1.5 Intravenous use	10-APR-2025 to 27-JUN-2025 2 months 18 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | Pyridoxine (C) | Metoclopramide (C) | Famotidine (C)									

SOC:Infections and infestations

202410GLO009167DE	GERMANY 59 Years Female	**Bronchitis (Bronchitis)***	Recovered	08-Oct-2024 28 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	11-SEP-2024 to 18-FEB-2025 5 months 8 days	Patient has event: infection. For study therapy Action Taken: dose not changed, Investigator Causality: Related, CC: Not Related. Outcome: Recovered.; Periodic Report Comments. The patient experienced bronchitis. Investigator: related. Company: not

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

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EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	11-SEP-2024 to 18-FEB-2025 5 months 8 days	related;Periodic Report Comments. Patient experienced event Bronchitis. Investigator states event related to Datopotamab deruxtecan, Durvalumab and not related with Cyclo-phosphamide, Epirubicin, Paclitaxel, Carboplatin.. Company physicians consider event unrelated to Datopotamab deruxtecan, Durvalumab Cyclo-phosphamide, Epirubicin, Paclitaxel, Carboplatin.
						Infusion	1120 milligram q3w Intravenous use	16-APR-2025 to 16-APR-2025 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | EPIRUBICIN (S) | CAPECITABINE (S) | CYCLOPHOSPHAMIDE (S) | Dexamethason (C) | Mcp (C) | Azithromycin (C) | Prednisolon (C) | Sterofundin (C) | Piptaz (C) | Aprepitant (C) | Aloxi (C)									
202410GLO012980BR	BRAZIL 41 Years Female	**Herpes zoster (Herpes zoster)***	Recovered	16-Oct-2024 14 days	CARBOPLATIN	Infusion	187.5 Intravenous use	03-OCT-2024 to 27-DEC-2024 2 months 25 days	
					PACLITAXEL	Infusion	80 milligram/sq. meter Intravenous use	03-OCT-2024 to 27-DEC-2024 2 months 25 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505928-59-00

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Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	03-OCT-2024 to 24-JAN-2025 3 months 22 days	
Concomitant Medication(s): | PEMBROLIZUMAB (S) | PACLITAXEL (S) | Hydrocortisone (C) | Salbutamol sulfate (C) | Fexofenadine hydrochloride (C) | Cimetidine (C)									
202411GLO006278SG	SINGAPORE 64 Years Female	**Pneumonia (Lung infection)***	Recovered	07-Nov-2024 27 days	CAPECITABINE	Tablet	1000 milligram/sq. meter Oral use	16-DEC-2024 to 27-DEC-2024 12 days	Periodic Report Comments. Patient experienced LUNG INFECTION, Investigator: related to Capecitabine, not related to Carboplatin, Cyclophosphamide, Doxorubicin Hydrochloride, Paclitaxel, Pembrolizumab, company: not related.
						Tablet	1250 milligram/sq. meter Oral use	12-OCT-2024 to 07-NOV-2024 27 days	
						Tablet	938 milligram/sq. meter Oral use	13-JAN-2025 to 20-JAN-2025 8 days	
Concomitant Medication(s): | PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Levothyroxine sodium (C) | Metoclopramide HCL (C) | White soft paraffin (C) | Dextromethorphan hbr (C) | Acetylcysteine (C) | Metoclopramide HCL (C)									

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Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202411GLO006307US	UNITED STATES 66 Years Female	**Diverticulitis (Diverticulitis)***	Recovered	02-Nov-2024 5 days	CARBOPLATIN	Infusion	Intravenous use	29-OCT-2024 to 29-OCT-2024 1 day	Patient experienced Pyrexia and Diverticulitis , Inv, related to PEMBROLIZUMAB, PACLITAXEL and CARBOPLATIN , not related to DOXORUBICIN and CYCLOPHOSPHAMIDE, the sponsor not considered the evidence to suggest a reasonable possibility of a causal relationship between the event and PEMBROLIZUMAB, PACLITAXEL and CARBOPLATIN , DOXORUBICIN and CYCLOPHOSPHAMIDE
					PACLITAXEL	Infusion	135 milligram/sq. meter Intravenous use	19-NOV-2024 to 19-NOV-2024 1 day	
						Infusion	140 milligram/sq. meter Intravenous use	29-OCT-2024 to 29-OCT-2024 1 day	
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	29-OCT-2024 to 29-OCT-2024 1 day	

Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | | (6S)-5-methyltetrahydrofolate | Animal bone nos | Ascorbic acid | Astragalus mongholicus | Betacarotene | Biotin | Calcium | Chromium | Dioscorea oppositifolia | Dl-Alpha Tocopherol | Ganoderma lucidum | Iron | Liver | Lycium chinense | Magnesium | Manganese | Mecobalamin | Menaquino (C) | Flagyl (C) | Hydrocodone (C) | Zosyn (C) | Flonase allergy relief (C) | Tylenol (C) | Aspirin (C) | Cefoxitin (C) | Neulasta (C)

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EudraCT No: 2023-505928-59-00

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Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202411GLO011526KR	KOREA, REPUBLIC OF 57 Years Female	**Chronic sinusitis (Chronic sinusitis)***	Recovered	08-Nov-2024 6 months 16 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/sq. meter q3w Intravenous use	24-APR-2024 to 25-SEP-2024 5 months 2 days	
Concomitant Medication(s): | DURVALUMAB (S) | CAPECITABINE (S) | Dexamethasone (C) | Akynzeo (C) | Phenil (C) | Tacenol (C) | Almagel-f (C) | Monit (C) | Rebistar (C) | Tantum (C) | Topiderm (C) | Twolion (C) | Ezasmin (C) | Rebamipide (C) | Hexamedin (C) | Hyalein (C)									
2024A146522	UNITED KINGDOM 74 Years Female	**Neutropenic sepsis (Neutropenic sepsis)***	Recovered	20-Jun-2024 9 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	480 milligram/sq. meter q3w Intravenous use	03-JUL-2024 to 14-AUG-2024 1 month 12 days	
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	12-JUN-2024 to 12-JUN-2024 1 day	
					EPIRUBICIN	Infusion	72 milligram/sq. meter q3w Intravenous use	03-JUL-2024 to 14-AUG-2024 1 month 12 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505928-59-00

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	90 milligram/sq. meter q3w Intravenous use	12-JUN-2024 to 12-JUN-2024 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | Losartan (C) | Atorvastatin (C) | Risedronate sodium (C) | Paracetamol (C) | Loratadine (C)									
2024A162733	SINGAPORE 64 Years Female	**Parainfluenzae virus infection (Parainfluenzae virus infection)** *	Recovered	15-Jul-2024 27 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	540 milligram/sq. meter q3w Intravenous use	10-JUL-2024 to 10-JUL-2024 1 day	Periodic Report Comment. The patient experienced LUNG INFECTION (PARAINFLUENZA VIRUS).,Inves: LUNG INFECTION (PARAINFLUENZA VIRUS) related to Doxorubicin, Cyclophosphamide; CCA: not related to study therapy
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	19-JUN-2024 to 19-JUN-2024 1 day	
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	19-JUN-2024 to 10-JUL-2024 22 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | CAPECITABINE (S) | Levothyroxine sodium (C) | Dexamethasone phosphate (C) | Dexamethasone (C)									

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A188896	AUSTRIA 54 Years Female	**Fungal infection (Mycosis)***	Recovered	27-Jul-2024 10 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	21-OCT-2024 to 21-OCT-2024 1 day	Periodic Report Comment. The patient experienced MYCOSIS THROAT. Inv: Related with study therapy. CCA: Not related with study therapy.;Periodic Report Comment. Patient experience Mucositis oral, mycosis throat, and mucosal inflammation. Investigator: Related to study therapy. CCA: Not related to Study therapy. Action taken: dose reduced and dose not change respectively.
						Injection	4 milligram/kilogram q3w Intravenous use	30-SEP-2024 to 30-SEP-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	07-AUG-2024 to 07-AUG-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	18-JUL-2024 to 18-JUL-2024 1 day	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	07-AUG-2024 to 07-AUG-2024 1 day	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	18-JUL-2024 to 18-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	21-OCT-2024 to 21-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-SEP-2024 to 30-SEP-2024 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | Amlodipin (C) | Novothyral (C) | Seractil (C) | Pantoloc (C) | Thyrex (C) | Dexamethason (C) | Diphenhydramin (C) | Famotidin (C) | Fortecortin (C) | Ivemend (C) | Zofran (C) | Molaxole (C) | Fenistil (C) | Granisetron (C) | Elomel (C) | Kaliumchlorid (C)									
202502GLO004200JP	JAPAN 45 Years Female	**Pneumonia bacterial (Pneumonia bacterial)***	Recovered	05-Feb-2025 1 month 12 days	CARBOPLATIN	Infusion		08-JAN-2025 to 08-JAN-2025 1 day	Initial. Female patient with event: pneumonia bacterial, Inv causality: related to carboplatin and paclitaxel, CCA: not related.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	12-MAR-2025 to 12-MAR-2025 1 day	
						Infusion	Intravenous use	15-JAN-2025 to 15-JAN-2025 1 day	
						Infusion	Intravenous use	19-FEB-2025 to 19-FEB-2025 1 day	
						Infusion	Intravenous use	19-MAR-2025 to 19-MAR-2025 1 day	
						Infusion	Intravenous use	22-JAN-2025 to 22-JAN-2025 1 day	

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						Infusion	Intravenous use	25-DEC-2024 to 25-DEC-2024 1 day	
						Infusion	Intravenous use	26-FEB-2025 to 26-FEB-2025 1 day	
						Infusion	Intravenous use	26-MAR-2025 to 26-MAR-2025 1 day	
						Infusion	Intravenous use	29-JAN-2025 to 29-JAN-2025 1 day	
					PACLITAXEL	Infusion	80 milligram/sq. meter qw Intravenous use	02-APR-2025 to 02-APR-2025 1 day	

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						Infusion	80 milligram/sq. meter qw Intravenous use	06-JAN-2025 to 06-JAN-2025 1 day	
						Infusion	80 milligram/sq. meter qw Intravenous use	12-MAR-2025 to 12-MAR-2025 1 day	
						Infusion	80 milligram/sq. meter qw Intravenous use	15-JAN-2025 to 15-JAN-2025 1 day	
						Infusion	80 milligram/sq. meter qw Intravenous use	19-FEB-2025 to 19-FEB-2025 1 day	
						Infusion	80 milligram/sq. meter qw Intravenous use	19-MAR-2025 to 19-MAR-2025 1 day	

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Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	80 milligram/sq. meter qw Intravenous use	22-JAN-2025 to 22-JAN-2025 1 day	
						Infusion	80 milligram/sq. meter qw Intravenous use	25-DEC-2024 to 25-DEC-2024 1 day	
						Infusion	80 milligram/sq. meter qw Intravenous use	26-FEB-2025 to 26-FEB-2025 1 day	
						Infusion	80 milligram/sq. meter qw Intravenous use	26-MAR-2025 to 26-MAR-2025 1 day	
						Infusion	80 milligram/sq. meter qw Intravenous use	29-JAN-2025 to 29-JAN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PACLITAXEL (S) | Dienogest (C) | Famotidine (C) | Granisetron (C) | Polaramine (C) | Magnesium oxide (C) | Mecobalamin (C) | Loxoprofen (C) | Rebamipide (C) | Astomin (C) | Fexofenadin (C) | Carbocisteine (C) | Codeine Phosphate (C)									
202503GLO004163GB	UNITED KINGDOM 52 Years Female	**Neutropenic sepsis (Neutropenic sepsis)***	Recovered	05-Mar-2025 8 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	450 milligram/sq. meter q3w Intravenous use	19-MAR-2025 to 30-APR-2025 1 month 12 days	PRC. The patient experienced febrile neutropenia. Investigator: did not assess causality for study therapy Carboplatin, Paclitaxel, Pembrolizumab and Cyclophosphamide. Company physician: Not related to study therapy Carboplatin, Paclitaxel, Pembrolizumab and Cyclophosphamide.
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	26-FEB-2025 to 26-FEB-2025 1 day	
					EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	26-FEB-2025 to 30-APR-2025 2 months 5 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | EPIRUBICIN (S) | Sumatriptan (C) | Vagifem (C) | Ondansetron (C) | Dexamethasone (C) | Chlorphenamine (C) | Domperidone (C) | Lansoprazole (C) | Loperamide (C) | Hyoscine butylbromide (C) | Epaderm (C)									
202503GLO026096MY	MALAYSIA 34 Years Female	**Pharyngitis (Pharyngitis)***	Recovered	27-Mar-2025 1 month 4 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	03-JUN-2025 to 24-JUN-2025 22 days	PRC. Investigator causality is related for the suspect DATOPOTAMAB DERUXTECAN & DURVALUMAB for the event Mucositis. Investigator causality is Not related for the suspect DURVALUMAB for the

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	13-MAY-2025 to 13-MAY-2025 1 day	event Infection & related for the suspect DATOPOTAMAB DERUXTECAN for event Mucositis. company causality is not lelated for both the event Mucositis & Infection related for the suspect DATOPOTAMAB DERUXTECAN & DURVALUMAB.;Periodic Report Comments. Investigator causality is related for the suspect DATOPOTAMAB DERUXTECAN & DURVALUMAB for the event Mucositis. Investigator causality is Not related for the suspect DURVALUMAB for the event Infection & related for the suspect DATOPOTAMAB DERUXTECAN for event Mucositis. company causality is not lelated for both the event Mucositis & Infection related for the suspect DATOPOTAMAB DERUXTECAN & DURVALUMAB.
						Infusion	1120 milligram q3w Intravenous use	14-APR-2025 to 14-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-MAR-2025 to 17-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	24-FEB-2025 to 24-FEB-2025 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Emend (C) | Dexamethasone (C) | Choline salicylate (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202503GLO026794MY	MALAYSIA 64 Years Female	**Upper respiratory tract infection (Upper respiratory tract infection)*** Febrile neutropenia (Febrile neutropenia)	Recovered	28-Mar-2025 9 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	20-MAR-2025 to 05-JUN-2025 2 months 17 days	
					EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	20-MAR-2025 to 05-JUN-2025 2 months 17 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Emend (C) | Difflam (C) | Augmentin (C) | Betadine (C)									
202504GLO003914TR	TURKEY 66 Years Female	**Urinary tract infection (Urinary tract infection)*** White blood cell count decreased (WBC decreased)*	Recovered	05-Apr-2025 17 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	14-APR-2025 to 26-MAY-2025 1 month 13 days	Periodic Report Comments. Patient experienced urinary tract infection Inv causality : RELATED to Doxorubicin and Cyclo-phosphamide NOT RELATED: Other suspects CCA: NOT RELATED
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	20-MAR-2025 to 20-MAR-2025 1 day	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DOXORUBICIN HYDROCHLORIDE	Infusion	114 milligram/sq. meter q3w Intravenous use	20-MAR-2025 to 20-MAR-2025 1 day	
						Infusion	95 milligram/sq. meter q3w Intravenous use	14-APR-2025 to 26-MAY-2025 1 month 13 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Euthyrox (C) | vemlidy (C) | systane (C) | ocurin (C) | Pheniramine (C) | Pantoprazole (C) | granisetron (C) | ecopirin (C) | fraven (C) | Arveles (C) | Avil (C) | NaCl (C) | Pandev (C) | Parol (C) | Redox (C)									
202504GLO003940IN	INDIA 61 Years Female	**Urinary tract infection (Urinary tract infection)***	Recovered	03-Apr-2025 8 months 4 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	25-JUN-2025 to 25-JUN-2025 1 day	Periodic Report Comments. Patient experienced Urinary tract infection and, Inv, not realted to Pembrolizumab, Epirubicin, Cyclo-phosphamide, Paclitaxel, Carboplatin
						Solution for infusion	200 milligram q3w Intravenous use	31-JUL-2024 to 29-MAY-2025 9 months 29 days	
Concomitant Medication(s): | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Glimiprime mp (C) | Levothyroxine (C) | Azithromycin (C) | Levosiz (C) | Paracetamol (C) | Ceftriaxone+sulbactam (C) | Perinorm (C) | Vildapride (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202504GLO019465MY	MALAYSIA 35 Years Female	**Neutropenic sepsis (Neutropenic sepsis)*** Pancytopenia (Pancytopenia)	Recovered	21-Apr-2025 12 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	10-APR-2025 to 10-APR-2025 1 day	Periodic Report Comments. The report concerns a female adult patient of Asian ethnic origin born in 1989 (age 35 years). The investigator considered that there was a reasonable possibility of a causal relationship between Cyclophosphamide, Doxorubicin and the following event(s): neutropenic sepsis and symptomatic pancytopenia. The investigator considered that there was a reasonable possibility of a causal relationship between the study therapy Pembrolizumab and the following event(s): neutropenic sepsis and symptomatic pancytopenia. The company physician did not consider that there was a reasonable possibility of a causal relationship between the study therapy and the event(s). The company physician did not consider that there was a reasonable possibility of a causal relationship between Cyclophosphamide and Doxorubicin and the following event(s): neutropenic sepsis and symptomatic pancytopenia.
		Neutropenic sepsis (Neutropenic sepsis)* Pancytopenia (Pancytopenia)*	Recovered	21-Apr-2025 12 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	10-APR-2025 to 10-APR-2025 1 day	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	02-JAN-2025 to 29-JUL-2025 6 months 28 days	

Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Iberet (C) | Maxolon (C) | Kytril (C) | Neupogen (C)

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Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202505GLO002503BR	BRAZIL 52 Years Female	**Abdominal sepsis (Abdominal sepsis)***	Recovered	04-May-2025 1 month 2 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	819.6 milligram/sq. meter q3w Intravenous use	03-APR-2025 to 24-APR-2025 22 days	The patient experienced Hypotension Investigator: Related to Pembrolizumab, Doxorubicin, Cyclophosphamide and Not Related to Paclitaxel, Carboplatin and Not Related to Company physician: Not related to study therapy.
					DOXORUBICIN HYDROCHLORIDE	Infusion	81.9 milligram/sq. meter q3w Intravenous use	03-APR-2025 to 24-APR-2025 22 days	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	05-DEC-2024 to 24-APR-2025 4 months 20 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Formoterol fumarate (C) | Clonazepam (C) | Paracetamol (C) | Escitalopram (C) | Cephalexin (C) | Ondansetron (C)									
202505GLO014115MY	MALAYSIA 35 Years Female	**Neutropenic sepsis (Neutropenic sepsis)*** Acute kidney injury (Acute kidney injury)* Pancytopenia (Pancytopenia)*	Recovered	16-May-2025 1 month 7 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	10-APR-2025 to 10-APR-2025 1 day	periodic report comment. Patient experienced Neutropenic Sepsis in septic shock, Acute kidney injury and electrolyte imbalances secondary to dehydration, Symptomatic Pancytopenia, investigator: related to CYCLOPHOSPHAMIDE, DOXORUBICIN HYDROCHLORIDE, not related to PACLITAXEL,

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DOXORUBICIN HYDROCHLORIDE	Infusion	Intravenous use	10-APR-2025 to 10-APR-2025 1 day	PEMBROLIZUMAB, CARBOPLATIN, cca: not related to CYCLOPHOSPHAMIDE, DOXORUBICIN HYDROCHLORIDE, PACLITAXEL, PEMBROLIZUMAB, CARBOPLATIN.
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Maxolon (C) | Iberet (C) | Sodium Chloride 0.9% & Dextrose 5% (C) | Neupogen (C) | Dexamethasone (C) | Chlorpheniramine (C) | Granisetron (C) | Paracetamol (C) | Ranitidine (C) | Kytril (C) | Magnesium sulphate (C) | Tazocin (C)									
202505GLO014328DE	GERMANY 45 Years Female	**Soft tissue infection (Soft tissue infection)***	Recovered	16-May-2025 2 months 14 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	03-MAR-2025 to 24-MAR-2025 22 days	
					EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	03-MAR-2025 to 24-MAR-2025 22 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Vitamin d (C) | Pantoprazol (C) | Buprofen (C) | Eliquis (C)									
202505GLO015513DE	GERMANY 59 Years Female	**Bronchitis (Bronchitis)***	Recovered	08-Oct-2024 28 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	02-OCT-2024 to 02-OCT-2024 1 day	

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Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	08-JAN-2025 to 08-JAN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-MAY-2025 to 08-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	10-DEC-2024 to 10-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	10-JUL-2025 to 10-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	11-SEP-2024 to 11-SEP-2024 1 day	

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Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	16-APR-2025 to 16-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	17-SEP-2025 to 17-SEP-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-FEB-2025 to 18-FEB-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-JUN-2025 to 18-JUN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-NOV-2024 to 20-NOV-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	21-AUG-2025 to 21-AUG-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-MAY-2025 to 28-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-JAN-2025 to 29-JAN-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-OCT-2024 to 29-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	31-JUL-2025 to 31-JUL-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | CARBOPLATIN (S) | PACLITAXEL (S) | Aprepitant (C) | Aloxi (C) | Dexamethason (C) | Pantoprazol (C) | Mcp (C)									
202505GLO022219JP	JAPAN Female	**Herpes zoster (Herpes zoster)***	Recovered	25-May-2025 1 month 4 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	22-APR-2025 to 30-JUN-2025 2 months 9 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Valsartan (C) | Bufferin (C) | Dexart (C) | Metoclopramide (C)									
202506GLO000754JP	JAPAN 57 Years Female	**Herpes zoster (Herpes zoster)***	Recovered	31-May-2025 4 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	28-MAY-2025 to 28-MAY-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Antebate (C) | White petrolatum (C) | Loxoprofen sodium hydrate (C) | Teprenone (C) | Metoclopramide (C)									
202506GLO005267JP	JAPAN 74 Years Female	**Septic shock (Septic shock)***	Recovered	06-Jun-2025 10 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter Intravenous use	28-MAY-2025 to 28-MAY-2025 1 day	
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter Intravenous use	28-MAY-2025 to 28-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | CARBOPLATIN (S) | PACLITAXEL (S) | DOXORUBICIN HYDROCHLORIDE (S) | | Bilanoa (C) | Amlodipine (C) | Metgluco (C) | Restamin kowa (C) | Antebate (C)									
202506GLO007768BE	BELGIUM 73 Years Female	**Bronchopulmonary aspergillosis (Pneumonia aspergillus)***	Recovered	26-May-2025 11 months 2 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	25-JUN-2024 to 19-MAY-2025 10 months 25 days	Periodic Report Comment. Patient experienced Respiratory infection [aspergillus], inv: not related to Dato-DXd, related to Durvalumab, cca: not related to Dato-DXd and Durvalumab.
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Hyaluron (C) | Macrogol (C) | Metformin (C) | Verpamil (C) | Daktarin (C) | Gliclazide (C) | Methylprednisolon (C) | Voriconazol (C) | Loperamide (C)									
202506GLO016941JP	JAPAN 57 Years Female	**Pneumonia (Pulmonary suppuration)***	Not Recovered	19-Jun-2025 23 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter Intravenous use	28-MAY-2025 to 28-MAY-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S)									
202507GLO000795BR	BRAZIL 52 Years Female	**Cytomegalovirus infection (Cytomegalovirus infection)***	Recovered	30-Jun-2025 2 months 28 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	03-APR-2025 to 24-APR-2025 22 days	PRC Comment. Patient experienced Cytomegalovirus infection: Investigator's causality related to study therapy PEMBROLIZUMAB, DOXORUBICIN HYDROCHLORIDE and CYCLOPHOSPHAMIDE. Not related to PACLITAXEL and CARBOPLATIN.
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 q3w Intravenous use	03-APR-2025 to 24-APR-2025 22 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	03-APR-2025 to 03-APR-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	05-DEC-2024 to 05-DEC-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	06-FEB-2025 to 06-FEB-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	09-JAN-2025 to 09-JAN-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	24-APR-2025 to 24-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	27-FEB-2025 to 27-FEB-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Formoterol fumarate (C) | Clonazepam (C) | Escitalopram (C) | Amoxicillin (C) | Ciprofloxacin (C) | Norepinephrine (C)									
202507GLO002542JP	JAPAN 37 Years Female	**Gastroenteritis (Gastroenteritis)***	Recovering	23-Jun-2025 13 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/kilogram q3w Intravenous use	11-JUN-2025 to 11-JUN-2025 1 day	PRC Comment. Patient experienced Gastroenteritis: Investigator's causality related to study therapy PEMBROLIZUMAB, EPIRUBICIN and CYCLOPHOSPHAMIDE, Not related to PACLITAXEL and CARBOPLATIN.
						Powder for solution for injection/infusion	924 milligram/kilogram q3w Intravenous use	12-AUG-2025 to 13-AUG-2025 2 days	
					EPIRUBICIN	Infusion	139 milligram q3w Intravenous use	11-JUN-2025 to 11-JUN-2025 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	139 milligram q3w Intravenous use	13-AUG-2025 to 13-AUG-2025 1 day	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	13-AUG-2025 to 13-AUG-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	19-MAR-2025 to 11-JUN-2025 2 months 24 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Sodium gualenate hydrate (C) | Magnesium oxide (C) | Pantethine (C) | Domperidone (C) | Heparinoid (C)									
202507GLO002659US	UNITED STATES 64 Years Female	**Sepsis (Sepsis)***	Recovered	02-Jul-2025 22 days	CARBOPLATIN	Infusion	Intravenous use	02-JUL-2025 to 24-JUL-2025 23 days	Periodic Report Comments. Patient experienced the event "Sepsis". INV not related to PEMBROLIZUMAB & CYCLOPHOSPHAMIDE , not reported for EPIRUBICIN, related to PACLITAXEL & CARBOPLATIN. Company causality not related to PEMBROLIZUMAB & CYCLOPHOSPHAMIDE & EPIRUBICIN & CARBOPLATIN and related

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
									to PACLITAXEL
						Infusion	Intravenous use	11-JUN-2025 to 25-JUN-2025 15 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | CYCLOPHOSPHAMIDE (S) | DOXORUBICIN HYDROCHLORIDE (S) | PACLITAXEL (S) | | Ibuprofen (C) | Levothyroxine (C) | Magnesium citrate (C) | Cephalexin (C)									
202507GLO002689VN	VIET NAM 40 Years Female	**Meningitis (Meningitis)***	Fatal	02-Jul-2025 4 months 6 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	26-DEC-2024 to 29-MAY-2025 5 months 4 days	
Concomitant Medication(s): | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | CARBOPLATIN (S) | PACLITAXEL (S) | Ficocyte (C) | Dexamethasone (C) | Aloxi (C)									
202507GLO005949PL	POLAND 67 Years Female	**Sepsis (Sepsis)***	Not Recovered	02-Jul-2025 6 months 13 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	07-APR-2025 to 07-APR-2025 1 day	Periodic Report Comments. Patient experienced acute kidney failure, investigator: not related to DATOPOTAMAB DERUXTECAN, related to DURVALUMAB, sepsis, investigator: related to DATOPOTAMAB DERUXTECAN, not related to DURVALUMAB, cca for both events: not related to DATOPOTAMAB DERUXTECAN, DURVALUMAB.
						Injection	6 milligram/kilogram q3w Intravenous use	10-JAN-2025 to 10-JAN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	17-MAR-2025 to 17-MAR-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	20-DEC-2024 to 20-DEC-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	21-FEB-2025 to 21-FEB-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	31-JAN-2025 to 31-JAN-2025 1 day	

Concomitant Medication(s): | DURVALUMAB (S) | Atarax (C) | Concor (C) | Trimbow (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO008115CA	CANADA 54 Years Female	**Sepsis (Sepsis)***	Recovered	08-Jul-2025 4 months 25 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	14-FEB-2025 to 17-JUL-2025 5 months 4 days	Periodic Report Comments. Patient Experienced Event (Sepsis). Causality as Reported Source Related with (Pembrolizumab, cyclophosphamide, doxorubicin.) and Not Related with (Carboplatin, Paclitaxel). Causality as Determined Source was Not Related for all suspects.
Concomitant Medication(s): | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Lorazepam (C) | Secaris (C) | Mometasone (C) | Rivaroxaban (C) | Dexamethasone (C)									
202507GLO009251CN	CHINA 42 Years Female	**Pharyngitis (Pharyngitis)***	Recovered	04-Jul-2025 2 months 24 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	11-APR-2025 to 04-JUL-2025 2 months 24 days	Periodic Report Comments. Patient has event pharyngitis. Action taken with DURVALUMAB, DATOPOTAMAB DERUXTECAN was no change. Investigator Causality:related, Company causality: not related.
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	11-APR-2025 to 04-JUL-2025 2 months 24 days	
Concomitant Medication(s): | DURVALUMAB (S) | Sodium hyaluronate (C)									
202507GLO012083CA	CANADA 64 Years Female	**Pneumonia necrotising (Pneumonia necrotizing)***	Not Recovered	14-Jul-2025 1 month 4 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter Intravenous use	11-JUN-2025 to 11-JUN-2025 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DOXORUBICIN	Infusion	60 milligram/sq. meter Intravenous use	11-JUN-2025 to 11-JUN-2025	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Omega (C) | Vitamin d (C) | Dexamethasone (C) | Diphenhydramine (C) | Zofran (C) | Decadron (C) | Claritin (C) | Clavulin (C) | Prednisone (C) | Tums (C) | Tylenol (C) | Claritin (C) | Benadryl (C) | Pepcid (C) | Medrol (C) | Ventolin (C) | Senokot (C) | Ranitidine (C)									
202507GLO019214GB	UNITED KINGDOM 43 Years Female	**Neutropenic sepsis (Neutropenic sepsis)***	Recovering	17-Jul-2025 nk	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	milligram/sq. meter Unknown	to	
					EPIRUBICIN	Infusion	milligram/sq. meter Unknown	to	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S)									
202507GLO022735MY	MALAYSIA 53 Years Female	**Neutropenic sepsis (Neutropenic sepsis)***	Recovered	21-Jul-2025 6 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter Unknown	04-AUG-2025 to 04-AUG-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for injection/infusion	600 milligram/sq. meter Unknown	16-JUL-2025 to 16-JUL-2025 1 day	
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter Unknown	04-AUG-2025 to 04-AUG-2025 1 day	
						Infusion	60 milligram/sq. meter Unknown	16-JUL-2025 to 16-JUL-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | BISOPROLOL (C) | LOSARTAN (C) | METFORMIN (C) | ATORVASTATIN (C) | GLYCERYL TRINITRATE (C)									
202508GLO003898CA	CANADA 56 Years Female	**Kidney infection (Kidney infection)***	Not Recovered	03-Aug-2025 1 year 2 months 28 days	DURVALUMAB	Infusion	1120 milligram Intravenous use	20-AUG-2024 to 20-AUG-2024 1 day	Periodic Report Comments. Patient experienced renal infection and sepsis. Inv: event related to Durvalumab, not related to Datopotamab Deruxtecan. CCA: not related.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	01-OCT-2024 to 01-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	02-JUL-2025 to 02-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	04-FEB-2025 to 04-FEB-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	07-MAY-2024 to 07-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	08-APR-2025 to 08-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	09-JUL-2024 to 09-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	10-DEC-2024 to 10-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	10-SEP-2024 to 10-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-JUN-2024 to 18-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-MAR-2025 to 18-MAR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

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Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	20-MAY-2025 to 20-MAY-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	23-JUL-2025 to 23-JUL-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-MAY-2024 to 28-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-APR-2025 to 29-APR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-JUL-2024 to 30-JUL-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	31-DEC-2024 to 31-DEC-2024 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Levothyroxine (C) | Ativan (C) | Zopiclone (C) | Rosuvastatin (C) | Vitamin d3 (C) | Dexamethasone (C) | Akynzeo (C) | Benadryl (C) | Pepcid (C) | Pantoloc (C) | Stemetil (C) | Senokot (C) | Zofran (C) | Acetaminophen (C) | Sucralfate (C) | Tamsulosin (C) | Solifenacin (C)									
202508GLO013833AT	AUSTRIA 31 Years Female	**Tooth abscess (Tooth abscess)***	Not Recovered	11-Aug-2025 4 months 2 days	DATOPOTAMAB DERUXTECAN	Injection	3 milligram/kilogram q3w Intravenous use	12-JUN-2025 to 04-SEP-2025 2 months 24 days	Periodic Report Comments. Patient has event Tooth abscess left Action taken DURVALUMAB and DATOPOTAMAB DERUXTECAN was temporary withdrawn. Investigator Causality related was related for DATOPOTAMAB DERUXTECAN and not related for DURVALUMAB and Company causality: not related.
						Injection	4 milligram/kilogram q3w Intravenous use	29-APR-2025 to 22-MAY-2025 24 days	
						Injection	6 milligram/kilogram q3w Intravenous use	10-APR-2025 to 10-APR-2025 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | Famotidin (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO016135JP	JAPAN 62 Years Female	**Pneumonia (Pneumonia)***	Recovered	20-Aug-2025 1 month 25 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	27-JUN-2025 to 08-AUG-2025 1 month 13 days	
					EPIRUBICIN	Infusion	Intravenous use	27-JUN-2025 to 08-AUG-2025 1 month 13 days	
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	14-MAR-2025 to 08-AUG-2025 4 months 26 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Aimix (C) | Bilanoa (C)									
202508GLO017379MY	MALAYSIA 53 Years Female	**Neutropenic sepsis (Neutropenic sepsis)***	Recovered	13-Aug-2025 29 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter Intravenous use	16-JUL-2025 to 04-AUG-2025 20 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter Intravenous use	16-JUL-2025 to 04-AUG-2025 20 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Bisoprolol (C) | Losartan (C) | Metformin (C) | Atorvastatin (C) | Glyceryl trinitrate (C) | Chlorpheniramine (C) | Dexamethasone (C) | Granisetron (C) | Paracetamol (C) | Ranitidine (C) | Metoclopramide (C) | Benadryl (C) | Loperamide (C) | Loratadine (C) | Pantoprazole (C) | Flagyl (C) | Rocephine (C) | Magnesium sulphate (C) | Magnesium oxide (C) | Zincofer (C) | Pegfilgrastim (C) | Magnesium trisilicate (C) | Oral rehydration salts (C) | Slow k (C) | Oral rehydration salts (C) | Aprepitant (C) | Maxolon (C) | Neupogen (C) | Sodium chloride (C) | Tazocin (C) | Magnesium sulfate (C)									
202508GLO020284US	UNITED STATES 35 Years Female	**Herpes zoster (Shingles)*** Febrile neutropenia (Febrile neutropenia)*	Not Recovered	16-Aug-2025 2 months 6 days	DOXORUBICIN HYDROCHLORIDE	Infusion	45 milligram q3w Intravenous use	11-JUN-2025 to 11-JUN-2025 1 day	
						Infusion	60 milligram q3w Intravenous use	01-JUL-2025 to 12-AUG-2025 1 month 12 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | CARBOPLATIN (S) | PACLITAXEL (S) | Albuterol (C) | Alprazolam (C) | Omeprazole (C)									
202508GLO020289DE	GERMANY 45 Years Female	**Cytomegalovirus gastritis (Cytomegalovirus gastritis)***	Not Recovered	22-Aug-2025 3 months	PEMBROLIZUMAB	Solution for infusion	200 q3w Intravenous use	23-MAY-2025 to 25-JUL-2025 2 months 3 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | PACLITAXEL (S) | CARBOPLATIN (S) | Dexamethason (C) | Granisetron (C) | Cimetidin (C) | Clemastin (C) | Loperamid (C)									
202509GLO017260DE	GERMANY 70 Years Female	**Atypical pneumonia (Atypical pneumonia)***	Not Recovered	19-Sep-2025 7 days 10 hrs 40 min	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	11-SEP-2025 13:20 to	Periodic Report Comments. Subject has event: Atypical Pneumonia Investigator causality and company causality Epirubicin, Cyclophosphamide w.r.t to event Atypical Pneumonia: Atypical PneumoniaRelated and Durvalumab, Paclitaxel, Datopotamab Deruxtecan, and Carboplatin: Not related
					EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	11-SEP-2025 12:15 to	
Concomitant Medication(s): DURVALUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | DATOPOTAMAB DERUXTECAN (S) | Ramipril (C) | Calcium (C) | Dekristol (C) | Alendronate (C) | Curcuma (C) | Resveratrol (C) | Dexamethason (C) | Akynzeo (C) | Clemastin (C) | Paracetamol (C) | Pantoprazol (C) | Clexane (C) | Eliquis (C) | Ondansetron (C) | Movicol (C) | Ampho moronal (C) | Tears again (C) | Aciclovir (C) | Tantum verde (C)									
202509GLO018878CN	CHINA 38 Years Female	**Upper respiratory tract infection (Upper respiratory tract infection)*** Febrile neutropenia (Febrile neutropenia)* Anaemia (Anemia)	Not Recovered	18-Sep-2025 3 months 1 day	PEMBROLIZUMAB	Solution for infusion	Intravenous use	18-JUN-2025 to 11-SEP-2025 2 months 25 days	
		Upper respiratory tract infection (Upper respiratory tract infection)* Febrile neutropenia (Febrile neutropenia) Anaemia (Anemia)	Not Recovered	18-Sep-2025 3 months 1 day	CARBOPLATIN	Infusion	Intravenous use	18-JUN-2025 to 21-AUG-2025 2 months 4 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	11-SEP-2025 to 11-SEP-2025 1 day	
					EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	11-SEP-2025 to 11-SEP-2025 1 day	
Concomitant Medication(s): | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S)									
202509GLO026233CN	CHINA 59 Years Female	**Campylobacter infection (Campylobacter jejuni infection)***	Recovered	29-Sep-2025 1 month 1 day	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	10-OCT-2025 to 10-OCT-2025 1 day	
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	29-AUG-2025 to 19-SEP-2025 22 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	10-OCT-2025 to 10-OCT-2025 1 day	
						Infusion	60 milligram/sq. meter q3w Intravenous use	29-AUG-2025 to 19-SEP-2025 22 days	
					DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	13-FEB-2025 to 30-MAY-2025 3 months 18 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | Gabapentin (C) | Trandolapril (C)									
202509GLO026265DE	GERMANY 40 Years Female	**Upper respiratory tract infection (Upper respiratory infection)***	Not Recovered	29-Sep-2025 nk	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	to	Periodic Report Comments. Patient experienced upper respiratory infection Related to Epirubicin, Cyclophosphamide and not related to Pembrolizumab, Paclitaxel and Carboplatin. Company causality assessment is not related.

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505928-59-00

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					EPIRUBICIN	Infusion Intravenous use		to	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | CARBOPLATIN (S) | EPIRUBICIN (S) | | Kalium verla (C) | Kaliumchloride (C)									
202510GLO000895FR	FRANCE 46 Years Female	**Septic shock (Septic shock)*** Febrile bone marrow aplasia (Febrile aplasia)*	Fatal	01-Oct-2025 3 months	PACLITAXEL	Infusion	80 milligram/sq. meter	02-JUL-2025 to 02-JUL-2025	
						Infusion	80 milligram/sq. meter	09-JUL-2025 to 09-JUL-2025	
						Infusion	80 milligram/sq. meter	18-AUG-2025 to 18-AUG-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	80 milligram/sq. meter qw	04-AUG-2025 to 04-AUG-2025 1 day	
						Infusion	80 milligram/sq. meter qw	11-AUG-2025 to 11-AUG-2025 1 day	
						Infusion	80 milligram/sq. meter qw	15-JUL-2025 to 15-JUL-2025 1 day	
						Infusion	80 milligram/sq. meter qw	21-JUL-2025 to 21-JUL-2025 1 day	
						Infusion	80 milligram/sq. meter qw	28-JUL-2025 to 28-JUL-2025 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): CARBOPLATIN (S) | | PEMBROLIZUMAB (S) | Thealose (C) | Alprazolam (C) | Augmentin (C) | Doliprane (C) | Metoclopramide (C) | Aranesp (C) | Methylprednisolone (C) | Acide ursodesoxycholique arrow (C) | Vitamin K1 (C) | Aciclovir accord (C)									
202510GLO001859US	UNITED STATES Female	**Sepsis (Sepsis)***	Recovering	01-Oct-2025 nk	CARBOPLATIN	Infusion	1.5	04-SEP-2025 to 04-SEP-2025	
						Infusion	1.5	06-AUG-2025 to 06-AUG-2025	
						Infusion	1.5	10-SEP-2025 to 10-SEP-2025	
						Infusion	1.5	13-AUG-2025 to 13-AUG-2025	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1.5	16-JUL-2025 to 16-JUL-2025	
						Infusion	1.5	17-SEP-2025 to 17-SEP-2025	
						Infusion	1.5	30-JUL-2025 to 30-JUL-2025	
						Infusion	1.5 Unknown	09-JUL-2025 to 09-JUL-2025 1 day	

Concomitant Medication(s): | PACLITAXEL (S) | PEMBROLIZUMAB (S) | Clopidogrel (C) | Metformin (C) | Empagliflozin (C) | Aspirin (C) | Losartan (C) | Atorvastatin (C) | Glipizide (C) | Ondansetron (C) | Prochlorperazine (C) | Loperamide (C) | Spironolactone (C) | Nitroglycerin (C) | Cefepime (C) | Vancomycin (C) | Glucagon (C) | Hydrocodone (C) | Hydromorphone (C) | Lovenox (C) | Melatonin (C) | Piperacillin (C) | Senna (C)

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202510GLO004236BR	BRAZIL 36 Years Female	**Influenza (Influenza A virus infection)***	Recovering	04-Oct-2025 4 months 13 days	PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	22-MAY-2025 to 01-OCT-2025 4 months 10 days	Periodic Report Comments. Patient experienced influenza A Related to Pembrolizumab, and not related to Doxorubicin Hydrochloride, Cyclophosphamide, Paclitaxel and Carboplatin. Company causality assessment is not related.
Concomitant Medication(s): | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | CARBOPLATIN (S) | PACLITAXEL (S)									
202510GLO014915CN	CHINA 32 Years Female	**Urinary tract infection (Complicated urinary tract infection)***	Not Recovered	15-Oct-2025 3 months 15 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	01-JUL-2025 to 02-SEP-2025 2 months 2 days	
					PEMBROLIZUMAB	Solution for infusion	Intravenous use	31-MAR-2025 to 02-SEP-2025 5 months 3 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | CARBOPLATIN (S) | PACLITAXEL (S)									

SOC:Injury, poisoning and procedural complications

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202505GLO006226BR	BRAZIL 39 Years Female	**Infusion related reaction (Infusion reaction)***	Recovered	07-May-2025 22 days	CARBOPLATIN	Infusion	1.5 Intravenous use	16-APR-2025 to 23-APR-2025 8 days	Periodic Report Comments. Patient has event: SEPSIS. Action Taken with study therapy was No change. Investigator Causality: Related CC: Not Related.
						Infusion	1.5 Intravenous use	30-APR-2025 to 21-MAY-2025 22 days	
					PACLITAXEL	Infusion	80 milligram/sq. meter Intravenous use	30-APR-2025 to 21-MAY-2025 22 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | | Ondansetron (C) | Dexamethasone (C) | Diphenhydramine (C) | Omeprazole (C) | Cimetidine (C) | Decadron (C)									
202506GLO024597US	UNITED STATES 78 Years Female	**Rib fracture (Rib fracture)***	Not Recovered	26-Jun-2025 2 months 26 days	CARBOPLATIN	Infusion	Intravenous use	01-APR-2025 to 01-APR-2025 1 day	Periodic Report Comments. Periodic Report Comments

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	08-APR-2025 to 29-APR-2025 22 days	
						Infusion	Intravenous use	13-MAY-2025 to 13-MAY-2025 1 day	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	01-APR-2025 to 13-MAY-2025 1 month 13 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | Compazine (C) | Dexamethasone (C) | Diphenhydramine (C) | Famotidine (C)									
202507GLO022711US	UNITED STATES 50 Years Female	**Infusion related reaction** **(Infusion related reaction)***	Recovered	19-Jun-2025 2 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	18-JUN-2025 to 10-JUL-2025 23 days	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	18-JUN-2025 to 10-JUL-2025 23 days	
Concomitant Medication(s): | DURVALUMAB (S)									
202507GLO024362DE	GERMANY 45 Years Female	**Infusion related reaction (Infusion related reaction)***	Recovered	25-Jul-2025 2 months 3 days	CARBOPLATIN	Infusion	Intravenous use	23-MAY-2025 to 25-JUL-2025 2 months 3 days	Periodic Report Comments. Patient experienced Infusion related Allergic reaction Related to Carboplatin and not related to Pembrolizumab and Paclitaxel. Company causality assessment is not related.
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) |									
202509GLO020299IT	ITALY 78 Years Female	**Infusion related reaction (Infusion reaction)***	Recovered	23-Sep-2025 1 month 24 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	31-JUL-2025 to 23-SEP-2025 1 month 24 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | CARBOPLATIN (S) | PACLITAXEL (S) | Toujeo (C) | Eutirox (C) | Lucen (C) | Olmesartan medoxomil (C) | Blefox (C) | Cortivis (C)									

SOC:Investigations

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202409GLO010809CN	CHINA 36 Years Female	**Amylase increased (Serum amylase increased)***	Recovered	29-Sep-2024 1 month 29 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram Intravenous use	01-AUG-2024 to 28-NOV-2024 3 months 28 days	the patient experienced CTC 3 serum amylase increased, inv. causality related. Com causality not related to study therapy
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	01-AUG-2024 to 11-JUL-2025 11 months 11 days	
Concomitant Medication(s): | DURVALUMAB (S) | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | Sodium hyaluronate (C) | Dexamethasone sodium phosphate (C) | Promethazine hydrochloride (C) | Vitamin b6 (C) | Omeprazole sodium (C) | Loratadine (C) | Ambroxol hydrochloride (C) | Diammonium glycyrrhizinate (C)									
202410GLO009258TR	TURKEY 48 Years Female	**Platelet count decreased (Platelet count decreased)*** Neutrophil count decreased (Neutrophil count decreased)* White blood cell count decreased (White blood cell decreased)*	Recovered	14-Oct-2024 1 month 24 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	21-AUG-2024 to 01-NOV-2024 2 months 12 days	
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	21-AUG-2024 to 01-NOV-2024 2 months 12 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | CARBOPLATIN (S) | PACLITAXEL (S) | | DOXORUBICIN HYDROCHLORIDE (S) | Avil (C) | Emetril (C) | Oksapar (C) | Panto (C) | Erythrocytes (C) | Emend (C) | Ursactive (C) | Contramal (C) | Granexa (C) | Potassium chloride (C) | Tazocin (C) | Paracetamol (C) | Tavanic (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202410GLO009374CN	CHINA 30 Years Female	**Aspartate aminotransferase increased (Aspartate aminotransferase increased)***	Recovered	06-Oct-2024 21 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	16-SEP-2024 to 06-MAR-2025 5 months 19 days	Patient experienced aspartate aminotransferase increased investigator causality is related with suspect therapy whereas company causality is not related.
Concomitant Medication(s): DURVALUMAB (S) | | Tenofovir disoproxil fumarate (C) | Bicyclol (C) | Compound glycyrrhizin (C) | Glutathione (C) | Compound glycyrrhizin (C) | Dexamethasone sodium phosphate (C) | Fosaprepitant dimeglumine (C) | Omeprazole sodium (C) | Palonosetron hydrochloride (C) | Paracetamol (C) | Promethazine hydrochloride (C)									
202411GLO019785TR	TURKEY 54 Years Female	**Platelet count decreased (Platelet count decreased)*** Neutrophil count decreased (Neutrophil count decreased)	Recovered	22-Nov-2024 11 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	12-NOV-2024 to 23-JAN-2025 2 months 12 days	
		Platelet count decreased (Platelet count decreased)* Neutrophil count decreased (Neutrophil count decreased)*	Recovered	22-Nov-2024 11 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	12-NOV-2024 to 23-JAN-2025 2 months 12 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Dexmethasone (C) | Hyonat (C) | Granexa (C) | Pheniramine (C) | Benexol (C) | Calcimax (C) | Folbiol (C) | Panto (C) | Zodinasil (C) | Bevitab (C) | Emend (C) | Granisetron (C) | Dekort (C) | Avil (C) | Moxitec (C) | Zygosis (C) | Cetryn (C)									
2024A165016	CHINA 31 Years Female	**Alanine aminotransferase increased (Alanine aminotransferase increased)***	Recovered	12-Jul-2024 15 days	CARBOPLATIN	Infusion	Intravenous use	28-JUN-2024 to 05-SEP-2024 2 months 9 days	Periodic Report Comment. Patient experienced alanine aminotransferase increased Inv:related to related to Carboplatin, Paclitaxel and Pembrolizumab, Inv, not related to Doxorubicin and Cyclophosphamide CCA: not related to study therapy

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PACLITAXEL	Infusion	Intravenous use	28-JUN-2024 to 19-SEP-2024 2 months 23 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | Ondansetron hydrochloride (C) | APREPITANT (C) | LACTULOSE (C)									
2024A190992	VIET NAM 52 Years Female	**Neutrophil count decreased (Neutrophil count decreased)***	Recovered	21-Aug-2024 2 months 30 days	CARBOPLATIN	Infusion	Intravenous use	23-MAY-2024 to 27-AUG-2024 3 months 5 days	
					PACLITAXEL	Infusion	80 milligram/sq. meter Intravenous use	23-MAY-2024 to 03-OCT-2024 4 months 11 days	
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	23-MAY-2024 to 27-AUG-2024 3 months 5 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | Tenofovir (C) | Dexamethason (C) | Dimedrol (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202501GLO029882CH	SWITZERLAND 41 Years Female	**Hepatic enzyme increased (Elevated liver enzymes)***	Recovered	31-Jan-2025 1 month 9 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	23-DEC-2024 to 13-JAN-2025 22 days	Periodic Report Comments. The patient experienced Unclear liver enzyme elevation, differential diagnosis therapy-induced. Investigator: Related to study therapy Durvalumab. Not related to Datopotamab Deruxtecan. CCA: Not related to Study therapy.
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Dexamethasone (C) | Dermovat (C) | Xyzal (C) | Lacrinorm (C) | Domperidon (C) | Ondansetron (C) | Pantoprazole (C) | Laxoberon (C) | Euthyrox (C) | Paracetamol (C) | Palonosetron (C) | Excipial U Lipolotio (C) | Novalgin (C) | Movicol (C) | Skinoren (C)									
202502GLO011848CN	CHINA 52 Years Female	**Platelet count decreased (Platelet count decreased)***	Recovered	15-Feb-2025 2 months 4 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	100 milligram/sq. meter q3w Intravenous use	03-JAN-2025 to 03-JAN-2025 1 day	
						Powder for solution for injection/infusion	100 milligram/sq. meter q3w Intravenous use	06-FEB-2025 to 06-FEB-2025 1 day	
						Powder for solution for injection/infusion	100 milligram/sq. meter q3w Intravenous use	12-DEC-2024 to 12-DEC-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					EPIRUBICIN	Infusion	150 milligram/sq. meter q3w Intravenous use	03-JAN-2025 to 03-JAN-2025 1 day	
						Infusion	150 milligram/sq. meter q3w Intravenous use	06-FEB-2025 to 06-FEB-2025 1 day	
						Infusion	150 milligram/sq. meter q3w Intravenous use	12-DEC-2024 to 12-DEC-2024 1 day	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	03-JAN-2025 to 03-JAN-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	06-FEB-2025 to 06-FEB-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	06-SEP-2024 to 06-SEP-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	07-NOV-2024 to 07-NOV-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	07-OCT-2024 to 07-OCT-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	12-DEC-2024 to 12-DEC-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	14-AUG-2024 to 14-AUG-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Amlodipine besylate (C) | Metformin (C) | Polyene phosphatidylcholine (C) | Bicyclol (C) | Dexamethasone sodium phosphate (C) | Methylprednisolone sodium succinate (C) | Palonosetron hydrochloride (C)									
202503GLO026521TR	TURKEY 66 Years Female	**White blood cell count decreased (WBC decreased)***	Recovered	28-Mar-2025 1 month 9 days	DOXORUBICIN HYDROCHLORIDE	Infusion	114 milligram/sq. meter q3w Intravenous use	20-FEB-2025 to 26-MAY-2025 3 months 7 days	The patient experienced Neutropenia and Decreased WBC. Investigator: related to Doxorubicin Hydrochloride, Cyclophosphamide, not related to Pembrolizumab, Paclitaxel, Carboplatin. Company: not related; Periodic Report Comments. Periodic comment: Patient experience Neutropenia and Decreased WBC . Investigator: Neutropenia Related to Doxorubicin and Cyclo-phosphamide. CCA: Not related to Study therapy. Investigator: Decreased WBC Related to Doxorubicin and Cyclo-phosphamide. CCA: Not related to Study therapy. Action Taken No change for all Study Therapy.;Periodic Report Comments. Periodic comment: Patient experience Neutropenia and Decreased WBC . Investigator: Neutropenia and Decreased WBC Related to Doxorubicin and Cyclo-phosphamide. CCA: Not related to Study therapy. Investigator: Decreased WBC Related to Doxorubicin and Cyclo-
					CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	20-MAR-2025 to 26-MAY-2025 2 months 7 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
									phosphamide. CCA: Not related to Study therapy. Action Taken No change for all Study Therapy.
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Euthyrox (C) | Vemlidy (C) | Systane (C) | Ocurin (C) | Pheniramine maleate (C) | Pantoprazole (C) | Granisetron (C) | Ecopirin (C) | Fraven (C)									
202504GLO010991US	UNITED STATES 62 Years Female	**Alanine aminotransferase increased (Alanine aminotransferase increased)*** Aspartate aminotransferase increased (Aspartate aminotransferase increased)	Not Recovered	10-Apr-2025 1 month 23 days	CARBOPLATIN	Infusion	Intravenous use	19-FEB-2025 to 09-APR-2025 1 month 22 days	Periodic Report Comments. The patient experienced elevated liver enzymes: The investigator causality for Pembrolizumab was related and for other its not related, company causality for all suspect was not related.
					PACLITAXEL	Infusion	162 milligram/sq. meter	02-APR-2025 to 02-APR-2025	
						Infusion	162 milligram/sq. meter	05-MAR-2025 to 05-MAR-2025	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	162 milligram/sq. meter	09-APR-2025 to 09-APR-2025 1 day	
						Infusion	162 milligram/sq. meter	12-MAR-2025 to 12-MAR-2025	
						Infusion	162 milligram/sq. meter	19-FEB-2025 to 19-FEB-2025 1 day	
						Infusion	162 milligram/sq. meter	19-MAR-2025 to 19-MAR-2025	
						Infusion	162 milligram/sq. meter	26-FEB-2025 to 26-FEB-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	162 milligram/sq. meter	26-MAR-2025 to 26-MAR-2025	
						Infusion	162 milligram/sq. meter qw Intravenous use	19-FEB-2025 to 09-APR-2025 1 month 22 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | CYCLOPHOSPHAMIDE (S) | Synthroid (C) | Telmisartan (C) | Hydrochlorothiazide (C) | Atorvastatin (C) | Colace (C) | Melatonin (C) | Benadryl (C) | Doxylamine succinate (C) | Prednisone (C)									
202504GLO027577IT	ITALY 36 Years Female	**Amylase increased (Serum amylase increased)***	Recovering	28-Apr-2025 2 months 4 days	DATOPOTAMAB DERUXTECAN	Injection	432 milligram/kilogram Intravenous use	25-FEB-2025 to 08-APR-2025 1 month 15 days	Periodic Report Comments. Patient experienced Serum amylase increased. Inv , Related to DATOPOTAMAB DERUXTECAN. Inv ,Not Related to DURVALUMAB. CCA : Not Related to DATOPOTAMAB DERUXTECAN. CCA : Not Related to DURVALUMAB.
Concomitant Medication(s): | DURVALUMAB (S) | Dexamethasone (C) | Artificial tears (C) | Chlorphenamine (C) | Paracetamol (C) | Pantoprazole (C) | Akynzeo (C)									
202505GLO013090MY	MALAYSIA 45 Years Female	**Amylase increased (Amylase increased)***	Not Recovered	14-May-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	to	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion	Intravenous use	to	
Concomitant Medication(s): | DURVALUMAB (S)									
202505GLO019700CN	CHINA 49 Years Female	**Neutrophil count decreased (Neutrophil count decreased)***	Recovered	22-May-2025 9 days	EPIRUBICIN	Infusion	90 milligram/sq. meter Intravenous use	14-MAY-2025 to 04-JUN-2025 22 days	Periodic Report Comments. Patient experienced Neutrophil count decreased: Related to Cyclophosphamide, Epirubicin and not related to Carboplatin, Paclitaxel and Pembrolizumab. Company causality assessment is not related.
						Infusion	90 milligram/sq. meter Intravenous use	25-JUN-2025 to 16-JUL-2025 22 days	
Concomitant Medication(s): CARBOPLATIN (S) | PEMBROLIZUMAB (S) | PACLITAXEL (S) | | CYCLOPHOSPHAMIDE (S) | Dexamethasone acetate (C) | Human insulin (C) | Potassium chloride (C) | Promethazine hydrochloride (C) | Tropisetron hydrochloride (C) | Paracetamol (C) | Vitamin b6 (C) | Raceanisodamine hydrochloride (C) | Ondansetron hydrochloride (C) | Telpegfilgrastim (C)									
202506GLO008845US	UNITED STATES 26 Years Female	**Platelet count decreased (Platelet count decreased)*** Febrile neutropenia (Febrile neutropenia)* Neutrophil count decreased (Neutrophil count decreased)* Anaemia (Anemia)*	Recovering	06-Jun-2025 nk	DOXORUBICIN HYDROCHLORIDE	Infusion	Intravenous use	to	Periodic Report Comments. Patient has event : Platelet count decreased, Febrile Neutropenia, neutrophil count decreased, Anemia. For study therapy Action Taken: no change, Investigator Causality: not Related, related for doxorubicin CC: Not Related. Outcome:

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
		Platelet count decreased (Platelet count decreased)* Febrile neutropenia (Febrile neutropenia) Neutrophil count decreased (Neutrophil count decreased)* Anaemia (Anemia)	Recovering	06-Jun-2025 nk	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	to	Recovering, recovere, recovering, recovering.
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | CARBOPLATIN (S) | | CYCLOPHOSPHAMIDE (S)									
202506GLO013173FR	FRANCE 53 Years Female	**Troponin T increased (Cardiac troponin T increased)***	Recovered	13-Jun-2025 5 months 5 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	09-JAN-2025 to 26-MAY-2025 4 months 18 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Prednisolone (C) | Primperan (C) | Paracetamol (C) | Macrogol (C) | Cetirizine (C)									
202507GLO013707JP	JAPAN 40 Years Female	**Neutrophil count decreased (Neutrophil count decreased)***	Recovered	15-Jul-2025 1 month 6 days	EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	10-JUN-2025 to 01-JUL-2025 22 days	Periodic Report Comments. Patient experienced Neutrophil count decreased, Investigator assessed the event to be related with Epirubicin and Cyclophosphamide, not related with Pembrolizumab, Paclitaxel and Carboplatin. CCA: not related.
						Infusion	90 milligram/sq. meter q3w Intravenous use	12-AUG-2025 to 12-AUG-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Dexart (C) | Mecobalamin (C) | White petrolatum (C) | Rozex (C) | Metoclopramide (C) | Esomeprazole (C) | Ursodeoxycholic acid (C)									

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO014825CA	CANADA 45 Years Female	**Neutrophil count decreased (Neutrophil count decreased)*** Productive cough (Productive cough)*	Recovered	15-Jul-2025 1 month 4 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter Intravenous use	12-JUN-2025 to 04-JUL-2025 23 days	
					DOXORUBICIN	Infusion	60 milligram/sq. meter Intravenous use	04-JUL-2025 to 04-JUL-2025 1 day	
						Infusion	60 milligram/sq. meter Intravenous use	12-JUN-2025 to 12-JUN-2025 1 day	
					CARBOPLATIN	Infusion	1.5 Intravenous use	02-APR-2025 to 02-APR-2025 1 day	
						Infusion	1.5 Intravenous use	05-JUN-2025 to 05-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1.5 Intravenous use	07-MAY-2025 to 07-MAY-2025 1 day	
						Infusion	1.5 Intravenous use	09-APR-2025 to 09-APR-2025 1 day	
						Infusion	1.5 Intravenous use	14-MAY-2025 to 14-MAY-2025 1 day	
						Infusion	1.5 Intravenous use	16-APR-2025 to 16-APR-2025 1 day	
						Infusion	1.5 Intravenous use	19-MAR-2025 to 19-MAR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1.5 Intravenous use	22-MAY-2025 to 22-MAY-2025 1 day	
						Infusion	1.5 Intravenous use	23-APR-2025 to 23-APR-2025 1 day	
						Infusion	1.5 Intravenous use	26-MAR-2025 to 26-MAR-2025 1 day	
						Infusion	1.5 Intravenous use	29-MAY-2025 to 29-MAY-2025 1 day	
						Infusion	1.5 Intravenous use	30-APR-2025 to 30-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PACLITAXEL	Infusion	80 milligram/sq. meter Intravenous use	02-APR-2025 to 02-APR-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	05-JUN-2025 to 05-JUN-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	07-MAY-2025 to 07-MAY-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	09-APR-2025 to 09-APR-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	14-MAY-2025 to 14-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	80 milligram/sq. meter Intravenous use	16-APR-2025 to 16-APR-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	19-MAR-2025 to 19-MAR-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	22-MAY-2025 to 22-MAY-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	23-APR-2025 to 23-APR-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	26-MAR-2025 to 26-MAR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	80 milligram/sq. meter Intravenous use	29-MAY-2025 to 29-MAY-2025 1 day	
						Infusion	80 milligram/sq. meter Intravenous use	30-APR-2025 to 30-APR-2025 1 day	
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	04-JUL-2025 to 04-JUL-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	09-APR-2025 to 09-APR-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	12-JUN-2025 to 12-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram Intravenous use	19-MAR-2025 to 19-MAR-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	22-MAY-2025 to 22-MAY-2025 1 day	
						Solution for infusion	200 milligram Intravenous use	30-APR-2025 to 30-APR-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Ondansetron (C) | Olanzapine (C) | Tylenol (C) | Tramacet (C) | Famotidine (C) | Benadryl (C) | Dexamethasone (C) | Loperamide (C) | Acetaminophen (C) | Azithromycin (C) | Cefazolin (C) | Ciprofloxacin (C) | Gravol (C) | Lapelga (C) | Pregabalin (C) | Prochlorperazine (C)									
202507GLO015058CN	CHINA 52 Years Female	**Lipase increased (Lipase increased)***	Recovered	07-May-2025 3 months 18 days	DATOPOTAMAB DERUXTECAN	Injection	279 milligram Intravenous use	20-JAN-2025 to 20-JUN-2025 5 months 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
		Lipase increased (Lipase increased)* Amylase increased (Amylase increased)*	Recovered	07-May-2025 3 months 18 days	DURVALUMAB	Infusion	1120 milligram Intravenous use	20-JAN-2025 to 20-JUN-2025 5 months 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | Levothyroxine (C) | Methylprednisolone (C) | Rivaroxaban (C) | Dexamethasone (C)									
202507GLO028033CN	CHINA 55 Years Female	**White blood cell count decreased (White blood cell decreased)*** Neutrophil count decreased (Neutrophil count decreased)	Recovered	31-Jul-2025 8 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	537 milligram/sq. meter Intravenous use	15-AUG-2025 to 26-SEP-2025 1 month 12 days	
						Powder for solution for injection/infusion	600 milligram/sq. meter Intravenous use	24-JUL-2025 to 24-JUL-2025 1 day	
		White blood cell count decreased (White blood cell decreased)* Neutrophil count decreased (Neutrophil count decreased)*	Recovered	31-Jul-2025 8 days	EPIRUBICIN	Infusion	79 milligram/sq. meter Intravenous use	15-AUG-2025 to 26-SEP-2025 1 month 12 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	90 milligram/sq. meter Intravenous use	24-JUL-2025 to 24-JUL-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Ondansetron hydrochloride (C) | Glycyrrhizin (C) | Vitamin C (C) | Bicyclol (C) | Esomeprazole (C) | Magnesium (C)									
202508GLO007727CN	CHINA 61 Years Female	**White blood cell count decreased (White blood cell count decreased)***	Recovered	08-Aug-2025 19 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	21-JUL-2025 to 02-OCT-2025 2 months 12 days	
					EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	31-JUL-2025 to 02-OCT-2025 2 months 2 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Diphenhydramine (C) | Ondansetron (C) | Dexamethasone (C)									
202508GLO021443US	UNITED STATES 58 Years Female	**Neutrophil count decreased (Neutrophil count decreased)*** Hypotension (Hypotension)	Recovered	25-Aug-2025 7 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	19-AUG-2025 to 09-SEP-2025 22 days	Periodic Report Comments. Patient experiencing Neutrophil Count decrease and Hypotension Grade 3 causality related to DOXORUBICIN HYDROCHLORIDE, CYCLOPHOSPHAMIDE and not related to CARBOPLATIN, PACLITAXEL,

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	30-SEP-2025 to 30-SEP-2025 1 day	PEMBROLIZUMAB ,CCA: not related.
		Neutrophil count decreased (Neutrophil count decreased)* Hypotension (Hypotension)*	Recovered	25-Aug-2025 7 days	DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	19-AUG-2025 to 09-SEP-2025 22 days	
						Infusion	60 milligram/sq. meter q3w Intravenous use	30-SEP-2025 to 30-SEP-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Atenolol (C) | Crestor (C) | Potassium chloride (C)									
202508GLO024991CN	CHINA 62 Years Female	**Platelet count decreased (Platelet count decreased)*** White blood cell count decreased (White blood cell decreased)* Neutrophil count decreased (Neutrophil count decreased)	Recovered	26-Aug-2025 24 days 4 hrs 50 min	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	01-AUG-2025 19:10 to 16-OCT-2025 22:23 2 months 15 days 3 hrs 13 min	Periodic Report Comments. Patient experienced platelet count decreased, white blood cell decreased and neutrophil count decreased. Inv: events related to Cyclophosphamide, Epirubicin, Pembrolizumab, not related to Carboplatin, Paclitaxel. CCA: not related.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
		Platelet count decreased (Platelet count decreased)*	Recovered	26-Aug-2025 24 days 6 hrs 35 min	EPIRUBICIN	Infusion	90 milligram/sq. meter Intravenous use	01-AUG-2025 17:25 to 16-OCT-2025 20:34 2 months 15 days 3 hrs 9 min	
		White blood cell count decreased (White blood cell decreased)* Neutrophil count decreased (Neutrophil count decreased)*							
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | CARBOPLATIN (S) | | EPIRUBICIN (S) | Tenofovir amibufenamide (C) | Levothyroxine sodium (C) | Diphenhydramine (C) | Cimetidine (C) | Netupitant (C) | Palonosetron hydrochloride (C) | Acetaminophen (C) | Dexamethasone sodium phosphate (C) | Fluconazole and sodium chloride (C) | Gentamicin (C) | Lidocaine hydrochloride (C) | Cefoperazone (C) | Rebamipide (C) | Mouth wash (C) | Bifid triple viable (C) | Dexrazoxane (C) | Diphenhydramine hydrochloride (C) | Omeprazole (C) | Ondansetron (C) | Coenzyme Q10 (C) | Rabeprazole sodium (C) | Mosapride citrate (C) | Tropisetron hydrochloride (C)									
202509GLO009914ES	SPAIN 46 Years Female	**Troponin I increased (High sensitivity troponin I increased)***	Not Recovered	10-Sep-2025 4 months 14 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	09-JUN-2025 to 09-JUN-2025 1 day	
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	19-MAY-2025 to 19-MAY-2025 1 day	
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	28-APR-2025 to 28-APR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	30-JUN-2025 to 30-JUN-2025 1 day	
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	09-JUN-2025 to 09-JUN-2025 1 day	
						Infusion	60 milligram/sq. meter q3w Intravenous use	19-MAY-2025 to 19-MAY-2025 1 day	
						Infusion	60 milligram/sq. meter q3w Intravenous use	28-APR-2025 to 28-APR-2025 1 day	
						Infusion	60 milligram/sq. meter q3w Intravenous use	30-JUN-2025 to 30-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Retinyl acetate (C) | Dexamethason (C) | Dexchlorpheniramine (C) | Famotidina (C) | Granisetron (C) | Filgrastim (C)									
202509GLO011024CN	CHINA 45 Years Female	**Platelet count decreased (Platelet count decreased)** White blood cell count decreased (White blood cell decreased) Neutrophil count decreased (Neutrophil count decreased)*	Recovered	03-Aug-2025 2 months 7 days	PEMBROLIZUMAB	Solution for infusion	Intravenous use	28-MAY-2025 to 26-SEP-2025 3 months 30 days	
		White blood cell count decreased (White blood cell decreased)* Neutrophil count decreased (Neutrophil count decreased)*	Recovered	12-Sep-2025 8 days	EPIRUBICIN	Infusion	Intravenous use	05-SEP-2025 to 26-SEP-2025 22 days	
					CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	04-SEP-2025 to 26-SEP-2025 23 days	
Concomitant Medication(s): | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Ora (C) | Glutathione (C)									
202509GLO018757US	UNITED STATES 78 Years Female	**Laboratory test abnormal (Lab test abnormal)***	Unknown	nk nk	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	19-AUG-2025 to	

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EudraCT No: 2023-505928-59-00

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DOXORUBICIN HYDROCHLORIDE	Infusion	Intravenous use	19-AUG-2025 to	
					DURVALUMAB	Infusion	Unknown	to	
					PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	22-MAY-2025 to	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | DOXORUBICIN HYDROCHLORIDE (S) | DURVALUMAB (S)									
202509GLO026291GB	UNITED KINGDOM 48 Years Female	**Alanine aminotransferase increased (ALT increased)***	Not Recovered	24-Sep-2025 2 months 10 days	CARBOPLATIN	Infusion	Intravenous use	15-JUL-2025 to 11-SEP-2025 1 month 28 days	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PACLITAXEL	Infusion	80 milligram/sq. meter qw	15-JUL-2025 to 18-SEP-2025 2 months 4 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | Dexamethasone (C) | Chlorphenamine (C)									
202510GLO000830CN	CHINA 40 Years Female	**Amylase increased (Serum amylase increased)***	Recovered	01-Sep-2025 5 months 20 days	DATOPOTAMAB DERUXTECAN	Injection	Unknown	13-MAR-2025 to 07-AUG-2025 4 months 26 days	
Concomitant Medication(s): | DURVALUMAB (S)									
202510GLO007837TW	TAIWAN 53 Years Female	**Neutrophil count decreased (Neutrophil count decreased)***	Recovered	08-Oct-2025 nk	EPIRUBICIN	Infusion	Intravenous use	to	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | CARBOPLATIN (S) | | CYCLOPHOSPHAMIDE (S) | Vemlidy (C) | Sevikar (C) | Sennapur (C) | Dexamethasone (C) | Dioctahedral smectite (C)									
202510GLO008843CN	CHINA 49 Years Female	**White blood cell count decreased (White blood cell count decreased)** Anaemia (Anemia) Febrile neutropenia (Febrile neutropenia)*	Not Recovered	30-Sep-2025 3 months 4 days	PEMBROLIZUMAB	Solution for infusion	Intravenous use	27-JUN-2025 to 25-SEP-2025 2 months 30 days	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
		White blood cell count decreased (White blood cell count decreased)*	Not Recovered	30-Sep-2025 6 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	25-SEP-2025 to 25-SEP-2025 1 day	
		Anaemia (Anemia) Febrile neutropenia (Febrile neutropenia)			EPIRUBICIN	Infusion	Intravenous use	25-SEP-2025 to 25-SEP-2025 1 day	
Concomitant Medication(s): | PACLITAXEL (S) | CARBOPLATIN (S) | CYCLOPHOSPHAMIDE (S) | EPIRUBICIN (S) | Celecoxib (C) | Cimetidine (C) | Dexamethasone (C) | Diphenhydramine (C) | Ilaprazole (C)									
202510GLO016344CN	CHINA 61 Years Female	**White blood cell count decreased (White blood cell decreased)***	Not Recovered	18-Oct-2025 nk	EPIRUBICIN	Infusion	Intravenous use	to	
		Neutrophil count decreased (Neutrophil count decreased)* Platelet count decreased (Platelet count decreased)*							
		White blood cell count decreased (White blood cell decreased)*	Not Recovered	18-Oct-2025 nk	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	to	
		Neutrophil count decreased (Neutrophil count decreased) Platelet count decreased (Platelet count decreased)*							
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S)									

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202510GLO023787CN	CHINA Female	**Lipase increased (Lipase increased)***	Recovered	07-May-2025 3 months 18 days	DATOPOTAMAB DERUXTECAN	Injection	Unknown	20-JAN-2025 to	

Concomitant Medication(s): | DURVALUMAB (S) | Dexamethasone (C) | Acetaminophen (C) | Diphenhydramine (C) | Ondansetron (C) | Roxithromycin (C) | Roxithromycin (C) | Bicyclol (C) | Methylprednisolone (C) | Prednisolone (C)

SOC:Metabolism and nutrition disorders

202412GLO002963PL	POLAND 67 Years Female	**Diabetes mellitus (Diabetes)***	Recovering	04-Dec-2024 2 months 3 days	PACLITAXEL	Infusion	80 milligram/sq. meter qw Intravenous use	02-OCT-2024 to 18-DEC-2024 2 months 17 days	

Concomitant Medication(s): PEMBROLIZUMAB (S) | | CARBOPLATIN (S) | CYCLOPHOSPHAMIDE (S) | DOXORUBICIN HYDROCHLORIDE (S) | Gensulin n (C) | Amoksiklav (C) | Atossa (C) | Metoclopramid (C)

2024A188383	JAPAN 58 Years Female	**Hyponatraemia (Hyponatremia)***	Recovered	14-Aug-2024 1 month 28 days					

Concomitant Medication(s):

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EudraCT No: 2023-505928-59-00

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Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202504GLO013411US	UNITED STATES 39 Years Female	**Hyperglycaemia (Hyperglycemia)***	Not Recovered	13-Apr-2025 1 month 25 days 10 hrs 55 min	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	02-JUL-2025 10:20 to 02-JUL-2025 10:53 33 min	Periodic Report Comments. Patient experienced Hyperglycemia, Inv, related Pembrolizumab and Paclitaxel and Carboplatin, the sponsor not considered the evidence to suggest a reasonable possibility of a causal relationship between the event and Pembrolizumab and Paclitaxel and Carboplatin; Periodic Report Comments. Patient experienced Hyperglycemia, Inv, related Pembrolizumab and Paclitaxel and Carboplatin, the sponsor not considered the evidence to suggest a reasonable possibility of a causal relationship between the event and Pembrolizumab and Paclitaxel and Carboplatin.
						Solution for infusion	200 milligram q3w Intravenous use	09-APR-2025 12:18 to 09-APR-2025 12:48 30 min	
						Solution for infusion	200 milligram q3w Intravenous use	11-JUN-2025 11:27 to 11-JUN-2025 12:01 34 min	
						Solution for infusion	200 milligram q3w Intravenous use	14-MAY-2025 11:21 to 14-MAY-2025 11:51 30 min	
						Solution for infusion	200 milligram q3w Intravenous use	18-FEB-2025 13:05 to 18-FEB-2025 13:35 30 min	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	19-MAR-2025 11:54 to 19-MAR-2025 12:24 30 min	
						Solution for infusion	200 milligram q3w Intravenous use	23-JUL-2025 11:26 to 23-JUL-2025 11:55 29 min	
					CARBOPLATIN	Infusion	1.5 Intravenous use	02-APR-2025 12:34 to 02-APR-2025 13:08 34 min	
						Infusion	1.5 Intravenous use	04-JUN-2025 12:00 to 04-JUN-2025 12:33 33 min	
						Infusion	1.5 Intravenous use	07-MAY-2025 11:16 to 07-MAY-2025 11:47 31 min	

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						Infusion	1.5 Intravenous use	09-APR-2025 14:33 to 09-APR-2025 15:04 31 min	
						Infusion	1.5 Intravenous use	12-MAR-2025 12:29 to 12-MAR-2025 12:57 28 min	
						Infusion	1.5 Intravenous use	14-MAY-2025 13:49 to 14-MAY-2025 14:30 41 min	
						Infusion	1.5 Intravenous use	18-FEB-2025 15:35 to 18-FEB-2025 16:05 30 min	
						Infusion	1.5 Intravenous use	19-MAR-2025 14:34 to 19-MAR-2025 15:02 28 min	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1.5 Intravenous use	26-FEB-2025 12:33 to 26-FEB-2025 13:05 32 min	
						Infusion	1.5 Intravenous use	26-MAR-2025 14:01 to 26-MAR-2025 14:32 31 min	
						Infusion	1.5 Intravenous use	28-MAY-2025 11:25 to 28-MAY-2025 11:56 31 min	
						Infusion	1.5 Intravenous use	30-APR-2025 14:40 to 30-APR-2025 15:10 30 min	
					PACLITAXEL	Infusion	65 milligram/sq. meter Intravenous use	04-JUN-2025 10:46 to 04-JUN-2025 11:49 1 hr 3 min	

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						Infusion	65 milligram/sq. meter Intravenous use	28-MAY-2025 10:20 to 28-MAY-2025 11:25 1 hr 5 min	
						Infusion	80 milligram/sq. meter Intravenous use	02-APR-2025 11:02 to 02-APR-2025 12:31 1 hr 29 min	
						Infusion	80 milligram/sq. meter Intravenous use	07-MAY-2025 10:15 to 07-MAY-2025 11:15 1 hr	
						Infusion	80 milligram/sq. meter Intravenous use	09-APR-2025 12:59 to 09-APR-2025 14:29 1 hr 30 min	
						Infusion	80 milligram/sq. meter Intravenous use	12-MAR-2025 11:21 to 12-MAR-2025 12:24 1 hr 3 min	

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						Infusion	80 milligram/sq. meter Intravenous use	14-MAY-2025 11:55 to 14-MAY-2025 13:33 1 hr 38 min	
						Infusion	80 milligram/sq. meter Intravenous use	18-FEB-2025 14:04 to 18-FEB-2025 15:25 1 hr 21 min	
						Infusion	80 milligram/sq. meter Intravenous use	19-MAR-2025 12:35 to 19-MAR-2025 12:56 21 min	
						Infusion	80 milligram/sq. meter Intravenous use	26-FEB-2025 11:15 to 26-FEB-2025 12:16 1 hr 1 min	
						Infusion	80 milligram/sq. meter Intravenous use	26-MAR-2025 12:52 to 26-MAR-2025 13:52 1 hr	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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						Infusion	80 milligram/sq. meter Intravenous use	30-APR-2025 13:38 to 30-APR-2025 14:39 1 hr 1 min	
Concomitant Medication(s): | CARBOPLATIN (S) | PACLITAXEL (S) | CYCLOPHOSPHAMIDE (S) | DOXORUBICIN (S) | Phentermine (C) | Biotin (C) | Omeprazole (C) | Zypraz (C) | Prochlorperazine (C) | Azithromycin (C) | Gabapentin (C) | Olanzapine (C) | Benadryl (C) | Levothyroxine (C) | Methocarbamol (C) | Tramadol (C) | Alprazolam (C) | Mounjaro (C) | Tirzepatide (C) | Vitamin d (C) | Multivitamins (C) | Lidocaine (C) | Pantoprazole (C) | Cetirizine (C) | Acetaminophen (C) | Insulin aspart (C) | Metformin (C) | Basaglar kwikpen (C) | Ubrelvy (C)									
202505GLO011551CN	CHINA 51 Years Female	**Hyponatraemia (Hyponatremia)*** Depressed level of consciousness (Consciousness clouding)*	Recovered	13-May-2025 5 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	09-MAY-2025 to 09-MAY-2025 1 day	Periodic Report Comments. Patient experienced clouding of consciousness and hyponatremia. Inv: events related to Durvalumab, not related to Datopotamab deruxtecan. CCA: not related.
Concomitant Medication(s): | DATOPOTAMAB DERUXTECAN (S) | Sodium chloride (C) | Ondansetron hydrochloride (C) | Potassium chloride (C)									
202505GLO020961CN	CHINA 37 Years Female	**Diabetic ketoacidosis (Diabetic ketoacidosis)***	Recovered with Sequelae	21-May-2025 4 months 8 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	27-FEB-2025 to 29-APR-2025 2 months 3 days	Periodic Report Comments. The patient experienced serious Diabetic ketoacidosis ,related to study therapy, CCA:Not related.
						Injection	6 milligram/kilogram q3w Intravenous use	14-JAN-2025 to 06-FEB-2025 24 days	

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Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	14-JAN-2025 to 29-APR-2025 3 months 16 days	
Concomitant Medication(s): | DURVALUMAB (S) | Ora (C) | Sodium hyaluronate (C) | Insulin degludec (C) | Lidocaine (C)									
202507GLO004661CN	CHINA 44 Years Female	**Hyponatraemia (Hyponatremia)***	Recovered	03-Jul-2025 29 days	EPIRUBICIN	Infusion	90 milligram/sq. meter q3w Intravenous use	05-JUN-2025 to 05-AUG-2025 2 months 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Bicyclol (C) | Levothyroxine sodium (C)									
202507GLO011075US	UNITED STATES 63 Years Female	**Dehydration (Dehydration)***	Recovered	20-Jun-2025 1 month 27 days	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	25-APR-2025 to 08-AUG-2025 3 months 15 days	
Concomitant Medication(s): | DURVALUMAB (S) | Atorvastatin (C) | Asprin (C) | Nystatin (C) | Prochlorperazine (C) | Ondansetron (C) | Palonosetron (C) | Acetaminophen (C) | Diphenhydramine (C)									
202507GLO011077CA	CANADA 71 Years Female	**Diabetic ketoacidosis (Type I diabetes mellitus with ketoacidosis)***	Recovered	08-Jul-2025 1 year 5 months 27 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	12-JAN-2024 to 19-FEB-2025 1 year 1 month 8 days	Periodic Report Comments. Patient experienced the event DM type I DKA, Investigator did not assess the causality with study therapy, CCA: not related with study therapy.
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Dermovate (C) | Vitamin d3 (C) | Synthroid (C)									

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO013696KR	KOREA, REPUBLIC OF 66 Years Female	**Hyperglycaemia (Hyperglycemia)***	Not Recovered	15-Jul-2025 1 year 1 month 17 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	28-MAY-2024 to 12-JUN-2025	PRC. Patient experienced Hyperglycemia. Investigator: not related with Datopotamab deruxtecan and capecitabine and related with durvalumab. Company physician: Not related with study therapy.
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | CAPECITABINE (S) | Hyabak (C) | Dexamethasone (C) | Dexamethasone disodium phosphate (C) | Pheniramine (C)									
202509GLO000664CN	CHINA 68 Years Female	**Decreased appetite (Appetite lost)***	Recovered	01-Sep-2025 1 month 15 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	18-JUL-2025 to 29-AUG-2025 1 month 12 days	Periodic Report Comments. The patient experienced Appetite lost. Investigator causality not related to Pembrolizumab, Paclitaxel and Carboplatin and related to Epirubicin, Cyclo-phosphamide. CCA not related.
Concomitant Medication(s): PEMBROLIZUMAB (S) | EPIRUBICIN (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Diphenhydramine hydrochloride (C) | Omeprazole sodium (C) | Polyene phosphatidylcholine (C) | Dexamethasone sodium phosphate (C) | Cimetidine (C) | Magnesium Isoglycyrrhizinate (C) | Human erythropoietin (C) | Tropisetron hydrochloride (C) | Compound paracetamol and diphenhydramine hydrochloride (C) | Levothyroxine (C) | Nifedipine (C) | Netupitant and palonosetron hydrochloride (C) | Potassium chloride (C) | Olanzapine (C) | Metoprolol (C) | Glycerin (C) | Polysaccharide iron (C) | Benzhydramine hydrochloride (C) | Metoprolol succinate (C) | Pantoprazole sodium (C) | Pegylated recombinant human granulocyte colony-stimulating factor (C) | Rebamipide (C) | Lactulose (C) | Mosapride citrate (C) | Leucogen (C) | Sheng xue bao (C) | Calcium gluconate (C) | Trimebutine maleate (C) | Silibinin (C)									
202509GLO017020KR	KOREA, REPUBLIC OF 66 Years Female	**Diabetes mellitus (Diabetes mellitus)***	Not Recovered	05-Aug-2025 1 year 2 months 9 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	28-MAY-2024 to 12-JUN-2025 1 year 16 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | CAPECITABINE (S) | Encover (C) | Akynzeo (C)									

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Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202510GLO006637BR	BRAZIL 47 Years Female	**Hypokalaemia (Hypokalemia)***	Not Recovered	12-Jul-2025 20 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	23-JUN-2025 to 01-SEP-2025 2 months 10 days	Periodic Report Comments. Patient experienced hypokalemia, Investigator assessed the event to be related with Cyclophosphamide and Doxorubicin and not related with Pembrolizumab, Paclitaxel, Carboplatin. CCA: not related.
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	23-JUN-2025 to 01-SEP-2025 2 months 10 days	

Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S)

SOC:Musculoskeletal and connective tissue disorders

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202501GLO004192US	UNITED STATES 71 Years Female	**Back pain (Back pain)***	Not Recovered	26-Dec-2024 2 months 24 days	CARBOPLATIN	Infusion	Intravenous use	03-OCT-2024 to 17-DEC-2024 2 months 15 days	The patient experienced pain (back) and pain (abdominal). Investigator: related to Pembrolizumab, Carboplatin for pain (back). Not related to Cyclophosphamide, Doxorubicin Hydrochloride, Paclitaxel for pain (back). Not related to Pembrolizumab, Carboplatin, Paclitaxel, Cyclophosphamide, Doxorubicin Hydrochloride. Company: Not related to Pembrolizumab, Carboplatin, Paclitaxel. Not applicable to Cyclophosphamide,

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
									Doxorubicin Hydrochloride.
Concomitant Medication(s): PEMBROLIZUMAB (S) | CYCLOPHOSPHAMIDE (S) | DOXORUBICIN HYDROCHLORIDE (S) | PACLITAXEL (S) | | Metformin (C) | Colace (C) | Prednisone (C)									
202506GLO017790US	UNITED STATES 40 Years Female	**Back pain (Back pain)***	Recovering	10-Jun-2025 7 months 20 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	22-OCT-2024 to 25-FEB-2025 4 months 4 days	Patient experienced back pain investigator causality not reported to Dato-DXd, durvalumab, CCA not related.;Periodic Report Comments. Patient experienced the event "Back pain" . INV casuality related to DATOPOTAMAB DERUXTECAN & not related to DURVALUMAB. Company causality not related to DATOPOTAMAB DERUXTECAN & DURVALUMAB.
Concomitant Medication(s): | DURVALUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | Diphenhydramine (C) | Ibuprofen (C) | Lidocaine (C) | Maalox (C) | Hydrocodone (C) | Acetaminophen (C)									

SOC:Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507EEA024453FR	FRANCE Female	**Malignant neoplasm progression (Malignant neoplasm progression)***	Unknown	nk nk	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	to	
					DURVALUMAB	Infusion	Intravenous use	to	
Concomitant Medication(s): | DURVALUMAB (S)									
SOC:Nervous system disorders									
202504GLO026550DE	GERMANY 70 Years Female	**Syncope (Syncope)***	Recovered	27-Apr-2025 2 months 11 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	17-FEB-2025 to 31-MAR-2025 1 month 15 days	Periodic Report Comments. Patient experienced event Syncopic event. Action taken with study therapy was No change. Investigator Causality: Related, CC: Not Related for Datopotamab Deruxtecan. Investigator Causality: Not Related, CC: Not Related for Durvalumab.
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	17-FEB-2025 to 31-MAR-2025 1 month 15 days	
Concomitant Medication(s): | DURVALUMAB (S) | Ramipril (C) | Calcium (C) | Dekristol (C) | Dexamethason (C) | Akynzeo (C) | Ampho moronal (C) | Movicol (C) | Ondansetron (C) | Clexane (C)									

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Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202504GLO028512DE	GERMANY 70 Years Female	**Syncope (Syncope)***	Recovered	01-May-2025 2 months 15 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	17-FEB-2025 to 17-JUL-2025 5 months 1 day	periodic report comment. Patient experienced fall with syncopic event, inv: related to DATOPOTAMAB DERUXTECAN and Durvalumab, cca: not related to DATOPOTAMAB DERUXTECAN and Durvalumab.
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	17-FEB-2025 to 17-JUL-2025 5 months 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | Ramipril (C) | Calcium (C) | Dekristol (C) | Dexamethason (C) | Akynzeo (C)									
202505GLO001429FR	FRANCE 49 Years Female	**Dizziness (Dizziness)***	Not Recovered	25-Feb-2025 1 month 2 days	CARBOPLATIN	Infusion	Intravenous use	20-MAR-2025 to 17-APR-2025 29 days	Periodic Report Comments. The patient experienced Dizziness on mobilization Investigator: Not related to Pembrolizumab and Related to Carboplatin, Paclitaxel. Company physician: Not related to study therapy.
						Infusion	Intravenous use	24-JAN-2025 to 07-MAR-2025 1 month 12 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | Omeprazole (C) | Quetiapine (C) | Paroxetine (C) | Doliprane (C)									

SOC:Renal and urinary disorders

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Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202503GLO012643DE	GERMANY 55 Years Female	**Renal failure (Renal failure)***	Recovered	13-Mar-2025 3 months 20 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	22-NOV-2024 to 14-FEB-2025 2 months 24 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Fosaprepitant (C) | Palonosetron (C) | Dexamethason (C) | Paracetamol (C) | Candesartan (C)									
202504GLO009366FR	FRANCE 59 Years Female	**Autoimmune nephritis (Autoimmune nephritis)***	Recovered	08-Apr-2025 29 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	11-MAR-2025 to 11-MAR-2025 1 day	Periodic Report Comments. Patient experienced suspected autoimmune nephritis. Investigator causality for all suspects: Related. CC for all suspects: Not Related. Outcome: Not Recovered. Action Taken: Withdrawn
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	11-MAR-2025 to 11-MAR-2025 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | Atorvastatine (C) | Polaramine (C) | Paracetamol A (C) | Solumedrol (C) | Zophren (C) | Forlax (C)									
202507GLO005949PL	POLAND 67 Years Female	**Acute kidney injury (Acute kidney failure)***	Not Recovered	01-Jul-2025 6 months 12 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	07-APR-2025 to 07-APR-2025 1 day	Periodic Report Comments. Patient experienced acute kidney failure, investigator: not related to DATOPOTAMAB DERUXTECAN, related to DURVALUMAB, sepsis, investigator: related to DATOPOTAMAB DERUXTECAN, not related to DURVALUMAB, cca for both events: not related to

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	10-JAN-2025 to 10-JAN-2025 1 day	DATOPOTAMAB DERUXTECAN, DURVALUMAB.
						Infusion	1120 milligram q3w Intravenous use	17-MAR-2025 to 17-MAR-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	20-DEC-2024 to 20-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	21-FEB-2025 to 21-FEB-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	31-JAN-2025 to 31-JAN-2025 1 day	

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Atarax (C) | Concor (C) | Trimbow (C)									
202508GLO023565IT	ITALY 56 Years Female	**Acute kidney injury (Acute kidney injury)***	Recovered	18-Aug-2025 2 months 29 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	21-MAY-2025 to 31-JUL-2025 2 months 11 days	Periodic Report Comment. Patient experienced Fever, Inv: related to study therapy, CCA: not related to study therapy.
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	21-MAY-2025 to 31-JUL-2025 2 months 11 days	
Concomitant Medication(s): | DURVALUMAB (S) | Omeprazole (C)									

SOC:Reproductive system and breast disorders

202510GLO012090CA	CANADA 37 Years Female	**Heavy menstrual bleeding (Menorrhagia)***	Not Recovered	07-Oct-2025 6 months 18 days	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	20-MAR-2025 to 25-JUL-2025 4 months 6 days	Periodic Report Comments. Patient experienced event Pain. Investigator states event related to DATOPOTAMAB DERUXTECAN and DURVALUMAB. Company physician considers event related to DATOPOTAMAB DERUXTECAN and DURVALUMAB.
Concomitant Medication(s): | DURVALUMAB (S) | Sertraline (C) | Dexamethasone (C) | Amoxicillin (C) | Triamcinolone acetonide (C) | Zolpidem (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Respiratory, thoracic and mediastinal disorders									
202410GLO025057ES	SPAIN 61 Years Female	**Immune-mediated lung disease (Immune-mediated pneumonitis)***	Recovered	25-Oct-2024 3 months 29 days	PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	27-JUN-2024 to 09-OCT-2024 3 months 13 days	The patient experienced Immune-mediated pneumonitis: Event related to Pembrolizumab and not related to Carboplatin, Cyclophosphamide, Epirubicin, Paclitaxel; CCA: related to Pembrolizumab and not related to Carboplatin, Cyclophosphamide, Epirubicin, Paclitaxel
Concomitant Medication(s): | EPIRUBICIN (S) | CYCLOPHOSPHAMIDE (S) | CARBOPLATIN (S) | PACLITAXEL (S) | Prednisone (C)									
2024A069295	KOREA, REPUBLIC OF 39 Years Female	**Interstitial lung disease (Interstitial lung disease)***	Recovered	19-Mar-2024 1 month 25 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	14-FEB-2024 to 14-FEB-2024 1 day	Periodic Report Comment. Patient with history of mucositis and productive cough. Labs included HRCT : Diffuse subpleural reticular opacity, GGO in both lungs, slightly increased.;Patient has event: Interstitial lung disease. For study therapy Action Taken: drug interrupted, Investigator Causality: Related, CC: Not Related. Outcome: Recovered.
						Injection	6 milligram/kilogram Intravenous use	24-JAN-2024 to 24-JAN-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	08-MAR-2024 to 08-MAR-2024 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CAPECITABINE (S) | Tacenol (C) | Hyalein (C) | Encover (C) | Tantum (C) | Remicut (C) | Dexamethasone (C) | Klenzo (C) | Lidocaina viscosa (C) | Codewon (C) | Muteran (C) | Aloxi (C) | Phenil (C) | Dexamethasone (C)									
202504GLO014920JP	JAPAN 53 Years Female	**Oropharyngeal pain (Sore throat)***	Recovered	13-Apr-2025 5 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	09-APR-2025 to 19-MAY-2025 1 month 11 days	
Concomitant Medication(s): | DURVALUMAB (S) | Hyalein (C) | Azunol (C) | Calonal (C) | Palonosetron (C) | Dexart (C) | Polaramine (C) | Nasea (C) | Sennoside (C)									
202504GLO017071SG	SINGAPORE 66 Years Female	**Pulmonary embolism (Pulmonary embolism)***	Recovering	17-Apr-2025 5 months 21 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	05-AUG-2025 to 05-AUG-2025 1 day	
						Infusion	1120 milligram q3w Intravenous use	07-JAN-2025 to 02-APR-2025 2 months 27 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	09-DEC-2024 to 09-DEC-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-NOV-2024 to 18-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-OCT-2024 to 05-AUG-2025 9 months 9 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | PACLITAXEL (S) | CARBOPLATIN (S)									
202505GLO023488US	UNITED STATES 55 Years Female	**Pulmonary embolism (Pulmonary embolism)***	Recovering	22-May-2025 1 month 23 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	31-MAR-2025 to 21-JUL-2025 3 months 21 days	
Concomitant Medication(s): | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | DOXORUBICIN HYDROCHLORIDE (S) | Pepcid (C) | Prevacid (C) | Prilosec (C) | Venlafaxine (C) | Crestor (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202506GLO021327BE	BELGIUM 37 Years Female	**Laryngeal inflammation (Laryngeal mucositis)***	Recovered	19-Mar-2025 10 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	10-MAR-2025 to 04-AUG-2025 4 months 26 days	
Concomitant Medication(s): | DURVALUMAB (S) | Alizapride (C) | Pantomed (C)									
202508GLO025049JP	JAPAN 62 Years Female	**Pneumonitis (Pneumonitis)***	Not Recovered	29-Aug-2025 2 months 3 days	EPIRUBICIN	Infusion	166.9 milligram q3w Intravenous use	27-JUN-2025 to 10-OCT-2025 3 months 14 days	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S)									
202508GLO025171US	UNITED STATES 71 Years Female	**Pulmonary embolism (Pulmonary embolism)***	Not Recovered	27-Aug-2025 13 days	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	600 milligram/sq. meter q3w Intravenous use	15-AUG-2025 to 15-AUG-2025 1 day	
					DOXORUBICIN HYDROCHLORIDE	Infusion	60 milligram/sq. meter q3w Intravenous use	15-AUG-2025 to 15-AUG-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					PEMBROLIZUMAB	Solution for infusion	200 milligram	09-MAY-2025 to 09-MAY-2025	
						Solution for infusion	200 milligram	18-JUL-2025 to 18-JUL-2025	
						Solution for infusion	200 milligram	27-JUN-2025 to 27-JUN-2025	
						Solution for infusion	200 milligram	30-MAY-2025 to 30-MAY-2025	
						Solution for infusion	200 milligram q3w Intravenous use	09-MAY-2025 to 28-JUL-2025 2 months 20 days	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Metoprolol (C) | Lovastatin (C) | Furosemide (C) | Lisinopril (C) | Asprin (C)									
SOC:Skin and subcutaneous tissue disorders									
2024A160977	CANADA 41 Years Female	**Rash maculo-papular (Rash maculo-papular)***	Recovered	08-Jul-2024 11 days	CARBOPLATIN	Infusion	q3w Intravenous use	28-JUN-2024 to 20-SEP-2024 2 months 24 days	Periodic Report Comment. female patient expereinced Rash maculo-papular-serious related to study therapy CCA related to pembrolizumab.
					PACLITAXEL	Infusion	157 milligram/sq. meter qw Intravenous use	28-JUN-2024 to 20-SEP-2024 2 months 24 days	
Concomitant Medication(s): PACLITAXEL (S) | PEMBROLIZUMAB (S) | | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | Benadryl (C) | Bilastine (C) | Multivitamin (C) | Ondansetron (C) | Vitamin c (C)									
202506GLO004137JP	JAPAN 47 Years Female	**Erythema multiforme (Erythema multiforme)***	Recovered	23-May-2025 8 days	CARBOPLATIN	Infusion	Intravenous use	16-MAY-2025 to 16-MAY-2025 1 day	Patient experienced fever, related to pembrolizumab, not related for carboplatin and paclitaxel, Erythema multiforme, related to pembrolizumab, related for carboplatin and paclitaxel. CCA, not related.
						Infusion	Intravenous use	23-MAY-2025 to 23-MAY-2025 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | Bayaspirin (C) | Rebamipide (C) | Dexart (C) | Famotidine (C) | Granisetron (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO025779TR	TURKEY 55 Years Female	**Cutaneous vasculitis (Leukocytoclastic vasculitis)***	Recovered	29-Jul-2025 9 months 5 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	25-OCT-2024 to 20-MAR-2025 4 months 24 days	
Concomitant Medication(s): | DURVALUMAB (S) | CAPECITABINE (S) | Kenacort a (C) | Methylprednisolone (C)									
202510GLO005605JP	JAPAN 63 Years Female	**Drug eruption (Papuloerythematous drug eruption)***	Recovering	04-Oct-2025 7 months 22 days	PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	13-FEB-2025 to 25-JUL-2025 5 months 13 days	
Concomitant Medication(s): | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S) | PACLITAXEL (S) | CARBOPLATIN (S) | Levofloxacin (C) | Granisetron hydrochloride (C)									
SOC:Vascular disorders									
202411GLO017171CA	CANADA 48 Years Female	**Deep vein thrombosis (Deep vein thrombosis)***	Recovered	19-Nov-2024 3 months 29 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	22-JUL-2024 to 27-NOV-2024 4 months 6 days	
					DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	22-JUL-2024 to 27-NOV-2024 4 months 6 days	
Concomitant Medication(s): | DURVALUMAB (S) | Zopiclone (C) | Tylenol (C) | Advil (C) | Pantoloc (C) | Venlafaxine (C) | Zantac (C) | Imodium (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO009845BR	BRAZIL 36 Years Female	**Hypotension (Hypotension)***	Recovered	13-Aug-2025 2 months 23 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	22-MAY-2025 to 01-OCT-2025 4 months 10 days	
Concomitant Medication(s): | PACLITAXEL (S) | CARBOPLATIN (S) | DOXORUBICIN HYDROCHLORIDE (S) | CYCLOPHOSPHAMIDE (S)									
202509GLO016934CA	CANADA 46 Years Female	**Capillary leak syndrome (Capillary leak syndrome)*** Haemophagocytic lymphohistiocytosis (Hemophagocytic lymphohistiocytosis)* Multiple organ dysfunction syndrome (Multi organ failure)*	Fatal	nk nk	CYCLOPHOSPHAMIDE	Powder for solution for injection/infusion	Intravenous use	to	
					DOXORUBICIN HYDROCHLORIDE	Infusion	200 milligram q3w Intravenous use	07-AUG-2025 to 28-AUG-2025 22 days	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	07-AUG-2025 10:34 to 18-SEP-2025 11:05 1 month 11 days 31 min	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926Q

Study ID: D926QC00001

EudraCT No: 2023-505928-59-00

Study Design: Not Blinded

Study Description: D926QC00001 TROPION-Breast04 - A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients with Untreated Triple-Negative or Hormone Receptor low/HER2-negative Breast Cancer (D926QC00001; TROPION Breast04)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
		Capillary leak syndrome (Capillary leak syndrome)*	Fatal	nk nk	CARBOPLATIN	Infusion	Intravenous use	07-AUG-2025 13:48 to 18-SEP-2025 14:40 1 month 11 days 52 min	
		Haemophagocytic lymphohistiocytosis (Hemophagocytic lymphohistiocytosis)* Multiple organ dysfunction syndrome (Multi organ failure)* Anaemia (Anemia)*			PACLITAXEL	Infusion	80 milligram/sq. meter q3w Intravenous use	07-AUG-2025 12:20 to 18-SEP-2025 11:50 1 month 10 days 23 hrs 30 min	

Concomitant Medication(s): PEMBROLIZUMAB (S) | DOXORUBICIN HYDROCHLORIDE (S) | | PACLITAXEL (S) | CARBOPLATIN (S) | Vitamin C (C) | Famotidine (C) | Benadryl (C) | Olanzapine (C) | Ondansetron (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926U

Study ID: D926UC00001

EudraCT No: 2023-509436-26-00

Study Design: Not Blinded

Study Description: D926UC00001 Proof of Principle (PoP) Study - A Phase II, Multicentre, Open-label, Master Protocol to Evaluate the Efficacy and Safety of Datopotamab-Deruxtecan (Dato-DXd) as Monotherapy and in Combination with Anticancer Agents in Patients with Advanced/Metastatic Solid Tumours

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Gastrointestinal disorders									
202505GLO022580ES	SPAIN 74.4 Years Female	**Stomatitis (Mucositis oral)***	Not Recovered	27-May-2025 6 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	22-MAY-2025 to 13-JUN-2025 23 days	Periodic Report Comments. The patient experienced serious ORAL MUCOSITIS related to study therapy . CCA:Not related.
Concomitant Medication(s): | 5-FLUOROURACIL (S) | Dexamethasone (C) | Mycostatin (C) | Aloclair (C) | Lidocaine (C) | Ondansetron (C) | Paracetamol (C) | Enema (C)									
202508GLO023927ES	SPAIN 70.7 Years Male	**Stomatitis (Mucositis oral)***	Recovered	28-Aug-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	06-MAY-2025 to 06-MAY-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	09-JUL-2025 to 09-JUL-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	17-JUN-2025 to 17-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926U

Study ID: D926UC00001

EudraCT No: 2023-509436-26-00

Study Design: Not Blinded

Study Description: D926UC00001 Proof of Principle (PoP) Study - A Phase II, Multicentre, Open-label, Master Protocol to Evaluate the Efficacy and Safety of Datopotamab-Deruxtecan (Dato-DXd) as Monotherapy and in Combination with Anticancer Agents in Patients with Advanced/Metastatic Solid Tumours

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	4 milligram/kilogram q3w Intravenous use	19-AUG-2025 to 30-SEP-2025 1 month 12 days	
						Injection	4 milligram/kilogram q3w Intravenous use	25-MAR-2025 to 25-MAR-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	27-MAY-2025 to 27-MAY-2025 1 day	
						Injection	4 milligram/kilogram q3w Intravenous use	29-JUL-2025 to 29-JUL-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	09-JAN-2025 to 09-JAN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926U

Study ID: D926UC00001

EudraCT No: 2023-509436-26-00

Study Design: Not Blinded

Study Description: D926UC00001 Proof of Principle (PoP) Study - A Phase II, Multicentre, Open-label, Master Protocol to Evaluate the Efficacy and Safety of Datopotamab-Deruxtecan (Dato-DXd) as Monotherapy and in Combination with Anticancer Agents in Patients with Advanced/Metastatic Solid Tumours

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	6 milligram/kilogram q3w Intravenous use	19-FEB-2025 to 19-FEB-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	30-JAN-2025 to 30-JAN-2025 1 day	
Concomitant Medication(s): | Atorvastatin (C) | Famotidine (C) | Lantus (C) | Noctamid (C) | Prednisone (C) | Sitagliptin (C) | Dexamethasone (C) | Ondansetron (C) | Paracetamol (C) | Polaramine (C) | Pantoprazole (C) | Gelclair (C) | Denvar (C) | Budesonide (C)									
SOC:Infections and infestations									
202412GLO018716CA	CANADA 64 Years Female	**Bacteraemia (Bacteremia)***	Recovered	20-Dec-2024 1 month 15 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	03-DEC-2024 to 03-DEC-2024 1 day	Patient experienced Liver abscess. Investigator causality related to study therapy, CCA not related.
						Injection	6 milligram/kilogram q3w Intravenous use	06-NOV-2024 to 06-NOV-2024 1 day	
Concomitant Medication(s): | Acetaminophene (C) | Dexamethasone (C) | Granisetron (C) | Esomeprazole (C) | Systane (C) | Nutricap (C) | Lorazepam (C) | Daltepan (C) | Celecoxib (C) | Hydromorphone (C) | Artificial tears (C) | Diphenhydramine (C) | Polyethylene (C) | Mouth wash (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926U

Study ID: D926UC00001

EudraCT No: 2023-509436-26-00

Study Design: Not Blinded

Study Description: D926UC00001 Proof of Principle (PoP) Study - A Phase II, Multicentre, Open-label, Master Protocol to Evaluate the Efficacy and Safety of Datopotamab-Deruxtecan (Dato-DXd) as Monotherapy and in Combination with Anticancer Agents in Patients with Advanced/Metastatic Solid Tumours

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Cardiac disorders									
202409GLO009425US	UNITED STATES 31.7 Years Female	**Arteriospasm coronary (Coronary vasospasm)***	Recovered	23-Sep-2024 4 days	CAPECITABINE	Tablet	Oral use	23-SEP-2024 to 02-OCT-2024 10 days	Event related to Capecitabine, Pembrolizumab. Company causality Not related to Capecitabine, Pembrolizumab.
						Tablet	1000 milligram/sq. meter q3w Oral use	20-SEP-2024 to 23-SEP-2024 4 days	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	19-SEP-2024 to 19-SEP-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	02-MAY-2025 to 02-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	05-FEB-2025 to 05-FEB-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	09-OCT-2024 to 09-OCT-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	11-APR-2025 to 11-APR-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	18-DEC-2024 to 18-DEC-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	20-MAR-2025 to 20-MAR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	27-FEB-2025 to 27-FEB-2025 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	30-OCT-2024 to 30-OCT-2024 1 day	

Concomitant Medication(s): PEMBROLIZUMAB (S) | | Alprazolam (C) | Fluoxetine (C) | Zolpidem (C) | Loperamide (C) | Dextroamphetamine (C) | Dexamethasone (C) | Lorazepam (C) | Omeprazole (C) | Acetaminophen (C) | Prednisone (C) | Doxycycline (C) | Amlodipine (C) | Adderall (C)

SOC:Eye disorders

202507GLO011755US	UNITED STATES 50.9 Years Female	**Retinal vascular disorder (Retinal vascular disorder)***	Recovering	17-Nov-2024 5 days	DATOPOTAMAB DERUXTECAN	Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	13-NOV-2024 to 13-NOV-2024 1 day	PRC. Patient experienced retinal vascular disorder (right eye). Investigator: related with study therapy. Company physician: not related.

Concomitant Medication(s): | Levothyroxine (C) | Dexamethasone (C) | Refresh celluvisc (C) | Latanoprost (C) | Artificial tears (C) | Prednisone (C) | Latanoprost + timolol mylan (C)

SOC:Gastrointestinal disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202409GLO014128US	UNITED STATES 37 Years Female	**Stomatitis (Mucositis oral)***	Recovered	06-Sep-2024 15 days	DATOPOTAMAB DERUXTECAN	Concentrate for solution for infusion	Intravenous use	23-AUG-2024 to 23-AUG-2024 1 day	Periodic Report Comments. patient experience mucositis/oral mucosal inflammation. study therapy-related, CCA- related.
Concomitant Medication(s): | Hydrocodone/acetaminophen (S) | Synthroid (C)									
2024A156797	UNITED STATES 34.5 Years Female	**Colitis (Colitis)***	Not Recovered	07-Jul-2024 5 months 3 days	DATOPOTAMAB DERUXTECAN	Concentrate for solution for infusion	4 milligram/kilogram q3w Intravenous use	10-JUN-2024 to 10-JUN-2024 1 day	
						Concentrate for solution for infusion	4 milligram/kilogram q3w Intravenous use	20-MAY-2024 to 20-MAY-2024 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	05-FEB-2024 to 05-FEB-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	05-FEB-2024 to 10-JUN-2024 4 months 6 days	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	08-APR-2024 to 08-APR-2024 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	18-MAR-2024 to 18-MAR-2024 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	26-FEB-2024 to 26-FEB-2024 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	29-APR-2024 to 29-APR-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | Nicotine (C) | Marijuana (C) | Lorazepam (C) | Lexapro (C) | Theratears (C) | Bupropion (C) | Dilaudid (C) | Morphine (C) | Acetaminophen (C) | Enoxaparin (C) | Melatonin (C) | Almodan (C) | Oxycodone (C) | Bentyl (C) | Simethicone (C) | Compazine (C) | Decadron (C) | Zofran (C) | Thera tears (C) | Bupropion HCL (C) | Trimethobenzamide (C) | Sodium chloride (C) | Ceftriaxone (C) | Doxycycline (C) | Flagyl (C) | Ondansetron (C)									
202501GLO009589GB	UNITED KINGDOM 49 Years Female	**Stomatitis (Mucositis oral)***	Recovered	09-Jan-2025 4 days	DATOPOTAMAB DERUXTECAN	Concentrate for solution for infusion	3 milligram/kilogram q3w Intravenous use	03-MAR-2025 to 03-MAR-2025 1 day	Patient experienced Oral mucositis. Investigator: related. Company: not related
						Concentrate for solution for infusion	3 milligram/kilogram q3w Intravenous use	06-MAY-2025 to 06-MAY-2025 1 day	
						Concentrate for solution for infusion	3 milligram/kilogram q3w Intravenous use	14-APR-2025 to 14-APR-2025 1 day	
						Concentrate for solution for infusion	3 milligram/kilogram q3w Intravenous use	16-JUN-2025 to 16-JUN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Concentrate for solution for infusion	3 milligram/kilogram q3w Intravenous use	24-MAR-2025 to 24-MAR-2025 1 day	
						Concentrate for solution for infusion	3 milligram/kilogram q3w Intravenous use	27-MAY-2025 to 27-MAY-2025 1 day	
						Concentrate for solution for infusion	4 milligram/kilogram q3w Intravenous use	10-FEB-2025 to 10-FEB-2025 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	06-JAN-2025 to 06-JAN-2025 1 day	

Concomitant Medication(s): | Dexamethasone (C) | Fluconazole (C) | Saline (C) | Difflam (C) | Levothyroxine (C) | Apixaban (C) | Pramipexole (C) | Gabapentin (C) | Macrogol (C) | Zopiclone (C) | Docusate sodium (C) | Phenergan (C) | Mirtazapine (C) | Lamotrigine (C)

SOC:Hepatobiliary disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202410GLO027152US	UNITED STATES 44 Years Female	**Suspected drug-induced liver injury (Suspected drug-induced liver injury)***	Recovering	14-Oct-2024 3 months 14 days	CAPECITABINE	Tablet	1500 milligram/sq. meter q3w Intravenous use	01-JUL-2024 to 23-DEC-2024 5 months 23 days	Periodic Report Comments. Patient experience Potential Hys Law [Immunotherapy related hepatitis.]. Investigator: Related to study therapy. CCA: related to Study therapy.
						Tablet	1500 milligram/sq. meter q3w Intravenous use	25-OCT-2024 to 30-OCT-2024 6 days	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	01-JUL-2024 to 01-JUL-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	03-SEP-2024 to 03-SEP-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	12-AUG-2024 to 12-AUG-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	14-OCT-2024 to 14-OCT-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	22-JUL-2024 to 22-JUL-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	23-SEP-2024 to 23-SEP-2024 1 day	
Concomitant Medication(s): PEMBROLIZUMAB (S) | | Sertraline (C) | Zyrtec (C) | Triamcinolone (C) | Loperamide (C) | Zolpidem (C) | Prochlorperazine (C) | Lorazepam (C) | Sulfamethoxazole (C) | Pantoprazole (C) | Prednisone (C) | Miralax (C) | Senna (C)									
2024A042491	CHINA 64.1 Years Female	**Hepatic function abnormal (Function liver abnormal)***	Recovered	18-Feb-2024 7 months 12 days	PEMBROLIZUMAB	Solution for infusion	200 milligram	07-JUL-2023 to 22-DEC-2023 5 months 16 days	Periodic Report Comment. Patient experienced abnormal liver function. INV: related to Pembrolizumab , not related to Capecitabine CCA: Not related
Concomitant Medication(s): | CAPECITABINE (S)									

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Infections and infestations									
202412GLO014760JP	JAPAN 65 Years Female	**Pneumonia (Lung infection)***	Fatal	16-Dec-2024 3 months 27 days	CAPECITABINE	Tablet	1800 milligram/sq. meter q3w Oral use	03-SEP-2024 to 03-SEP-2024 1 day	Periodic Report Comments. Patient experienced serious Lung infection. Inv: event related to Capecitabine, not related to Pembrolizumab. CCA: not related.;Patient experienced serious Lung infection. Inv: event related to Capecitabine, not related to Pembrolizumab. CCA: not related.
						Tablet	1800 milligram/sq. meter q3w Oral use	06-NOV-2024 to 06-NOV-2024 1 day	
						Tablet	1800 milligram/sq. meter q3w Oral use	07-OCT-2024 to 07-OCT-2024 1 day	
						Tablet	1800 milligram/sq. meter q3w Oral use	09-SEP-2024 to 09-SEP-2024 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2022-002680-30

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Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Tablet	1800 milligram/sq. meter q3w Oral use	20-AUG-2024 to 20-AUG-2024 1 day	
						Tablet	1800 milligram/sq. meter q3w Oral use	20-NOV-2024 to 11-DEC-2024 22 days	
						Tablet	1800 milligram/sq. meter q3w Oral use	21-OCT-2024 to 21-OCT-2024 1 day	
						Tablet	1800 milligram/sq. meter q3w Oral use	23-SEP-2024 to 23-SEP-2024 1 day	
						Tablet	3600 milligram/sq. meter q3w Oral use	07-NOV-2024 to 19-NOV-2024 13 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2022-002680-30

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Tablet	3600 milligram/sq. meter q3w Oral use	08-OCT-2024 to 20-OCT-2024 13 days	
						Tablet	3600 milligram/sq. meter q3w Oral use	10-SEP-2024 to 22-SEP-2024 13 days	
						Tablet	3600 milligram/sq. meter q3w Oral use	21-AUG-2024 to 02-SEP-2024 13 days	
Concomitant Medication(s): | PEMBROLIZUMAB (S) | Heparinoid (C) | Myser (C) | Artificial tear (C) | Az combination (C) | Cefepime dihydrochloride (C) | Daptomycin (C)									
2024A139483	CANADA 63.4 Years Female	**Gastroenteritis (Gastroenteritis)***	Recovered	03-Jun-2024 3 months 27 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	08-FEB-2024 to 08-FEB-2024 1 day	Periodic Report Comment. Patient experienced gastrointestinal disorder. Inv: event related to Capecitabine and Pembrolizumab. Com causality not related.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

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EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution for infusion	200 milligram q3w Intravenous use	09-MAY-2024 to 09-MAY-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	11-APR-2024 to 11-APR-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	21-MAR-2024 to 21-MAR-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	29-FEB-2024 to 29-FEB-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	30-MAY-2024 to 30-MAY-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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EudraCT No: 2022-002680-30

Study Design: Not Blinded

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | CAPECITABINE (S) | Lorazepam (C) | Mirtazapine (C) | Venlafaxine (C) | Telmisartan (C) | Bupropion (C) | Imodium (C) | Tylenol (C) | Mg normal saline (C) | Potassium chloride (C) | Ringer's lactate solution (C) | Cosyntropin (C) | Dalteparina de sodio (C) | Dimenhydrinate (C) | Magnesium sulfate (C) | Peglyte (C) | Acetaminophen (C) | Tazocin (C) | Alkonium (C) | Chlorhexidine (C) | Dextroketamine (C) | Methylprednisolone (C) | Norepinephrine (C) | Normal saline (C) | Ceftriaxone sodium (C) | Ativan (C) | Pantoprazole (C) | Humulin r (C) | Ringers lactate (C) | Vitamin d (C) | Zithromax (C)									
2024A172083	CHINA 36.5 Years Female	**Pneumonia (Pneumonia)***	Not Recovered	17-Jun-2024 4 months 16 days	DATOPOTAMAB DERUXTECAN	Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	02-FEB-2024 to 02-FEB-2024 1 day	Periodic Report Comment. Patient experienced l lung inflammation. Inv: event related to study therapy. CCA not related.;Periodic Report Comment. Patient experienced Pneumonia, Inv: related to study therapy, CCA: not related to study therapy.
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	02-FEB-2024 to 31-MAY-2024 3 months 30 days	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	08-MAR-2024 to 08-MAR-2024 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	10-MAY-2024 to 10-MAY-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	19-APR-2024 to 19-APR-2024 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	29-MAR-2024 to 29-MAR-2024 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	31-MAY-2024 to 31-MAY-2024 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | Lactulose Almus (C) | Acetaminophen (C) | Promethazine hydrochloride (C) | Dexamethasone sodium phosphate (C) | Diclofenac sodium (C) | Esomeprazole sodium (C) | Palonosetron hydrochloride (C) | Paracetamol (C) | Vitamin b6 (C) | Vitamin C (C) | Acetylcysteine (C) | Moxifloxacin (C) | Penicillin (C) | Piperacillin (C) | Lactulose (C) | Omeprazole sodium (C) | Acetaminophen (C) | Lidocaine hydrochloride (C) | Sulfamethoxazole (C) | Minocycline hydrochloride (C) | Methylprednisolone (C)									
2024A176368	KOREA, REPUBLIC OF 66 Years Female	**Pneumonia (Pneumonia)***	Recovered	28-Jul-2024 2 months 16 days	DATOPOTAMAB DERUXTECAN	Concentrate for solution for infusion	4 milligram/kilogram q3w Intravenous use	05-JUN-2024 to 05-JUN-2024 1 day	Periodic Report Comment. the patient experienced moderate pneumonia, related to Datopotamab Deruxtecan and Durvalumab, Com causality not related.; Periodic Report Comment. Patient experienced event pneumonia. Investigator states event pneumonia related to Datopotamab

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Concentrate for solution for infusion	4 milligram/kilogram q3w Intravenous use	15-JUL-2024 to 15-JUL-2024 1 day	Deruxtecan and Durvalumab. Company physician considers event pneumonia not related to Datopotamab Deruxtecan and related to Durvalumab.
						Concentrate for solution for infusion	4 milligram/kilogram q3w Intravenous use	24-JUN-2024 to 24-JUN-2024 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	05-JUN-2024 to 05-JUN-2024 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	13-MAY-2024 to 13-MAY-2024 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	15-JUL-2024 to 15-JUL-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	24-JUN-2024 to 24-JUN-2024 1 day	

Concomitant Medication(s): | DURVALUMAB (S) | Solondo (C) | Amcillin (C) | Distilled water (C) | Sancuso (C) | Tantum (C)

SOC:Injury, poisoning and procedural complications

202508GLO011150KR	KOREA, REPUBLIC OF 42 Female	**Exposure during pregnancy (Drug exposure during pregnancy)*** Abortion spontaneous (Miscarriage)*	Unknown	nk nk	DATOPOTAMAB DERUXTECAN	Concentrate for solution for infusion	Intravenous use	to	

Concomitant Medication(s):

SOC:Investigations

2023A271271	CHINA 55 Years Female	**Amylase increased (Serum amylase increased)***	Recovered	27-Nov-2023 17 weeks 5 days					

Concomitant Medication(s):

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A054428	BRAZIL 48.1 Years Female	**Amylase increased (Amylase increased)***	Recovered	07-Feb-2024 2 months 25 days	DATOPOTAMAB DERUXTECAN	Concentrate for solution for infusion	6 milligram/kilogram Intravenous use	14-NOV-2023 to 20-MAR-2024 4 months 7 days	Periodic Report Comment. Patient experienced amylasemia grade 3 elevated amylase, Inv: Related , CCA: not related.
Concomitant Medication(s): | Metformin (C) | Atenolol (C) | Hyabak (C) | Triamcinolone acetonide (C) | Acyclovir (C) | Clobetazol (C)									
2024A120233	GERMANY 53.3 Years Female	**Amylase increased (Amylase increased)***	Recovered	06-May-2024 1 month 10 days	DATOPOTAMAB DERUXTECAN	Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	27-MAR-2024 to 27-NOV-2024 8 months 1 day	Periodic Report Comment. Patient experienced AMYLASE INCREASED. Inv: Related to DATOPOTAMAB DERUXTECAN. CCA: Not related to study therapy.; Periodic Report Comments. Patient has event: AMYLASE INCREASED, Action Taken: Study therapy was Withdraw. Investigator Causality: Related, Company Causality: Not Related.
Concomitant Medication(s): | Euthyrox (C) | Vigantol (C) | Remifemin (C) | Equinovo (C) | Vitamin b komplex (C) | Dexamethasone (C) | Akynzeo (C) | Aminfluorid (C) | Cimetidin (C) | Glandomed (C) | Histakut (C) | Paracetamol (C) | NaCl (C) | Sea buckthorn (C) | Euphrasia (C) | Lidocain (C)									

SOC:Metabolism and nutrition disorders

202412GLO000051CN	CHINA 54.8 Years Female	**Type 1 diabetes mellitus (Type 1 diabetes mellitus)*** Hypothyroidism (Hypothyroidism)	Not Recovered	27-Oct-2024 11 months 13 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	06-DEC-2023 to 06-DEC-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	09-APR-2024 to 09-APR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	13-MAR-2024 to 13-MAR-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	14-JUN-2024 to 14-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	15-NOV-2023 to 15-NOV-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	21-FEB-2024 to 21-FEB-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	23-MAY-2024 to 23-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-DEC-2023 to 27-DEC-2023 1 day	
						Infusion	1120 milligram q3w Intravenous use	29-APR-2024 to 29-APR-2024 1 day	
		Type 1 diabetes mellitus (Type 1 diabetes mellitus)* Hypothyroidism (Hypothyroidism)*	Not Recovered	27-Oct-2024 11 months 13 days	DATOPOTAMAB DERUXTECAN	Concentrate for solution for infusion	6 milligram q3w Intravenous use	15-NOV-2023 to 23-MAY-2024 6 months 9 days	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	06-DEC-2023 to 06-DEC-2023 1 day	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	09-APR-2024 to 09-APR-2024 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	13-MAR-2024 to 13-MAR-2024 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	15-NOV-2023 to 15-NOV-2023 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	21-FEB-2024 to 21-FEB-2024 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	23-MAY-2024 to 23-MAY-2024 1 day	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	27-DEC-2023 to 27-DEC-2023 1 day	
						Concentrate for solution for infusion	6 milligram/kilogram q3w Intravenous use	29-APR-2024 to 29-APR-2024 1 day	

Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Calcium carbonate (C) | Novorapid penfill (C) | Olanzapine (C) | Clonazepam (C) | Bicyclol (C) | Omeprazole sodium (C) | Dexamethasone acetate (C) | Insulin degludec (C)

SOC:Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202510GLO025189GB	UNITED KINGDOM 40 Years Female	**Acute myeloid leukaemia (Acute myeloid leukaemia)***	Not Recovered	12-Oct-2025 2 years 4 months 8 days	CAPECITABINE	Tablet	500 milligram/sq. meter q3w Oral use	05-JUN-2023 to 18-JUN-2023 14 days	Periodic Report Comments. Patient experienced event acute myeloid leukaemia (secondary to oncology chemotherapy). Investigator states event related to Cyclophosphamide, Epirubicin and Capecitabine. Company physician considers event related to Cyclophosphamide, Epirubicin and unrelated to Capecitabine.
						Tablet	750 milligram/sq. meter q3w Oral use	26-JUN-2023 to 09-JUL-2023 14 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Tablet	850 milligram/sq. meter q3w Oral use	17-JUL-2023 to	
Concomitant Medication(s): | Epirubicin (S) | Cyclophosphamide (S) | Ferrous fumarate (C) | Vitamin b12 (C) | Cod liver oil (C) | FLAG-IDA (C) | Midostaurin (C)									
SOC:Nervous system disorders									
202507GLO024466GB	UNITED KINGDOM 44.6 Years Female	**Facial paralysis (Facial palsy)***	Recovered	28-Jul-2025 1 year 2 months 8 days	DURVALUMAB	Infusion	Intravenous use	09-JUL-2024 to 09-JUL-2024 1 day	Periodic Report Comments. Patient experienced facial nerve palsy. Inv: event related to Durvalumab, not related to Datopotamab Deruxtecan. CCA: not related.
						Infusion	Intravenous use	18-JUN-2024 to 18-JUN-2024 1 day	
						Infusion	Intravenous use	21-MAY-2024 to 21-MAY-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	30-JUL-2024 to 30-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	09-JUL-2024 to 09-JUL-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	18-JUN-2024 to 18-JUN-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	21-MAY-2024 to 21-MAY-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	22-OCT-2024 to 22-OCT-2024 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	24-SEP-2024 to 24-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	30-JUL-2024 to 30-JUL-2024 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Omeprazole (C) | Dexamethasone (C)									

SOC:Respiratory, thoracic and mediastinal disorders

202412GLO023472BE	BELGIUM 50 Years Female	**Pulmonary hypertension (Pulmonary hypertension)***	Fatal	27-Dec-2024 4 months 15 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	13-AUG-2024 to 13-AUG-2024 1 day	Patient experienced pulmonary hypertension. Inv causality related to Durvalumab and not related to Datopotamab deruxtecan; CCA: not related to Durvalumab, Datopotamab deruxtecan.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1120 milligram q3w Intravenous use	03-SEP-2024 to 03-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	05-NOV-2024 to 05-NOV-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	15-OCT-2024 to 15-OCT-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	24-SEP-2024 to 24-SEP-2024 1 day	
						Infusion	1120 milligram q3w Intravenous use	28-NOV-2024 to 28-NOV-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D926X

Study ID: D926XC00001

EudraCT No: 2022-002680-30

Study Design: Not Blinded

Study Description: D926XC00001 TROPION-Breast03 (Dato-DXd + PDx adj residula disease TNBC) - A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPIONBreast03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): | DATOPOTAMAB DERUXTECAN (S) | Oxazepam (C) | Paracetamol (C) | Sertraline (C) | Magnesium hydroxide (C) | Pantoprazole (C) | Systane complete (C) | Enoxaparin (C) | Macrogol (C)									

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9311

Study ID: D9311C00001

EudraCT No: 2022-502746-27-00

Study Design: Double Blinded

Study Description: D9311C00001 DUO-E 1L maintenance Endometrial Cancer - A Randomised, Multicentre, Double-blind, Placebo-controlled, Phase III Study of First-line Carboplatin and Paclitaxel in Combination with Durvalumab, Followed by Maintenance Durvalumab with or without Olaparib in Patients with Newly Diagnosed Advanced or Recurrent Endometrial Cancer (DUO-E)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Gastrointestinal disorders									
202509EEA011300PL	POLAND 73 Years Female	**Rectal haemorrhage (Rectal bleeding)*** Colitis (Colitis)*	Unknown	nk nk					

Concomitant Medication(s):

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D9311

EudraCT No:

Study Design: Not Blinded

Study ID: D9311L00001

Study Description: A Phase IIIB study to evaluate the use of durvalumab in combination with platinum-based chemotherapy followed by durvalumab with olaparib as first-line treatment in Patients with Newly Diagnosed pMMR Advanced or Recurrent Endometrial Cancer in Spain

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Skin and subcutaneous tissue disorders									
202506GLO016893ES	SPAIN 76 Years Female	**Rash erythematous (Erythematous rash)***	Recovered	07-Apr-2025 nk	PACLITAXEL	Infusion	Unknown	to	

Concomitant Medication(s): DURVALUMAB (S) | OLAPARIB (S) | | CARBOPLATIN (S)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933A

Study ID: D933AC00005

EudraCT No:

Study Design: Not Blinded

Study Description: Imfinzi BTC Japan PMS _ Japan Post-Marketing Surveillance (PMS) Study - CEI/SCEI. - Imfinzi BTC Japan PMS _ Japan Post-Marketing Surveillance (PMS) Study - CEI/SCEI.

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Investigations									
202411GLO005011JP	JAPAN 69 Years Male	**Neutrophil count decreased (Neutrophil count decreased)***	Recovered	17-Nov-2023 29 days	DURVALUMAB	Infusion	1500 milligram q4w IV drip	20-OCT-2023 to	

Concomitant Medication(s): | Gemcitabine hydrochloride (S) | Cisplatin (S)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933G

Study ID: D933GC00001

EudraCT No: 2023-509053-32-00

Study Design: Double Blinded

Study Description: D933GC00001 TACE with Durva and Durva+Bev in Patients with LR-HCC - A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter Study of Transarterial Chemoembolization (TACE) in Combination with either Durvalumab Monotherapy or Durvalumab plus Bevacizumab Therapy in Patients with Locoregional Hepatocellular Carcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Cardiac disorders									
2023A232644	BRAZIL 66 Years Male	**Angina unstable (Unstable angina)***	Recovered	09-Oct-2023 nk					
Concomitant Medication(s):									
SOC:Metabolism and nutrition disorders									
202509GLO006273CN	CHINA 65 Years Male	**Hyperglycaemia (Hyperglycemia)***	Unknown	20-Aug-2025 nk					
Concomitant Medication(s):									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933G

EudraCT No:

Study Design: Not Blinded

Study ID: D933GC00002

Study Description: D933GC00002 EMERALD-Y90 - Phase II Single-Arm Study of Durvalumab and Bevacizumab Following Transarterial Radioembolization Using Yttrium-90 Glass Microspheres (TheraSphere™) in Unresectable Hepatocellular Carcinoma Amenable to Locoregional Therapy

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Gastrointestinal disorders									
202503GLO012396US	UNITED STATES 57 Years Male	**Small intestinal perforation (Intestinal perforation small)*** Varices oesophageal (Esophageal varices)*	Fatal	12-Mar-2025 4 months 16 days	BEVACIZUMAB	Infusion	15 milligram/kilogram q3w Intravenous use	25-OCT-2024 to 31-JAN-2025 3 months 7 days	Periodic Report Comments. The patient experienced abdominal pain, bowel perforation, encephalopathy, esophageal varices (non-bleeding), banded, gi bleed, liver failure, upper gi bleed and vomiting. Investigator: All events not related to Durvalumab. Events bowel perforation, esophageal varices (non-bleeding), banded, gi bleed and upper gi bleed related to Bevacizumab. Events: abdominal pain, encephalopathy, liver failure and vomiting not related to Bevacizumab. Company: All events not related. Study Procedure: Investigator: Related to abdominal pain, bowel perforation, esophageal varices (non-bleeding), banded, gi bleed, liver failure. Company: abdominal pain, bowel perforation, gi bleed, liver failure.
Concomitant Medication(s): DURVALUMAB (S) | | Valsartan (C) | Amlodipine (C) | Testosterone (C) | Valacyclovir (C) | Spironolactone (C) | Hydrocortisone (C) | Albuterol (C) | Insulin (C)									
SOC:Infections and infestations									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933G

Study ID: D933GC00002

EudraCT No:

Study Design: Not Blinded

Study Description: D933GC00002 EMERALD-Y90 - Phase II Single-Arm Study of Durvalumab and Bevacizumab Following Transarterial Radioembolization Using Yttrium-90 Glass Microspheres (TheraSphere™) in Unresectable Hepatocellular Carcinoma Amenable to Locoregional Therapy

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202505GLO008655US	UNITED STATES 67 Years Male	**Cellulitis (Cellulitis)***	Recovered	18-Apr-2025 1 month 4 days 10 hrs 54 min	DURVALUMAB	Infusion Infusion	1120 milligram q3w Intravenous use 1500 milligram q3w Intravenous use	27-MAR-2025 14:06 to 22-AUG-2025 14:02 4 months 25 days 23 hrs 56 min 13-MAR-2025 13:06 to 13-MAR-2025 14:06 1 hr	Periodic Report Comments. Patient has events Cellulitis of left lower extremity Generalized Abdomen pain, Action taken with study therapy was temporarily withdrawn. Investigator Causality: Related, CC: Not Related of study therapy for event Cellulitis of left lower extremity.;Patient experienced cellulitis of left lower extremity Inv causality: RELATED To Durvalumab NOT RELATED to Bevacizumab CCC: NOT RELATED and also experienced generalized abdomen pain Inv causality: NOT RELATED to both suspects CCC: NOT RELATED
Concomitant Medication(s): | BEVACIZUMAB (S) | Meropenem (C) | Vancomycin (C) | Furosemide (C) | Dorzolamide (C) | Pantoprazole (C) | Methocarbamol (C) | Finasteride (C) | Tamsulosin (C) | Meclizine (C) | Acetaminophen (C) | Levothyroxine (C)									
202506GLO017006US	UNITED STATES 68 Years Male	**Skin infection (Skin infection)***	Recovered	18-Jun-2025 2 months 23 days	BEVACIZUMAB	Infusion	Intravenous use	27-MAR-2025 to 13-JUN-2025 2 months 18 days	
Concomitant Medication(s): DURVALUMAB (S) | | Levaquin (C) | Vancomycin (C) | Pantoprazole (C) | Meropenem (C)									

SOC:Respiratory, thoracic and mediastinal disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933G

Study ID: D933GC00002

EudraCT No:

Study Design: Not Blinded

Study Description: D933GC00002 EMERALD-Y90 - Phase II Single-Arm Study of Durvalumab and Bevacizumab Following Transarterial Radioembolization Using Yttrium-90 Glass Microspheres (TheraSphere™) in Unresectable Hepatocellular Carcinoma Amenable to Locoregional Therapy

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202509GLO014888US	UNITED STATES 68 Years Male	**Dyspnoea (Shortness of breath) ***	Not Recovered	17-Sep-2025 4 months 19 days	DURVALUMAB	Infusion	1120 milligram Intravenous use	14-MAY-2025 to 27-AUG-2025 3 months 14 days	
						Infusion	1500 milligram Intravenous use	30-APR-2025 to 30-APR-2025 1 day	
Concomitant Medication(s): | BEVACIZUMAB (S) | Insulin aspart (C) | Pantoprazole (C) | Fenofibrate (C) | Losartan (C)									
202510GLO027088US	UNITED STATES 74 Years Male	**Dyspnoea (Dyspnea)***	Not Recovered	20-Oct-2025 nk	DURVALUMAB	Infusion	1120 milligram q3w Unknown	to	
Concomitant Medication(s): | BEVACIZUMAB (S) | Furosemide (C) | Glipizide (C) | Lisinopril (C) | Metformin (C) | Pantoprazole (C) | Rosuvastatin (C) | Tamsulosin (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933Q

Study ID: D933QC00001

EudraCT No: 2023-509602-29-00

Study Design: Double Blinded

Study Description: D933QC00001 (Adriatic) Durva + Treme LD SCLC - A Phase III, Randomized, Double-blind, Placebo-controlled, Multi-center, International Study of Durvalumab or Durvalumab and Tremelimumab as Consolidation Treatment for Patients with Limited Stage Small Cell Lung Cancer Who Have Not Progressed Following Concurrent Chemoradiation Therapy (ADRIATIC)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Skin and subcutaneous tissue disorders									
202507GLO025755IE	IRELAND Unknown	**Rash (Rash)***	Recovered	25-Jul-2025 8 months 5 days					

Concomitant Medication(s):

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933R

Study ID: D933RC00002

EudraCT No:

Study Design: Not Blinded

Study Description: A Multicentre, Phase IIIb, Open-label, Single-arm, Global Study to Investigate Safety and Efficacy with Neoadjuvant Durvalumab in Combination with Chemotherapy Followed by Adjuvant Durvalumab Treatment in Participants at Least 18 Years of Age with Muscle-invasive Bladder Cancer (NIAGARA-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
202508GLO011284AU	AUSTRALIA 74 Years Male	**Transitional cell carcinoma (Urothelial carcinoma)***	Recovered	15-Aug-2025 16 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	31-JUL-2025 to 09-OCT-2025 2 months 9 days	Periodic Report Comments. Patient experienced Urothelial cancer bleeding Related to Durvalumab, Cisplatin, Gemcitabine. Company causality assessment is not related with Durvalumab and Not applicable for Cisplatin and Gemcitabine.
Concomitant Medication(s): | Gemcitabine (S) | Cisplatin (S) | Allopurinol (C) | Spironolactone (C) | Dilart (C) | Magnesium sulphate (C)									
SOC:Nervous system disorders									
202510GLO025982AU	AUSTRALIA 62 Years Male	**Syncope (Syncope)***	Not Recovered	24-Oct-2025 2 months 16 days 11 hrs 40 min	CISPLATIN	Infusion Infusion	Intravenous use Intravenous use	02-OCT-2025 11:25 to 02-OCT-2025 12:25 1 hr 04-SEP-2025 11:25 to 04-SEP-2025 12:25 1 hr	Periodic Report Comment. Patient experienced syncope. Investigator did not report causal relation between event syncope and Durvalumab, Cisplatin, Doxorubicin, Methotrexate and Vinblastine. Company physician considers event syncope related to Durvalumab, Cisplatin, Doxorubicin, Methotrexate and Vinblastine.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933R

Study ID: D933RC00002

EudraCT No:

Study Design: Not Blinded

Study Description: A Multicentre, Phase IIIb, Open-label, Single-arm, Global Study to Investigate Safety and Efficacy with Neoadjuvant Durvalumab in Combination with Chemotherapy Followed by Adjuvant Durvalumab Treatment in Participants at Least 18 Years of Age with Muscle-invasive Bladder Cancer (NIAGARA-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	07-AUG-2025 12:20 to 07-AUG-2025 13:20 1 hr	
						Infusion	Intravenous use	14-OCT-2025 11:54 to 14-OCT-2025 12:54 1 hr	
						Infusion	Intravenous use	21-AUG-2025 11:41 to 21-AUG-2025 12:41 1 hr	
					VINBLASTINE	Infusion	Intravenous use	02-OCT-2025 10:05 to 02-OCT-2025 10:12 7 min	
						Infusion	Intravenous use	04-SEP-2025 10:03 to 04-SEP-2025 10:13 10 min	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933R

Study ID: D933RC00002

EudraCT No:

Study Design: Not Blinded

Study Description: A Multicentre, Phase IIIb, Open-label, Single-arm, Global Study to Investigate Safety and Efficacy with Neoadjuvant Durvalumab in Combination with Chemotherapy Followed by Adjuvant Durvalumab Treatment in Participants at Least 18 Years of Age with Muscle-invasive Bladder Cancer (NIAGARA-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	07-AUG-2025 10:49 to 07-AUG-2025 10:58 9 min	
						Infusion	Intravenous use	14-OCT-2025 10:13 to 14-OCT-2025 10:23 10 min	
						Infusion	Intravenous use	18-SEP-2025 10:48 to 18-SEP-2025 10:50 2 min	
						Infusion	Intravenous use	21-AUG-2025 10:25 to 21-AUG-2025 10:35 10 min	
					DOXORUBICIN	Infusion	Intravenous use	02-OCT-2025 09:30 to 02-OCT-2025 09:45 15 min	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933R

Study ID: D933RC00002

EudraCT No:

Study Design: Not Blinded

Study Description: A Multicentre, Phase IIIb, Open-label, Single-arm, Global Study to Investigate Safety and Efficacy with Neoadjuvant Durvalumab in Combination with Chemotherapy Followed by Adjuvant Durvalumab Treatment in Participants at Least 18 Years of Age with Muscle-invasive Bladder Cancer (NIAGARA-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	04-SEP-2025 09:35 to 04-SEP-2025 09:50 15 min	
						Infusion	Intravenous use	07-AUG-2025 10:10 to 07-AUG-2025 10:25 15 min	
						Infusion	Intravenous use	14-OCT-2025 09:29 to 14-OCT-2025 09:45 16 min	
						Infusion	Intravenous use	18-SEP-2025 10:11 to 18-SEP-2025 10:24 13 min	
						Infusion	Intravenous use	21-AUG-2025 10:00 to 21-AUG-2025 10:13 13 min	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933R

Study ID: D933RC00002

EudraCT No:

Study Design: Not Blinded

Study Description: A Multicentre, Phase IIIb, Open-label, Single-arm, Global Study to Investigate Safety and Efficacy with Neoadjuvant Durvalumab in Combination with Chemotherapy Followed by Adjuvant Durvalumab Treatment in Participants at Least 18 Years of Age with Muscle-invasive Bladder Cancer (NIAGARA-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					METHOTREXATE	Injection	Intravenous use	01-OCT-2025 10:38 to 01-OCT-2025 11:12 34 min	
						Injection	Intravenous use	03-SEP-2025 13:33 to 03-SEP-2025 13:38 5 min	
						Injection	Intravenous use	06-AUG-2025 13:16 to 06-AUG-2025 13:21 5 min	
						Injection	Intravenous use	13-OCT-2025 11:47 to 13-OCT-2025 11:52 5 min	
						Injection	Intravenous use	17-SEP-2025 14:45 to 17-SEP-2025 14:50 5 min	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933R

Study ID: D933RC00002

EudraCT No:

Study Design: Not Blinded

Study Description: A Multicentre, Phase IIIb, Open-label, Single-arm, Global Study to Investigate Safety and Efficacy with Neoadjuvant Durvalumab in Combination with Chemotherapy Followed by Adjuvant Durvalumab Treatment in Participants at Least 18 Years of Age with Muscle-invasive Bladder Cancer (NIAGARA-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Injection	Intravenous use	20-AUG-2025 11:30 to 20-AUG-2025 11:35 5 min	
					DURVALUMAB	Infusion	Intravenous use	01-OCT-2025 10:38 to 01-OCT-2025 11:12 34 min	
						Infusion	Intravenous use	03-SEP-2025 11:55 to 03-SEP-2025 12:25 30 min	
						Infusion	Intravenous use	06-AUG-2025 11:08 to 06-AUG-2025 12:08 1 hr	

Concomitant Medication(s): DURVALUMAB (S) | VINBLASTINE (S) | DOXORUBICIN (S) | | METHOTREXATE (S) | Pantoprazol (C) | Aspirin (C) | Carvediol (C) | Isosorbide mononitrate (C) | Irbesartan (C) | Rosuvastatin (C) | Ezetimibe (C) | Inclisiran (C) | Magnesium aspartate (C) | Pulmicort (C) | Ticagrelor (C) | Ondansetron (C) | Hydralyte Effervescent (C) | Dexamethasone (C) | Akynzeo (C) | Magnesium sulphate (C) | Sodium chloride (C) | Senna and docusate sodium (C) | Metoclopramide (C) | Pegfilgrastim (C) | Sodium bicarbonate (C) | Movicol (C) | Hydrocortisone (C) | Gaviscon (C) | Loratadine (C)

SOC:Renal and urinary disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933R

Study ID: D933RC00002

EudraCT No:

Study Design: Not Blinded

Study Description: A Multicentre, Phase IIIb, Open-label, Single-arm, Global Study to Investigate Safety and Efficacy with Neoadjuvant Durvalumab in Combination with Chemotherapy Followed by Adjuvant Durvalumab Treatment in Participants at Least 18 Years of Age with Muscle-invasive Bladder Cancer (NIAGARA-2)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO025849AU	AUSTRALIA 74 Years Male	**Acute kidney injury (Acute kidney injury)***	Recovered	28-Aug-2025 27 days 12 hrs 35 min	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	09-OCT-2025 12:28 to 09-OCT-2025 12:58 30 min	Periodic Report Comments. Patient has event Acute kidney injury. Action taken with study therapy was No change. Investigator Causality: Related, CC: Not Related;Periodic Report Comments. Subject has event: Acute kidney injury, Action taken with study drug: No change, Investigator causality: Related, Company Causality: Not Related
						Infusion	1500 milligram q3w Intravenous use	18-SEP-2025 11:33 to 18-SEP-2025 12:03 30 min	
						Infusion	1500 milligram q3w Intravenous use	21-AUG-2025 11:37 to 21-AUG-2025 12:07 30 min	
						Infusion	1500 milligram q3w Intravenous use	31-JUL-2025 11:25 to 31-JUL-2025 12:25 1 hr	

Concomitant Medication(s): | GEMCITABINE (S) | CISPLATIN (S) | Allopurinol (C) | Spironolactone (C) | Frusemide (C) | Valsartan (C) | Rivaroxaban (C) | Pantoprazole (C) | Thiamine (C) | Dilart (C) | Duodart (C) | Magnesium sulphate (C) | Progout (C) | Metoclopramide (C) | Akynzeo (C) | Dexamethasone (C) | Sodium chloride (C) | Rosuvastatin (C) | Pegfilgrastim (C) | Ozempic (C) | Palonosetron (C) | Movicol (C) | Aranesp (C) | Tazocin (C) | Flucloxacillin (C)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
2019SE49020	SPAIN 63 Years Male	**Febrile neutropenia (Febrile neutropenia)***	Recovered	28-Mar-2019 1 week 6 days	CARBOPLATIN	Infusion	Intravenous use	08-MAY-2019 to 08-MAY-2019 1 day	Periodic Report Comment. The patient had grade two febrile neutropenia. The patient had history of hypertension, dyslipidemia and ischemic cardiopathy. Reported causality yes. Company causality Yes.
						Infusion	Intravenous use	15-JUL-2019 to 15-JUL-2019 1 day	
						Infusion	Intravenous use	15-MAR-2019 to 15-MAR-2019 1 day	
						Infusion	Intravenous use	21-JUN-2019 to 21-JUN-2019 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	31-MAY-2019 to 31-MAY-2019 1 day	
Concomitant Medication(s): DURVALUMAB (S) | | GEMCITABINE (S) | Aspirin (C) | Atenolol (C) | Enalapril (C) | Omeprazole (C) | Pravastatin (C) | Dexamethason (C)									
SOC:Gastrointestinal disorders									
2020SE10374	TURKEY 59 Years Male	**Enterocolitis (Enterocolitis)***	Fatal	20-Jan-2020 3 weeks 6 days	TREMELIMUMAB	Infusion	75 milligram q3w Intravenous use	24-DEC-2019 to 24-DEC-2019 1 day	Periodic Report Comment. The patient described fluid defecation 6-8 times a day and fecal culture, parasitic examination and fecal microscopy were negative. The patient who did not respond to CPR was accepted exitus at 07:01. (CRP: 139.05, Procalcitonin: 4.77).;Periodic Report Comments. Patient has event: SEPSIS, ENTEROCOLITIS Action Taken with study therapy was DURVALUMAB, TREMELIMUMAB No Change, Investigator Causality: Not related and CC: Not related. For SEPSIS, ENTEROCOLITIS. TREMELIMUMAB Investigator Causality: Related and CC: Related for SEPSIS.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): DURVALUMAB (S) | | Prednol (S) | Infliximab (S) | Cisplatin (S) | Gemcitabine (S) | Imipenem (C) | Urispas (C) | Betmiga (C) | Dexketoprofen (C) | Avil (C) | Dekort (C) | Ulcuran (C) | Kytril (C) | KCl (C) | Magnesium sulfate (C) | Mannitol (C) | Metpamid (C) | Emend (C) | Ativan (C) | Parol (C) | Flagyl (C) | NaCl (C) | Tazocin (C) | Oseltamivir (C) | Kalinor (C) | Magnonorm (C) | Oliclinomel (C) | Salicylic acid (C) | Uroderm (C) | Fucidin (C) | Hametum (C) | Clexane (C) | Quetiapine (C) | Lasix (C) | Meronem (C) | Norodol (C) | Targocid (C) | Amikacin (C) | Norepinephrine bitartrate (C) | Magnesium (C) | Cipro (C)									
SOC:General disorders and administration site conditions									
2022A097054	CHINA 54 Years Female	**Pyrexia (Fever)***	Recovered	25-Feb-2022 2 weeks	DURVALUMAB	Infusion	1500 milligram Intravenous use	01-APR-2022 to 01-APR-2022 1 day	Periodic Report Comment. Pt exp Fever. Inv causality: related to Durvalumab, Tremelimumab, Cisplatin and Gemcitabine.
						Infusion	1500 milligram Intravenous use	04-AUG-2022 to 04-AUG-2022 1 day	
						Infusion	1500 milligram Intravenous use	04-AUG-2023 to 04-AUG-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram Intravenous use	04-JUL-2023 to 04-JUL-2023 1 day	
						Infusion	1500 milligram Intravenous use	06-JUN-2023 to 06-JUN-2023 1 day	
						Infusion	1500 milligram Intravenous use	07-DEC-2022 to 07-DEC-2022 1 day	
						Infusion	1500 milligram Intravenous use	08-FEB-2023 to 08-FEB-2023 1 day	
						Infusion	1500 milligram Intravenous use	09-MAR-2023 to 09-MAR-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram Intravenous use	09-MAY-2023 to 09-MAY-2023 1 day	
						Infusion	1500 milligram Intravenous use	10-NOV-2022 to 10-NOV-2022 1 day	
						Infusion	1500 milligram Intravenous use	11-APR-2023 to 11-APR-2023 1 day	
						Infusion	1500 milligram Intravenous use	11-FEB-2022 to 11-FEB-2022 1 day	
						Infusion	1500 milligram Intravenous use	11-JAN-2023 to 11-JAN-2023 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram Intravenous use	12-JUL-2022 to 12-JUL-2022 1 day	
						Infusion	1500 milligram Intravenous use	12-OCT-2022 to 12-OCT-2022 1 day	
						Infusion	1500 milligram Intravenous use	17-JUN-2022 to 17-JUN-2022 1 day	
						Infusion	1500 milligram Intravenous use	26-APR-2022 to 26-APR-2022 1 day	
						Infusion	1500 milligram Intravenous use	27-MAY-2022 to 27-MAY-2022 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram Intravenous use	30-AUG-2022 to 30-AUG-2022 1 day	
						Infusion	1500 milligram Intravenous use	31-AUG-2023 to 31-AUG-2023 1 day	
					GEMCITABINE	Infusion	Intravenous use	01-APR-2022 15:40 to 01-APR-2022 16:12 1 day	
						Infusion	Intravenous use	07-APR-2022 17:53 to 07-APR-2022 19:43 1 day	
						Infusion	Intravenous use	07-MAY-2022 17:47 to 07-MAY-2022 18:20 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	11-FEB-2022 15:03 to 11-FEB-2022 15:32 1 day	
						Infusion	Intravenous use	12-JUL-2022 15:53 to 12-JUL-2022 16:19 1 day	
						Infusion	Intravenous use	17-JUN-2022 12:20 to 17-JUN-2022 12:47 1 day	
						Infusion	Intravenous use	21-JUL-2022 17:00 to 21-JUL-2022 17:26 1 day	
						Infusion	Intravenous use	24-JUN-2022 17:11 to 24-JUN-2022 17:50 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	Intravenous use	26-APR-2022 14:54 to 26-APR-2022 15:16 1 day	
						Infusion	Intravenous use	27-MAY-2022 15:07 to 27-MAY-2022 15:34 1 day	
					TREMELIMUMAB	Infusion	75 milligram q3w Intravenous use	01-APR-2022 10:45 to 01-APR-2022 11:43 1 day	
						Infusion	75 milligram q3w Intravenous use	11-FEB-2022 11:13 to 11-FEB-2022 12:00 1 day	
						Infusion	75 milligram q3w Intravenous use	26-APR-2022 10:49 to 26-APR-2022 11:52 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	75 milligram q3w Intravenous use	27-MAY-2022 10:44 to 27-MAY-2022 11:42 1 day	
Concomitant Medication(s): | TREMELIMUMAB (S) | CISPLATIN (S) | GEMCITABINE (S)									

SOC:Hepatobiliary disorders

2020SF50051	ISRAEL 74 Years Male	**Hepatotoxicity (Hepatotoxicity) ***	Recovered	16-Nov-2020 6 weeks 1 day	TREMELIMUMAB	Infusion	75 milligram q3w Intravenous use	04-OCT-2020 to 04-OCT-2020 1 day	Periodic Report Comment. lab results showed sgot=209 Gr3; sgpt=232 Gr2).Inv: Event hepatotoxicity related to Durvalumab and Tremelimumab and unrelated to Gemcitabine, Carboplatin. Event Sepsis unrelated to all study study therapy.
						Infusion	75 milligram q3w Intravenous use	01-NOV-2020 to 01-NOV-2020 1 day	
						Infusion	75 milligram q3w Intravenous use	03-JAN-2021 to 03-JAN-2021 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	75 milligram q3w Intravenous use	06-DEC-2020 to 06-DEC-2020 1 day	

Concomitant Medication(s): DURVALUMAB (S) | | GEMCITABINE (S) | CARBOPLATIN (S) | Rokacet (C) | Targin (C) | Avilac (C) | Micropirin (C) | Rocephin (C) | Salinex (C) | Clexane (C) | Folic acid (C)

SOC:Infections and infestations

2021A240004	KOREA, REPUBLIC OF 54 Years Female	**Pneumonia (Pneumonia)***	Fatal	27-Mar-2021 4 months 3 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	25-NOV-2020 to 17-MAR-2021 3 months 21 days	Periodic Report Comment. The patient experienced Pneumonia, Inv- related to durvalumab and unrelated to tremelimumab, cisplatin, gemcitabine. Company: not related;Periodic Report Comments. The patient experienced Pneumonia, Inv-related to durvalumab and unrelated to tremelimumab, cisplatin, gemcitabine. Company: not related

Concomitant Medication(s): | TREMELIMUMAB (S) | CISPLATIN (S) | GEMCITABINE (S) | Macperan (C) | Magmil (C) | Rosuzet (C) | Anplone (C) | Tyrenol (C) | Rovatitan (C) | Muteran (C) | Actifed (C) | Jardiance duo (C) | Kanarb (C) | Adipam (C) | Desowen (C) | Zyprexa (C) | Duphalac (C) | Lasix (C)

SOC:Investigations

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2022A318063	CHINA 61 Years Male	**Amylase increased (Serum amylase increased)***	Not Recovered	12-Nov-2020 1 month 21 days	DURVALUMAB	Infusion	1500 milligram q3w Intravenous use	06-NOV-2020 to 06-NOV-2020 1 day	Periodic Report Comment. Patient experienced severe multiple occurrences of increased serum amylase, serious. Inv: Event related to durvalumab Company: Event unrelated to durvalumab.
						Infusion	1500 milligram q3w Intravenous use	08-JAN-2021 to 08-JAN-2021 1 day	
						Infusion	1500 milligram q3w Intravenous use	10-FEB-2022 to 10-FEB-2022 1 day	
						Infusion	1500 milligram q3w Intravenous use	11-JUL-2022 to 11-JUL-2022 1 day	
						Infusion	1500 milligram q3w Intravenous use	13-JAN-2022 to 13-JAN-2022 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram q3w Intravenous use	13-JUN-2022 to 13-JUN-2022 1 day	
						Infusion	1500 milligram q3w Intravenous use	14-OCT-2020 to 14-OCT-2020 1 day	
						Infusion	1500 milligram q3w Intravenous use	15-DEC-2021 to 15-DEC-2021 1 day	
						Infusion	1500 milligram q3w Intravenous use	16-MAY-2022 to 16-MAY-2022 1 day	
						Infusion	1500 milligram q3w Intravenous use	18-DEC-2020 to 18-DEC-2020 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram q3w Intravenous use	18-NOV-2021 to 18-NOV-2021 1 day	
						Infusion	1500 milligram q3w Intravenous use	19-AUG-2021 to 19-AUG-2021 1 day	
						Infusion	1500 milligram q3w Intravenous use	19-JUL-2021 to 19-JUL-2021 1 day	
						Infusion	1500 milligram q3w Intravenous use	19-OCT-2021 to 19-OCT-2021 1 day	
						Infusion	1500 milligram q3w Intravenous use	20-MAY-2021 to 20-MAY-2021 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram q3w Intravenous use	21-JUN-2021 to 21-JUN-2021 1 day	
						Infusion	1500 milligram q3w Intravenous use	22-APR-2021 to 22-APR-2021 1 day	
						Infusion	1500 milligram q3w Intravenous use	22-SEP-2021 to 22-SEP-2021 1 day	
						Infusion	1500 milligram q3w Intravenous use	23-SEP-2020 to 23-SEP-2020 1 day	
						Infusion	1500 milligram q3w Intravenous use	25-FEB-2021 to 25-FEB-2021 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D933S

Study ID: D933SC00001

EudraCT No: 2024-510976-19-00

Study Design: Not Blinded

Study Description: D933SC00001 Ph 3 Durva+Treme+SOC in first line bladder cancer - A Phase III, Randomized, Open-Label, Controlled, Multi-Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	1500 milligram q3w Intravenous use	25-MAR-2021 to 25-MAR-2021 1 day	
						Infusion	1500 milligram q3w Intravenous use	27-NOV-2020 to 27-NOV-2020 1 day	
						Infusion	1500 milligram q3w Intravenous use	29-JAN-2021 to 29-JAN-2021 1 day	

Concomitant Medication(s): | Cisplatin (S) | Gemcitabine (S) | Palonosetron hydrochloride (C) | Dexamethasone sodium phosphate (C) | Recombinant human granulocyte colony stimulating factor (C) | Methoclopramide (C) | Sodium (C) | Monoammonium glycyrrhizinate (C) | Pegylated recombinant human granulocyte colony-stimulating factor (C) | Licorice (C) | Prednisone (C) | Dezocine (C) | Ornidazole (C) | Haemocoagulase (C)

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967J

Study ID: D967JC00001

EudraCT No: 2023-505309-18-00

Study Design: Not Blinded

Study Description: D967JC00001 HER2+ Dose Finding (PoC) Study (HER2+) - A Phase 1b/2 Multicentre, Open-label, Modular, Dose-finding and Dose-expansion Study to Explore the Safety, Tolerability, and Anti-tumour Activity of Trastuzumab Deruxtecan (T-DXd) in Combination with other Anti-cancer Agents in Patients with HER2-positive Metastatic Breast Cancer (DESTINY-Breast07)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Hepatobiliary disorders									
202508GLO009648RU	RUSSIAN FEDERATION 65 Years Female	**Hepatitis toxic (Hepatitis toxic) ***	Not Recovered	01-Aug-2025 3 years 9 months 8 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	340 milligram Intravenous use	25-OCT-2021 to 15-JUL-2025 3 years 8 months 21 days	
Concomitant Medication(s): | Valsacor (C)									
SOC:Infections and infestations									
202507GLO024369TW	TAIWAN Female	**Spontaneous bacterial peritonitis (Spontaneous bacterial peritonitis)*** Interstitial lung disease (Interstitial lung disease)	Recovering	25-Jul-2025 10 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	16-JUL-2025 to 16-JUL-2025 1 day	Periodic Report Comments. Patient has events Anemia, Spontaneous bacterial Peritonitis. Action taken with study therapy was Unknown. Investigator Causality: Not Reported, CC: Not Related; Periodic Report Comments. PRC Format - Patient has event : Spontaneous bacterial Peritonitis, Action Taken : Withdrawn, Investor Causality: related, Company Causality : Not Related. Patient has event : Interstitial lung disease, Action Taken : Withdrawn, Investor Causality: related, Company Causality : Related.
Concomitant Medication(s):									

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967J

Study ID: D967JC00001

EudraCT No: 2023-505309-18-00

Study Design: Not Blinded

Study Description: D967JC00001 HER2+ Dose Finding (PoC) Study (HER2+) - A Phase 1b/2 Multicentre, Open-label, Modular, Dose-finding and Dose-expansion Study to Explore the Safety, Tolerability, and Anti-tumour Activity of Trastuzumab Deruxtecan (T-DXd) in Combination with other Anti-cancer Agents in Patients with HER2-positive Metastatic Breast Cancer (DESTINY-Breast07)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO015969TR	TURKEY Female	**Infection (Infection)***	Recovering	19-Aug-2025 6 days	PERTUZUMAB	Infusion	Intravenous use	14-AUG-2025 to	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	Intravenous use	14-AUG-2025 to	

Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Docetaxel (S)

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

EudraCT No: 2019-004483-22 **Study Design:** Not Blinded

Study ID: D967LC00001

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
202505GLO007107ES	SPAIN 62 Years Male	**Febrile neutropenia (Febrile neutropenia)***	Recovered	08-May-2025 1 month 13 days	AZD2936	Solution	750 milligram q3w Intravenous use	26-MAR-2025 to 02-JUL-2025 3 months 7 days	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | CAPECITABINE (S) | Candesartan cilexetil (C) | Hydrochlorothiazide (C) | Bisoprolol (C) | Esomeprazole (C) | Domperidone (C) | Vitamin d (C) | Fluconazole (C) | Loperamide (C)									
202507GLO008120KR	KOREA, REPUBLIC OF 76 Years Male	**Thrombocytopenia (Thrombocytopenia)*** Neutropenia (Neutropenia)*	Recovered	26-Jun-2025 4 months 15 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	04-APR-2025 to 04-APR-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	09-MAY-2025 to 09-MAY-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	13-MAR-2025 to 13-MAR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	19-JUN-2025 to 19-JUN-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	21-AUG-2025 to 21-AUG-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	30-MAY-2025 to 30-MAY-2025 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	12-FEB-2025 to 12-FEB-2025 1 day	

Concomitant Medication(s): | CAPECITABINE (S) | RILVEGOSTOMIG (S) | Megace (C) | Amaryl (C) | Tenelia (C) | Dexid (C) | Pravix (C) | Glupa (C) | Macperan (C) | Lopaine (C) | Tantum (C)

SOC:Endocrine disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202501GLO003189GB	UNITED KINGDOM 54 Years Male	**Adrenal insufficiency (Hypoadrenalism)***	Recovered	30-Dec-2024 7 months 3 days	CAPECITABINE	Tablet	750 milligram/sq. meter q3w Oral use	28-MAY-2024 to 24-DEC-2024 6 months 27 days	The patient experienced Hypoadrenalism & Hypoparathyroidism. Investigator: related to Capecitabine, MEDI5752. Not related to Trastuzumab Deruxtecan. Company: not related;Periodic Report Comments. Patient experienced HYPOADRENALISM and Hypoparathyroidism Inv, TRASTUZUMAB DERUXTECAN and CAPECITABINE and MEDI5752,Inv, TRASTUZUMAB DERUXTECAN and CAPECITABINE and MEDI5752 ,Inv, related to , TRASTUZUMAB DERUXTECAN and CAPECITABINE and MEDI5752 ,CCA :related , TRASTUZUMAB DERUXTECAN and CAPECITABINE and MEDI5752 ,Inv, related to , TRASTUZUMAB DERUXTECAN and CAPECITABINE and MEDI5752 CCA: not related to , TRASTUZUMAB DERUXTECAN and CAPECITABINE and MEDI5752 ,Inv, related to TRASTUZUMAB DERUXTECAN and CAPECITABINE and
					MEDI5752	Infusion	500 milligram q3w Intravenous use	28-MAY-2024 to 10-DEC-2024 6 months 13 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
									MEDI5752

Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | MEDI5752 (S) | Aprepitant (C) | Ondansetron (C) | Omeprazole (C) | Prednisolone (C) | Fluoxetine (C) | Metoclopramide (C) | Loperamide (C) | Levomepromazine (C) | Ondansetron (C) | Aprepitant (C) | Fluoxetine (C) | Metoclopramide (C)

SOC:Gastrointestinal disorders

202410GLO014259US	UNITED STATES 49 Years Male	**Colitis (Colitis)***	Recovered	31-Aug-2024 nk	5-FU	Infusion	480 milligram/sq. meter q3w Intravenous use	11-OCT-2024 to 02-MAR-2025 4 months 20 days	Periodic Report Comments. Patient experienced colitis,.., Inves: related to study therapy, comp: not related to study therapy.
						Infusion	480 milligram/sq. meter q3w Intravenous use	19-MAR-2025 to 07-JUL-2025 3 months 19 days	
						Infusion	600 milligram/sq. meter Intravenous use	01-AUG-2024 to 18-SEP-2024 1 month 18 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	4.4 milligram/kilogram Intravenous use	11-OCT-2024 to 13-DEC-2024 2 months 3 days	
						Powder for solution for infusion	4.4 milligram/kilogram Intravenous use	15-JAN-2025 to 15-JAN-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram Intravenous use	19-MAR-2025 to 02-JUL-2025 3 months 14 days	
						Powder for solution for infusion	5.4 milligram/kilogram Intravenous use	05-FEB-2025 to 26-FEB-2025 22 days	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	01-AUG-2024 to 13-SEP-2024 1 month 13 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | MEDI5752 (S) | Clonazepam (C) | Wellbutrin (C) | Pantoprazole (C) | Oxycodone (C) | Acetaminophen (C) | Olanzapine (C) | Ondansetron (C) | Prochlorperazine (C)									
202505GLO023312CN	CHINA 52 Years Female	**Gastrointestinal haemorrhage (Hemorrhage gastrointestinal)***	Recovered	22-May-2025 10 months 27 days	MEDI5752	Infusion	250 milligram q3w Intravenous use	02-JUL-2025 to 02-JUL-2025 1 day	Periodic Report Comment. Patient experienced alimentary tract hemorrhage. Investigator: Related with study therapy Company physician: Not related.
						Infusion	250 milligram q3w Intravenous use	04-MAR-2025 to 04-MAR-2025 1 day	
						Infusion	250 milligram q3w Intravenous use	09-MAY-2025 to 09-MAY-2025 1 day	
						Infusion	250 milligram q3w Intravenous use	11-FEB-2025 to 11-FEB-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	250 milligram q3w Intravenous use	15-AUG-2025 to 15-AUG-2025 1 day	
						Infusion	250 milligram q3w Intravenous use	17-APR-2025 to 17-APR-2025 1 day	
						Infusion	250 milligram q3w Intravenous use	21-JAN-2025 to 21-JAN-2025 1 day	
						Infusion	250 milligram q3w Intravenous use	25-JUL-2025 to 25-JUL-2025 1 day	
						Infusion	250 milligram q3w Intravenous use	26-MAR-2025 to 26-MAR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	250 milligram q3w Intravenous use	31-DEC-2024 to 31-DEC-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	07-AUG-2024 to 07-AUG-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	09-OCT-2024 to 09-OCT-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	11-DEC-2024 to 11-DEC-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	17-JUL-2024 to 17-JUL-2024 1 day	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

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EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Infusion	500 milligram q3w Intravenous use	19-SEP-2024 to 19-SEP-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	20-NOV-2024 to 20-NOV-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	26-JUN-2024 to 26-JUN-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	28-AUG-2024 to 28-AUG-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	30-OCT-2024 to 30-OCT-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

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EudraCT No: 2019-004483-22

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Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	02-JUL-2025 to 02-JUL-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	04-MAR-2025 to 04-MAR-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	09-MAY-2025 to 09-MAY-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	09-OCT-2024 to 09-OCT-2024 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	11-DEC-2024 to 11-DEC-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	11-FEB-2025 to 11-FEB-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	15-AUG-2025 to 15-AUG-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	17-APR-2025 to 17-APR-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	19-SEP-2024 to 19-SEP-2024 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	20-NOV-2024 to 20-NOV-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	21-JAN-2025 to 21-JAN-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	25-JUL-2025 to 25-JUL-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	26-MAR-2025 to 26-MAR-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	28-AUG-2024 to 28-AUG-2024 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	30-OCT-2024 to 30-OCT-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	31-DEC-2024 to 31-DEC-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	07-AUG-2024 to 07-AUG-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	17-JUL-2024 to 17-JUL-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	26-JUN-2024 to 26-JUN-2024 1 day	

Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | CAPECITABINE (S) | Diphenhydramine hydrochloride (C) | Esomeprazole sodium (C)

SOC:General disorders and administration site conditions

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202510GLO013392PL	POLAND 70 Years Male	**Obstruction (Obstruction)***	Recovering	13-Oct-2025 7 months 4 days	CAPECITABINE	Tablet	750 milligram/sq. meter Intravenous use	10-MAR-2025 to 18-MAR-2025 9 days	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | 5-FLUOROURACIL (S) | AZD2936 (S) |									
SOC:Hepatobiliary disorders									
202410GLO008848DE	GERMANY 58 Years Male	**Autoimmune hepatitis (Autoimmune hepatitis)*** Aspartate aminotransferase increased (AST increased)	Fatal	10-Oct-2024 4 months 19 days	MEDI5752	Infusion	500 milligram Intravenous use	22-MAY-2024 to 22-AUG-2024 3 months 1 day	Initial source document. The patient experienced acute liver failure, serious . Investigator: Trastuzumab Deruxtecan to related . Sponsor.Not related.;Patient experienced Hepatitis investigation causality was not related with suspect therapy.
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | CAPECITABINE (S) | Ramipril (C) | Pantoprazol (C) | Movicol (C) | L-thyroxin (C) | Prednisolone (C) | Buscopan (C)									
SOC:Infections and infestations									
202510GLO001735PL	POLAND 51 Years Female	**Pneumonia (Pneumonia)***	Fatal	22-Sep-2025 238 days	ENHERTU	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	10-MAR-2025 to 10-MAR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	12-MAY-2025 to 12-MAY-2025 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	17-FEB-2025 to 17-FEB-2025 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	18-AUG-2025 to 18-AUG-2025 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	22-APR-2025 to 22-APR-2025 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	25-JUL-2025 to 25-JUL-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	27-JAN-2025 to 27-JAN-2025 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	30-JUN-2025 to 30-JUN-2025 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	31-MAR-2025 to 31-MAR-2025 1 day	
					RILVEGOSTOMIG	Solution	750 milligram Unknown	10-MAR-2025 to 10-MAR-2025 1 day	
						Solution	750 milligram Unknown	12-MAY-2025 to 12-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution	750 milligram Unknown	17-FEB-2025 to 17-FEB-2025 1 day	
						Solution	750 milligram Unknown	18-AUG-2025 to 18-AUG-2025 1 day	
						Solution	750 milligram Unknown	22-APR-2025 to 22-APR-2025 1 day	
						Solution	750 milligram Unknown	25-JUL-2025 to 25-JUL-2025 1 day	
						Solution	750 milligram Unknown	27-JAN-2025 to 27-JAN-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution	750 milligram Unknown	30-JUN-2025 to 30-JUN-2025 1 day	
						Solution	750 milligram Unknown	31-MAR-2025 to 31-MAR-2025 1 day	
Concomitant Medication(s): | CAPECITABINE (S) | RILVEGOSTOMIG (S)									

SOC:Investigations

202504GLO027429BR	BRAZIL 63 Years Female	**Troponin I increased (Troponin I increased)***	Recovered	21-Apr-2025 1 month 11 days	AZD2936	Solution	750 milligram Intravenous use	11-MAR-2025 to 15-JUL-2025 4 months 5 days	periodic report comment. Patient experienced INCREASED OF TROPONIN I, inv: related to TRASTUZUMAB DERUXTECAN, RILVEGOSTOMIG, not related to CAPECITABINE, cca: not related to TRASTUZUMAB DERUXTECAN, CAPECITABINE, RILVEGOSTOMIG; Periodic Report Comments. Patient experienced INCREASED OF TROPONIN I, inv: related to TRASTUZUMAB
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	11-MAR-2025 to 15-JUL-2025 4 months 5 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
									DERUXTECAN, RILVEGOSTOMIG, not related to CAPECITABINE, cca: not related to TRASTUZUMAB DERUXTECAN, CAPECITABINE, RILVEGOSTOMIG Action taken of TRASTUZUMAB UPDATED TO Dose reduced.
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | CAPECITABINE (S) | | Olmesartan (C) | Metformin (C) | Linagliptin (C) | Linadib (C)									

SOC:Metabolism and nutrition disorders

202509GLO003458CN	CHINA 52 Years Female	**Malnutrition (Malnutrition)***	Not Recovered	03-Sep-2025 1 year 2 months 9 days	MEDI5752	Infusion	250 milligram q3w Intravenous use	31-DEC-2024 to 17-APR-2025 3 months 18 days	Periodic Report Comments. Patient experienced vomiting. Inv: event related to Medi5752, Trastuzumab Deruxtecan and not related to capecitabine. CCA: not related.
						Infusion	500 milligram q3w Intravenous use	26-JUN-2024 to 11-DEC-2024 5 months 16 days	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	04-MAR-2025 to 04-MAR-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	09-OCT-2024 to 09-OCT-2024 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	11-DEC-2024 to 11-DEC-2024 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	11-FEB-2025 to 11-FEB-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	17-APR-2025 to 17-APR-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	19-SEP-2024 to 19-SEP-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	20-NOV-2024 to 20-NOV-2024 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	21-JAN-2025 to 21-JAN-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	26-MAR-2025 to 26-MAR-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	28-AUG-2024 to 28-AUG-2024 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	30-OCT-2024 to 30-OCT-2024 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	31-DEC-2024 to 31-DEC-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	07-AUG-2024 to 07-AUG-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	17-JUL-2024 to 17-JUL-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	26-JUN-2024 to 26-JUN-2024 1 day	

Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | CAPECITABINE (S) | | Diphenhydramine hydrochloride (C) | Betamethasone sodium phosphate (C) | Metoclopramide dihydrochloride (C) | Dolasetron mesylate (C)

SOC:Skin and subcutaneous tissue disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO006937US	UNITED STATES 38 Years Male	**Rash maculo-papular (Rash maculo-papular)***	Not Recovered	05-Jul-2025 128 days	CAPECITABINE	Tablet	750 milligram/sq. meter q3w Oral use	13-MAR-2025 to 17-JUL-2025 4 months 5 days	Patient experienced Rash maculo-papular. Investigator causality related to trastuzumab deruxtecan, capecitabine, AZD2936, CCA not related.
						Tablet	750 milligram/sq. meter q3w Oral use	27-FEB-2025 to 27-FEB-2025 1 day	
						Tablet	750 milligram/sq. meter q3w Oral use	28-FEB-2025 to 12-MAR-2025 13 days	
					RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	21-MAR-2025 to 31-JUL-2025 4 months 11 days	
						Solution	750 milligram q3w Intravenous use	27-FEB-2025 to 27-FEB-2025 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	01-MAY-2025 to 01-MAY-2025 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	10-APR-2025 to 10-APR-2025 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	21-MAR-2025 to 21-MAR-2025 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	22-MAY-2025 to 31-JUL-2025 2 months 10 days	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	27-FEB-2025 to 27-FEB-2025 1 day	

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967L

Study ID: D967LC00001

EudraCT No: 2019-004483-22

Study Design: Not Blinded

Study Description: DS-8201 in HER2+ Gastric Cancer (DESTINY-Gastric03) - A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants with HER2 Overexpressing Gastric Cancer (DESTINY-Gastric03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | RILVEGOSTOMIG (S) | Docusate sodium (C) | Ondansetron (C) | Omeprazole (C) | Magnesium citrate (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967Y

EudraCT No: 2020-003260-31 **Study Design:** Not Blinded

Study ID: D967YC00001

Study Description: D967YC00001 Phase 1b Dose Escalation/Expansion - T-DXd+Imfinzi+CTx 1L NSCLC (DESTINY-Lung03) - A Phase Ib Multicenter, Open-label Study to Evaluate the Safety and Tolerability of Trastuzumab Deruxtecan (T-DXd) and Immunotherapy Agents With and Without Chemotherapy Agents in First-line Treatment of Patients with Advanced or Metastatic Non-squamous Non-small Cell Lung Cancer (NSCLC) and Human Epidermal Growth Factor Receptor 2 (HER2) Overexpression (OE) (DESTINY-Lung03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Blood and lymphatic system disorders									
202411GLO014230PH	PHILIPPINES 58 Years Female	**Anaemia of chronic disease (Anemia of chronic disease)*** Platelet count decreased (Platelet count decreased)	Not Recovered	23-Sep-2024 nk	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	06-NOV-2024 to 23-APR-2025 5 months 18 days	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	15-OCT-2024 to 15-OCT-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	24-SEP-2024 to 24-SEP-2024 1 day	
Concomitant Medication(s): | MEDI5752 (S) | Losartan (C) | Folic acid | Iron (C) | Betamethasone (C) | Epoetin alfa (C) | Bilastine (C) | Palonosetron (C) | Ondansetron (C) | Ciprofloxacin (C) | Paracetamol (C) | Calamine (C) | Metoclopramide (C)									
202504GLO027986PH	PHILIPPINES 76 Years Male	**Anaemia (Anemia)*** Neutropenia (Neutropenia)*	Recovered	13-Mar-2025 15 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	3.2 milligram/kilogram q3w Intravenous use	05-AUG-2025 to 27-AUG-2025 23 days	Periodic Report Comments. Patient experienced anemia and neutropenia. Investigator Causality: Not Related CC: Not Related. TRASTUZUMAB DERUXTECAN Anemia.

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967Y

Study ID: D967YC00001

EudraCT No: 2020-003260-31

Study Design: Not Blinded

Study Description: D967YC00001 Phase 1b Dose Escalation/Expansion - T-DXd+Imfinzi+CTx 1L NSCLC (DESTINY-Lung03) - A Phase Ib Multicenter, Open-label Study to Evaluate the Safety and Tolerability of Trastuzumab Deruxtecan (T-DXd) and Immunotherapy Agents With and Without Chemotherapy Agents in First-line Treatment of Patients with Advanced or Metastatic Non-squamous Non-small Cell Lung Cancer (NSCLC) and Human Epidermal Growth Factor Receptor 2 (HER2) Overexpression (OE) (DESTINY-Lung03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	23-JUN-2025 to 23-JUN-2025 1 day	Investigator Causality: Related CC: Not Related. AZD2936 Neutropenia.
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	27-FEB-2025 to 07-MAY-2025 2 months 11 days	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	29-MAY-2025 to 29-MAY-2025 1 day	
		Neutropenia (Neutropenia)*	Recovered	08-Apr-2025 1 month 13 days	AZD2936	Solution	750 milligram q3w Intravenous use	05-AUG-2025 to 27-AUG-2025 23 days	
						Solution	750 milligram q3w Intravenous use	18-MAR-2025 to 29-MAY-2025 2 months 12 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967Y

Study ID: D967YC00001

EudraCT No: 2020-003260-31

Study Design: Not Blinded

Study Description: D967YC00001 Phase 1b Dose Escalation/Expansion - T-DXd+Imfinzi+CTx 1L NSCLC (DESTINY-Lung03) - A Phase Ib Multicenter, Open-label Study to Evaluate the Safety and Tolerability of Trastuzumab Deruxtecan (T-DXd) and Immunotherapy Agents With and Without Chemotherapy Agents in First-line Treatment of Patients with Advanced or Metastatic Non-squamous Non-small Cell Lung Cancer (NSCLC) and Human Epidermal Growth Factor Receptor 2 (HER2) Overexpression (OE) (DESTINY-Lung03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Solution	750 milligram q3w Intravenous use	23-JUN-2025 to 23-JUN-2025 1 day	
						Solution	750 milligram q3w Intravenous use	27-FEB-2025 to 27-FEB-2025 1 day	
Concomitant Medication(s): | AZD2936 (S) | Amlodipine (C) | Atenolol (C) | Atorvastatin calcium (C) | Clopidogrel (C) | Irbesartan (C) | Folic acid (C) | Ferrous sulfate (C) | Moriamin forte (C) | Ondansetron (C)									
202505GLO017984PH	PHILIPPINES 76 Years Male	**Neutropenia (Neutropenia)***	Recovered	06-May-2025 2 months 10 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	3.2 milligram/kilogram q3w Intravenous use	23-JUN-2025 to 23-JUN-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	29-MAY-2025 to 29-MAY-2025 1 day	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967Y

Study ID: D967YC00001

EudraCT No: 2020-003260-31

Study Design: Not Blinded

Study Description: D967YC00001 Phase 1b Dose Escalation/Expansion - T-DXd+Imfinzi+CTx 1L NSCLC (DESTINY-Lung03) - A Phase Ib Multicenter, Open-label Study to Evaluate the Safety and Tolerability of Trastuzumab Deruxtecan (T-DXd) and Immunotherapy Agents With and Without Chemotherapy Agents in First-line Treatment of Patients with Advanced or Metastatic Non-squamous Non-small Cell Lung Cancer (NSCLC) and Human Epidermal Growth Factor Receptor 2 (HER2) Overexpression (OE) (DESTINY-Lung03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	27-FEB-2025 to 07-MAY-2025 2 months 11 days	
Concomitant Medication(s): | AZD2936 (S) | Amlodipine (C) | Atenolol (C) | Atorvastatin calcium (C) | Clopidogrel (C) | Irbesartan (C) | Bilastine (C) | Folic acid (C) | Ferrous sulfate (C) | Moriamin forte (C)									
202507GLO013801TW	TAIWAN 63 Years Male	**Neutropenia (Neutropenia)***	Recovered	29-Oct-2024 15 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram Intravenous use	15-OCT-2024 to 15-OCT-2024 1 day	
Concomitant Medication(s): | MEDI5752 (S) | Eurodin (C) | Tamsulosin (C) | Through (C)									
202508GLO023705PH	PHILIPPINES 64 Years Female	**Neutropenia (Neutropenia)***	Recovered	01-Sep-2025 7 months 6 days	AZD2936	Solution	750 milligram q3w Intravenous use	25-SEP-2025 to 15-OCT-2025 21 days	
						Solution	750 milligram q3w Intravenous use	27-JAN-2025 to 01-SEP-2025 7 months 6 days	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Vildagliptin (C) | Glimepiride (C) | Amlodipine (C)									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967Y

Study ID: D967YC00001

EudraCT No: 2020-003260-31

Study Design: Not Blinded

Study Description: D967YC00001 Phase 1b Dose Escalation/Expansion - T-DXd+Imfinzi+CTx 1L NSCLC (DESTINY-Lung03) - A Phase Ib Multicenter, Open-label Study to Evaluate the Safety and Tolerability of Trastuzumab Deruxtecan (T-DXd) and Immunotherapy Agents With and Without Chemotherapy Agents in First-line Treatment of Patients with Advanced or Metastatic Non-squamous Non-small Cell Lung Cancer (NSCLC) and Human Epidermal Growth Factor Receptor 2 (HER2) Overexpression (OE) (DESTINY-Lung03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
SOC:Cardiac disorders									
202412GLO013683MY	MALAYSIA 68 Years Female	**Myocardial infarction (Myocardial infarction)***	Fatal	18-Nov-2024 28 days	MEDI5752	Infusion	Intravenous use	22-OCT-2024 to 12-NOV-2024 22 days	Periodic Report Comments. The patient Female experienced serious myocardial infarction related to Trastuzumab Deruxtecan. CCA:Not related
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Amlodipine (C) | Atorvastatin (C) | Glucoxit (C) | Perindopril (C) | Vitamin b complex (C) | Gabapentin (C) | Magnesium trisilicate (C) | Tramadol (C)									
SOC:Endocrine disorders									
202507GLO001819PH	PHILIPPINES 65 Years Male	**Hypothyroidism (Hypothyroidism)***	Recovering	01-Jul-2025 5 months 17 days	AZD2936	Solution	750 milligram q3w Intravenous use	15-JAN-2025 to 10-JUN-2025 4 months 27 days	Periodic Report Comments. The patient experienced HEART BLOCK. Investigator causality related to Study therapy Rilvegostomig and CCA not related. Investigator causality not related TRASTUZUMAB DERUXTECAN and CCA not related
						Solution	750 milligram q3w Intravenous use	22-JUL-2025 to 12-AUG-2025 22 days	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Insulin lispro (C)									
SOC:General disorders and administration site conditions									

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Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967Y

Study ID: D967YC00001

EudraCT No: 2020-003260-31

Study Design: Not Blinded

Study Description: D967YC00001 Phase 1b Dose Escalation/Expansion - T-DXd+Imfinzi+CTx 1L NSCLC (DESTINY-Lung03) - A Phase Ib Multicenter, Open-label Study to Evaluate the Safety and Tolerability of Trastuzumab Deruxtecan (T-DXd) and Immunotherapy Agents With and Without Chemotherapy Agents in First-line Treatment of Patients with Advanced or Metastatic Non-squamous Non-small Cell Lung Cancer (NSCLC) and Human Epidermal Growth Factor Receptor 2 (HER2) Overexpression (OE) (DESTINY-Lung03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202509GLO017456PH	PHILIPPINES 62 Years Male	**Sudden cardiac death (Sudden cardiac death)***	Fatal	18-Sep-2025 3 days	AZD2936	Solution	750 milligram q3w Intravenous use	16-SEP-2025 to 16-SEP-2025 1 day	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	16-SEP-2025 to 16-SEP-2025 1 day	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Prednisone (C) | Digoxin (C) | Apixaban (C)									

SOC:Infections and infestations

202412GLO006760PH	PHILIPPINES 66 Years Male	**Pneumonia (Lung infection)***	Fatal	08-Dec-2024 4 months 2 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	07-AUG-2024 to 20-NOV-2024 3 months 14 days	Periodic Report Comments. Periodic comment: Patient experience Lung infection and PULMONARY EMBOLISM. Investigator: Related to MEDI5752 CCA: Not related to Study therapy. Action taken : No change.
Concomitant Medication(s): | MEDI5752 (S) | Minerals (C) | Fluticasone (C) | Losartan (C) | Diphenhydramine (C) | Levocetirizine (C) | Folic acid (C) | Erythropoietin (C)									
202505GLO002377PH	PHILIPPINES 58 Years Female	**Pneumonia (Lung infection)***	Fatal	03-May-2025 7 months 10 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	02-APR-2025 to 23-APR-2025 22 days	

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Project ID: D967Y

Study ID: D967YC00001

EudraCT No: 2020-003260-31

Study Design: Not Blinded

Study Description: D967YC00001 Phase 1b Dose Escalation/Expansion - T-DXd+Imfinzi+CTx 1L NSCLC (DESTINY-Lung03) - A Phase Ib Multicenter, Open-label Study to Evaluate the Safety and Tolerability of Trastuzumab Deruxtecan (T-DXd) and Immunotherapy Agents With and Without Chemotherapy Agents in First-line Treatment of Patients with Advanced or Metastatic Non-squamous Non-small Cell Lung Cancer (NSCLC) and Human Epidermal Growth Factor Receptor 2 (HER2) Overexpression (OE) (DESTINY-Lung03)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	24-SEP-2024 to 12-MAR-2025 5 months 17 days	
Concomitant Medication(s): | MEDI5752 (S) | Losartan (C)									
SOC:Investigations									
2024A149789	TAIWAN 65 Years Female	**Neutrophil count decreased (Neutrophil count decreased)***	Recovered	24-Jun-2024 2 months 7 days	CARBOPLATIN	Infusion	Intravenous use	16-MAY-2024 to 13-JUN-2024 29 days	Periodic Report Comment. Patient experienced multiple events. Inv: Related with study therapy, CCA-not related
						Infusion	Intravenous use	18-APR-2024 to 18-APR-2024 1 day	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | MEDI5752 (S) | | Acetaminophen (C) | Medicon a (C) | Ambroxol (C) | Megestrol (C) | Foster (C) | Montelukast (C) | Furosemide (C)									
SOC:Respiratory, thoracic and mediastinal disorders									

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

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202411GLO021174PH	PHILIPPINES 66 Years Male	**Interstitial lung disease (Interstitial lung disease)***	Not Recovered	23-Nov-2024 3 months 17 days	MEDI5752	Infusion	500 milligram q3w Intravenous use	07-AUG-2024 to 07-AUG-2024 1 day	Periodic Report Comments. Patient experienced interstitial lung disease Inv causality: RELATED to both suspects CCC: NOT RELATED and experienced the event decreased platelet count Inv causality: RELATED to Trastuzumab Deruxtecan NOT RELATED to MEDI5752 CCC: NOT RELATED
						Infusion	500 milligram q3w Intravenous use	07-OCT-2024 to 07-OCT-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	18-SEP-2024 to 18-SEP-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	20-NOV-2024 to 20-NOV-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	29-AUG-2024 to 29-AUG-2024 1 day	

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						Infusion	500 milligram q3w Intravenous use	29-OCT-2024 to 29-OCT-2024 1 day	
Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | Diphenhydramine (C) | Levocetirizine (C) | Folic acid (C) | Vitamins nos (C) | Salmeterol (C) | Losartan (C) | Erythropoietin (C)									
202412GLO006760PH	PHILIPPINES 66 Years Male	**Pulmonary embolism (Pulmonary embolism)***	Fatal	14-Dec-2024 4 months 8 days	MEDI5752	Infusion	500 milligram q3w Intravenous use	07-AUG-2024 to 20-NOV-2024 3 months 14 days	Periodic Report Comments. Periodic comment: Patient experience Lung infection and PULMONARY EMBOLISM. Investigator: Related to MEDI5752 CCA: Not related to Study therapy. Action taken : No change.
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Minerals (C) | Fluticasone (C) | Losartan (C) | Diphenhydramine (C) | Levocetirizine (C) | Folic acid (C) | Erythropoietin (C)									
2024A114211	KOREA, REPUBLIC OF 75 Years Male	**Pneumonitis (Pneumonitis)*** Pneumonia (Lung infection)*	Fatal	13-May-2024 1 month 21 days 12 hrs 20 min	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use 5.4 milligram/kilogram q3w Intravenous use	02-MAY-2024 to 02-MAY-2024 1 day 11-APR-2024 16:05 to 11-APR-2024 16:35 30 min	Periodic Report Comment. Patient experienced pneumonitis and lung infection, Related to study drugs Trastuzumab Deruxtecan and to Medi5752, CCA: Not Related to Trastuzumab Deruxtecan and to Medi5752.

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						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	21-MAR-2024 11:40 to 21-MAR-2024 13:20 1 hr 40 min	
					MEDI5752	Infusion	500 milligram q3w Intravenous use	02-MAY-2024 to 02-MAY-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	11-APR-2024 to 11-APR-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	21-MAR-2024 09:40 to 02-MAY-2024 1 month 10 days 14 hrs 20 min	

Concomitant Medication(s): | MEDI5752 (S) | Clopidogrel (C) | Keppra (C) | Eylea (C) | Atozet (C) | Lopaine (C) | Magmil (C) | Peniramin (C) | Lanston (C) | Lacticare (C) | Sancuso (C) | Nasea od (C) | Megace F (C) | Scansolone (C) | Sama Tantum gargle (C) | Norzyme (C) | Foipan (C) | Tropherin (C) | Hyabak (C) | Neurontin (C) | Phenylephrine hydrochloride | Zinc oxide (C)

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202507GLO000729TW	TAIWAN 77 Years Male	**Pneumonitis (Pneumonitis)***	Not Recovered	24-Jun-2025 7 months 6 days	AZD2936	Solution	Intravenous use	19-NOV-2024 to 12-JUN-2025 6 months 25 days	Periodic Report Comments. Patient experienced pneumonitis. Inv: event related to study therapy. CCA: not related.
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Zopiclone (C) | Alprazolam (C) | Acetylcysteine (C) | Famotidine (C) | Clobetasol (C)									
202509GLO002499PH	PHILIPPINES 65 Years Male	**Interstitial lung disease (Interstitial lung disease)*** Ventricular arrhythmia (Ventricular arrhythmia)*	Recovering	02-Sep-2025 7 months 19 days	AZD2936	Solution	750 milligram q3w Intravenous use	15-JAN-2025 to 12-AUG-2025 6 months 29 days	Periodic Report Comments. Patient experienced interstitial lung disease, abdominal infection and ventricular arrhythmia. Inv: both suspect not related to abdominal infection, related to interstitial lung disease.
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Insulin lispro (C) | Sitagliptin metformin (C) | Budesonide | Indacaterol (C) | Ipratropium bromide | Salbutamol sulfate (C) | Trimetazidine (C) | Clopidogrel (C)									

Sponsored Study where the IMP has been used as a comparator in other projects

Total count of Cases: 705

Total count of SUSARs: 811

Definition of code

MedDRA abbreviations

PT	Preferred Term
SOC	System Organ Class

Concomitant medication details

C	Concomitant Product
I	Interacting Product
S	Suspect Product
T	Study Treatment Product

Other abbreviations

AE	Adverse Event
ADR	Adverse Drug Reaction
SAE	Serious Adverse Event
SSAR	Suspected Serious Adverse Reaction
SUSAR	Suspected Unexpected Serious Adverse Reaction
nk	Not known
AZ	AstraZeneca

Alphabetical Listing of MedDRA SOCs
MedDRA Version: 28.1

Blood and lymphatic system disorders
Cardiac disorders
Ear and labyrinth disorders
Endocrine disorders
Eye disorders
Gastrointestinal disorders
General disorders and administration site conditions
Hepatobiliary disorders
Immune system disorders
Infections and infestations
Injury, poisoning and procedural complications
Investigations
Metabolism and nutrition disorders
Musculoskeletal and connective tissue disorders
Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Nervous system disorders
Psychiatric disorders
Renal and urinary disorders
Reproductive system and breast disorders
Respiratory, thoracic and mediastinal disorders
Skin and subcutaneous tissue disorders
Vascular disorders

Line Listing of Suspected Unexpected Serious Adverse Reactions from AstraZeneca sponsored clinical studies

Filter Selection:

No filter selected for this report.