Periodic Safety Statement of SUSARs

Drug Substance	Rilvegostomig (AZD2936)
Date	21 January 2026

Periodic Safety Statement of Suspected Unexpected Serious Adverse Reactions (SUSARs) Rilvegostomig (AZD2936)

Period covered: 06 July 2025 to 05 January 2026

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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 06 July 2025 to 05 January 2026 for AstraZeneca Investigational Medicinal Product (IMP) rilvegostomig (AZD2936). The Line Listing attached to this safety statement includes SUSAR reports from all treatment arms of AstraZeneca sponsored clinical studies of rilvegostomig (AZD2936), 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).

During the reporting period, pneumonitis/interstitial lung disease, hepatic events and diarrhoea/colitis were recategorized from potential to identified risks. The necessary changes have been made to the Investigator's Brochure. The benefit-risk profile for rilvegostomig (AZD2936) remains unchanged.

Unlike the current Periodic SUSAR Line Listing (PSLL) outputs, the previous PSLL did not include the SUSARs reported from AstraZeneca sponsored studies involving the rilvegostomig (AZD2936). as a comparator, combination, or an additional investigational product. To ensure accurate and comprehensive data presentation, the current PSLL encompasses a 19 September 2024 to 05 January 2026 period, integrating both the prior and current 6-month periods. Hence with the additional reports, there is an increase in the number of SUSARs in this PSLL. Review of these additional SUSARs neither changed the overall safety profile for the rilvegostomig (AZD2936) nor AstraZeneca's assessment of benefit-risk profile of rilvegostomig (AZD2936).

Periodic Safety Statement of SUSARs Appendix A

Drug Substance	Rilvegostomig (AZD2936)
Date	21 January 2026

Appendix A

Periodic SUSAR Line Listings

Period covered: 19 September 2024 to 05 January 2026

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

Project ID: D6187

Study ID: D6187C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Master Protocol of an Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumour Activity of Novel Combinations in Participants with Locally Advanced or Metastatic Non-Small Cell Lung Cancer (LIBRA)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
202508GLO012019CN	CHINA 59 Years Male	**Pyrexia (Fever)***	Not Recovered	14-Aug-2025 nk	AZD2936	Solution	750 milligram q3w Intravenous use	14-AUG-2025 12:06 to	Periodic Report Comments. Patient experienced Fever, investigator assessed the event fever related with study therapy, Patient also experienced back pain, constipation, elevated aspartate transferase, hypocalcemia, hyponatremia, hypophosphatemia and plasma fibrogen content; Investigator assessed these events not related with study therapy. Company physician assessed all the events not related with study therapy.; Periodic Report Comments. Patient experienced Fever, investigator assessed the event fever related with study therapy, Patient also experienced back pain, constipation, elevated aspartate transferase, hypocalcemia, hyponatremia, hypophosphatemia and plasma fibrogen content, alanine aminotransferase increased, lymphocyte count decreased, hypertension, blood creatinine increased, atrial fibrillation, hypochloremia Investigator assessed these events not related with study therapy. Company physician assessed all the events not related with study therapy.;
					RAMUCIRUMAB	Infusion	575 milligram q3w Intravenous use	25-SEP-2025 18:29 to	
						Infusion	580 milligram q3w Intravenous use	04-SEP-2025 17:35 to	
						Infusion	580 milligram q3w Intravenous use	14-AUG-2025 16:27 to	
						Infusion	600 milligram q3w Intravenous use	16-OCT-2025 to	

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

Project ID: D6187

Study ID: D6187C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Master Protocol of an Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumour Activity of Novel Combinations in Participants with Locally Advanced or Metastatic Non-Small Cell Lung Cancer (LIBRA)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
									Periodic Report Comments. Patient experienced Fever, investigator assessed the event fever related with study therapy, Patient also experienced abdominal distension, back pain, constipation, elevated aspartate transferase, elevated creatinine, elevated troponin i, elevated troponin t, hypertension, hyponatremia, hypophosphatemia, lymphocyte count decreased, multiple occurence of alt elevation, multiple occurrence of hypocalcemia and plasma fibrogen content. Investigator assessed these events not related with study therapy. Company physician assessed all the events not related with study therapy.

Concomitant Medication(s): | RAMUCIRUMAB (S) | Famotidine (C) | Celecoxib (C) | Oxycodone (C) | Flurbiprofen (C) | Diphenhydramine (C) | Ibuprofen (C) | Lactulose (C) | Esomeprazole (C) | Polyene (C) | Glucose (C) | Amino acid (C) | Vitamins with minerals (C) | Dexamethasone (C) | Hydrotalcite (C) | Piperacillin sodium (C) | Acetaminophen (C)

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

Project ID: D6900

Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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									
202409GLO002829ES	SPAIN 53 Years Female	**Anaemia (Anaemia)***	Recovering	22-Apr-2024 6 days	AZD8205	Infusion	.4 milligram/kilogram Intravenous use	17-APR-2024 to 28-APR-2024 12 days	
Concomitant Medication(s):									
202410GLO001549GB	UNITED KINGDOM 67 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	02-Oct-2024 nk	AZD8205	Infusion		to	PRC comment. Female patient experienced serious event FEBRILE NEUTROPENIA, INV-Related, CCA-not related
						Infusion	149.4 milligram q3w Intravenous use	05-SEP-2024 to 05-SEP-2024 1 day	
						Infusion	149.4 milligram q3w Intravenous use	25-SEP-2024 to 25-SEP-2024 1 day	
						Infusion	224.2 milligram q3w Intravenous use	05-AUG-2024 to 05-AUG-2024 1 day	
						Infusion	224.2 milligram q3w Intravenous use	16-JUL-2024 to 16-JUL-2024 1 day	

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

Project ID: D6900

Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
						Infusion	224.2 milligram q3w Intravenous use	17-JUN-2024 to 17-JUN-2024 1 day	
						Infusion	224.2 milligram q3w Intravenous use	21-MAY-2024 to 21-MAY-2024 1 day	
						Infusion	224.2 milligram q3w Intravenous use	21-OCT-2024 to 21-OCT-2024 1 day	
Concomitant Medication(s):									
202410GLO008900HU	HUNGARY 62 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	10-Oct-2024 29 days	AZD8205	Infusion	245 milligram q3w Intravenous use	03-OCT-2024 to 03-OCT-2024 1 day	Periodic Report Comments. Patient experienced Febrile neutropenia Inv causality: Related CCA: Not related
						Infusion	252 milligram q3w Intravenous use	12-SEP-2024 to 12-SEP-2024 1 day	
Concomitant Medication(s): | Xalacom (C) | Amlodipine/valsartan sandoz (C) | Valsartan (C) | Eliquis (C) | Nebivolol (C) | Atorvastatin (C) | Famotidin (C) | Cataflam (C) | Pantoprazol (C) | Tazocin (C) | NaCl (C) | Vitamin b6 (C) | Ondansetron (C) | Kaldyum (C) | Accofil (C) | Vancomycin (C) | Metronidazol (C) | Isolyte (C) | Metamizol natrium (C) | Drotaverin (C) | Tramadol (C) | Legalon (C) | Clexan (C) | Albumin (C)									
202411GLO025986IT	ITALY 68 Years Female	**Anaemia (Anemia)***	Recovered	03-Oct-2024 29 days	AZD8205	Infusion	137.6 milligram q3w Intravenous use	28-NOV-2024 to 28-NOV-2024 1 day	Periodic Report Comments. female patient experienced serious event ANEMIA INV-related, CCA -not related

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

Project ID: D6900

Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
						Infusion	206.4 milligram q3w Intravenous use	05-SEP-2024 to 05-SEP-2024 1 day	
						Infusion	206.4 milligram q3w Intravenous use	17-OCT-2024 to 17-OCT-2024 1 day	
						Infusion	206.4 milligram q3w Intravenous use	26-SEP-2024 to 26-SEP-2024 1 day	
						Infusion	66.4 milligram q3w Intravenous use	16-JAN-2025 to 16-JAN-2025 1 day	
						Infusion	66.4 milligram q3w Intravenous use	21-MAR-2025 to 21-MAR-2025 1 day	
						Infusion	66.4 milligram q3w Intravenous use	27-DEC-2024 to 27-DEC-2024 1 day	
						Infusion	66.4 milligram q3w Intravenous use	28-FEB-2025 to 28-FEB-2025 1 day	

Concomitant Medication(s): | Eutirox (C) | Paracetamol (C) | Ferrous (C) | Clexane (C)

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

Project ID: D6900

Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
2024A208365	NETHERLANDS 57 Years Female	**Febrile neutropenia (Febrile neutropenia)*** Diarrhoea (Diarrhea)*	Recovered with Sequelae	08-Sep-2024 1 week 6 days	AZD8205	Infusion	321 milligram q3w Intravenous use	26-AUG-2024 to 26-AUG-2024 1 day	Periodic Report Comments. Patient experienced febrile neutropenia and diarrhea. Inv: both events related to Azd8205. CCA: not related.
Concomitant Medication(s):									
202501GLO026103GB	UNITED KINGDOM 65 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	28-Jan-2025 2 months 29 days	AZD8205	Infusion	138 milligram q3w Intravenous use	02-JAN-2025 to 02-JAN-2025 1 day	Periodic Report Comments. The patient experienced febrile neutropenia and small intestinal obstruction. Investigator: related to febrile neutropenia and not related to small intestinal obstruction with AZD8205. Company: not related
						Infusion	138 milligram q3w Intravenous use	12-DEC-2024 to 12-DEC-2024 1 day	
						Infusion	138 milligram q3w Intravenous use	23-JAN-2025 to 23-JAN-2025 1 day	
						Infusion	154 milligram q3w Intravenous use	21-NOV-2024 to 21-NOV-2024 1 day	
						Infusion	154 milligram q3w Intravenous use	31-OCT-2024 to 31-OCT-2024	
Concomitant Medication(s): | Ramipril (C) | Atorvastatin (C) | Lansoprazole (C) | Loperamide (C) | Cyclizine (C) | Hyoscine butylbromide (C) | Ferrous sulfate (C) | Amikacin (C)									

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Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
202502GLO024893ES	SPAIN 66 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	27-Feb-2025 30 days	AZD8205	Infusion Infusion	113 milligram q3w Intravenous use 170 milligram q3w Intravenous use	22-APR-2025 to 29-JAN-2025 to	Periodic report comments. Patient experienced FEBRILE NEUTROPENIA, Investigator: related to study therapy, company: not related to study therapy.
Concomitant Medication(s): | Levothyroxine (C) | Paracetamol (C) | Zolpidem (C) | Metoclopramide (C) | Ondansetron (C) | Omeprazole (C) | Bisoprolol (C)									
202505GLO008964AU	AUSTRALIA 49 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	08-May-2025 10 months 13 days	AZD8205	Infusion Infusion	112 milligram q3w Intravenous use 98 milligram q3w Intravenous use	26-JUN-2024 to 26-JUN-2024 1 day 19-MAR-2025 to 28-MAY-2025 2 months 10 days	Periodic Report Comments. Patient experienced febrile neutropenia. Investigator: related with study therapy. Company physician: Not related.
Concomitant Medication(s): | Codeine Phosphate (C) | Loperamide (C) | Multivitamin (C) | Glucose (C) | Sodium bicarbonate (C) | Sodium chloride (C) | Thiamine (C) | Magnesium glycinate (C) | Metoclopramide (C) | Compound sodium lactate (C) | Dexamethasone (C)									
202508GLO019122HU	HUNGARY 49 Years Female	**Anaemia (Anemia)***	Recovered	17-Apr-2025 3 months 5 days	AZD8205	Infusion	176 milligram q3w Intravenous use	13-JAN-2025 to	
Concomitant Medication(s): | Rosuvastatin (C) | Tanydon (C) | Nebivolol (C) | Accofil (C)									
202509GLO005940AU	AUSTRALIA Unknown	**Febrile neutropenia (Febrile neutropenia)***	Recovered	08-Sep-2025 nk	AZD8205	Infusion	Intravenous use	to	Patient experienced FEBRILE NEUTROPENIA Inv causality: RELATED to AZD8205 NOT

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

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Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
									RELATED to AZD2936 CCA: NOT RELATED
Concomitant Medication(s): | AZD2936 (S)									
202509GLO012329ES	SPAIN	**Neutropenia (Neutropenia)***	Recovered	14-Sep-2025 nk	AZD8205	Infusion	Intravenous use	to	
Concomitant Medication(s):									
202512GLO004394AU	AUSTRALIA 73 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Not Recovered	05-Dec-2025 4 months 12 days	AZD8205	Infusion	134 milligram Intravenous use	06-NOV-2025 to	Periodic Report Comments. Patient experienced event Febrile neutropenia. Investigator states event related to AZD8205 and not related to AZD2936. CCC- not related.
						Infusion	134 milligram Intravenous use	16-OCT-2025 to	
						Infusion	134 milligram Intravenous use	25-SEP-2025 to	
						Infusion	134 milligram Intravenous use	27-NOV-2025 to	
						Infusion	188 milligram Intravenous use	28-AUG-2025 to	

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

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Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
						Infusion	226 milligram Intravenous use	24-JUL-2025 to	
Concomitant Medication(s): | AZD2936 (S) | Endone (C) | Akynzeo (C) | Telmisartan (C) | Rosuvastatin (C) | Pantoprazole (C) | Chlorvescent (C) | Magnesium aspartate (C) | Pregabalin (C) | Coloxyl (C) | Senna (C) | Dexamethasone (C) | Lipegfilgrastim (C)									
202512GLO004780IT	ITALY 64 Years Female	**Neutropenia (Neutropenia)***	Not Recovered	04-Dec-2025 nk	AZD2936	Solution	Unknown	to	
Concomitant Medication(s): AZD8205 (S) | | Levothyroxine (C) | Metformin (C) | Bisoprolol (C) | Vitamin d (C) | Potassium canrenoate (C) | Enoxaparin (C) | Furosemide (C)									
202512GLO020715GB	UNITED KINGDOM 70 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Not Recovered	21-Dec-2025 nk	AZD2936	Solution	Intravenous use	to	
					AZD8205	Infusion	Intravenous use	to	
Concomitant Medication(s): AZD8205 (S) | | Tamsulosin hydrochloride (C) | Senna (C) | Olanzapine (C)									

SOC:Cardiac disorders

2023A119533	AUSTRALIA 64 Years Female	**Myocarditis (Myocarditis)***	Recovered	22-May-2023 2 months 7 days	AZD8205	Infusion	210 milligram q3w Intravenous use	03-MAY-2023 to	Periodic Report Comment. the patient experienced Myocarditis) , Investigator related to study therapy AZD8205.

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Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
						Infusion	210 milligram q3w Intravenous use	16-MAR-2023 to	
						Infusion	210 milligram q3w Intravenous use	14-APR-2023 to	

Concomitant Medication(s): | AMITRIPTYLINE (C) | APIXABAN (C) | DILTIAZEM (C) | BIFIDUMBACTERIN (C) | Magnesium aspartate (C) | PANADOL OSTEO (C) | PALONOSETRON (C) | METOCLOPRAMIDE (C)

SOC:Gastrointestinal disorders

202412GLO017098US	UNITED STATES 50 Years Female	**Abdominal pain upper (Abdominal pain upper)***	Recovered	13-Dec-2024 5 months 20 days	AZD8205	Infusion	126.6 milligram q3w Intravenous use	04-NOV-2024 to 04-NOV-2024 1 day	The patient experienced CTC 3 ABDOMINAL PAIN (EPIGASTRIC), Inv. Causality: related, CCA: not related.
						Infusion	126.6 milligram q3w Intravenous use	14-OCT-2024 to 14-OCT-2024 1 day	
						Infusion	129.6 milligram q3w Intravenous use	02-DEC-2024 to 02-DEC-2024 1 day	
						Infusion	129.6 milligram q3w Intravenous use	10-MAR-2025 to 10-MAR-2025 1 day	
						Infusion	129.6 milligram q3w	13-JAN-2025 to 13-JAN-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
							Intravenous use	1 day	
						Infusion	129.6 milligram q3w	17-FEB-2025 to 17-FEB-2025	
							Intravenous use	1 day	
						Infusion	129.6 milligram q3w	23-DEC-2024 to 23-DEC-2024	
							Intravenous use	1 day	
						Infusion	192 milligram q3w	05-AUG-2024 to 05-AUG-2024	
							Intravenous use	1 day	
						Infusion	192 milligram q3w	15-JUL-2024 to 15-JUL-2024	
							Intravenous use	1 day	
						Infusion	192 milligram q3w	23-SEP-2024 to 23-SEP-2024	
							Intravenous use	1 day	
						Infusion	192 milligram q3w	24-JUN-2024 to 24-JUN-2024	
							Intravenous use	1 day	
						Infusion	192 milligram q3w	26-AUG-2024 to 26-AUG-2024	
							Intravenous use	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): | Flonase (C) | Protonix (C) | Eliquis (C) | Ativan (C) | Levothyroxine (C) | Dilaudid (C) | Compazine (C) | Colace (C)									
2024A082665	UNITED STATES 71 Years Female	**Diarrhoea (Diarrhea)*** Syncope (Syncope)*	Recovered	11-Mar-2024 4 weeks	AZD8205	Infusion	180 milligram q3w Intravenous use	04-MAR-2024 13:34 to 04-MAR-2024 14:12 38 min	Periodic Report Comment. Female patient experienced event Diarrhea, Inv: Related, CCA: Not related
						Infusion	180 milligram q3w Intravenous use	10-APR-2024 to 10-APR-2024 1 day	
						Infusion	180 milligram q3w Intravenous use	12-FEB-2024 13:24 to 12-FEB-2024 14:36 1 hr 12 min	
						Infusion	180 milligram q3w Intravenous use	25-MAR-2024 13:30 to 25-MAR-2024 14:01 31 min	
Concomitant Medication(s): | Dyazide (C) | Ambien (C) | Gabapentin (C) | Cymbalta (C) | Acetaminophen (C) | Rivaroxaban (C) | Ativan (C) | Xanax (C)									
2024A103197	JAPAN 47 Years Female	**Nausea (Nausea)***	Recovered	04-Apr-2024 1 day	AZD8205	Infusion	136.32 milligram q3w Intravenous use	03-APR-2024 to	PRC. The patient experienced Nausea. Investigator: related to AZD8205 Company physician: Not related to study therapy.
						Infusion	136.32 milligram q3w Intravenous use	23-APR-2024 to	

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

Project ID: D6900

Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
Concomitant Medication(s): | Magmitt (C) | Metoclopramide (C) | Olanzapine (C) | Calonal (C) | Loxonin (C)									
2024A202310	NETHERLANDS 57 Years Female	**Diarrhoea (Diarrhea)***	Recovered	29-Aug-2024 3 days	AZD8205	Infusion	321 milligram q3w Intravenous use	26-AUG-2024 to 26-AUG-2024 1 day	Periodic Report Comment. The patient experienced DIARRHEA. Inv: related to study therap. CCA: Not related to study therapy.
Concomitant Medication(s): | AMLODIPINE (C) | APIXABAN (C) | DESLORATADINE (C)									
2024A208360	UNITED STATES 51 Years Unknown	**Vomiting (Vomiting)***	Recovered	06-Sep-2024 2 months 14 days	AZD8205	Infusion Infusion Infusion Infusion Infusion	126.6 milligram q3w Intravenous use 126.6 milligram q3w Intravenous use 129.6 milligram q3w Intravenous use 129.6 milligram q3w Intravenous use 129.6 milligram q3w Intravenous use	04-NOV-2024 to 04-NOV-2024 1 day 14-OCT-2024 to 14-OCT-2024 1 day 02-DEC-2024 to 02-DEC-2024 1 day 10-MAR-2025 to 10-MAR-2025 1 day 13-JAN-2025 to 13-JAN-2025 1 day	Periodic Report Comment. The patient experienced NAUSEA, VOMITTING AND DIARRHEA Related.Company-Not related.;Periodic Report Comments. The patient experienced VOMITTING Related. Company-Not related.

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

Project ID: D6900

Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
						Infusion	129.6 milligram q3w	17-FEB-2025 to 17-FEB-2025	
							Intravenous use	1 day	
						Infusion	129.6 milligram q3w	23-DEC-2024 to 23-DEC-2024	
							Intravenous use	1 day	
						Infusion	192 milligram q3w	05-AUG-2024 to 05-AUG-2024	
							Intravenous use	1 day	
						Infusion	192 milligram q3w	15-JUL-2024 to 15-JUL-2024	
							Intravenous use	1 day	
						Infusion	192 milligram q3w	23-SEP-2024 to 23-SEP-2024	
							Intravenous use	1 day	
						Infusion	192 milligram q3w	24-JUN-2024 to 24-JUN-2024	
							Intravenous use	1 day	
						Infusion	192 milligram q3w	26-AUG-2024 to 26-AUG-2024	
							Intravenous use	1 day	

Concomitant Medication(s): | FLONASE (C)

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EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
202503GLO023714NL	NETHERLANDS 57 Years Female	**Diarrhoea (Diarrhea)*** Neutrophil count decreased (Neutrophil count decreased)*	Recovered	19-Mar-2025 1 month 16 days	AZD8205	Infusion Infusion	181.8 milligram q3w Intravenous use 223.2 milligram q3w Intravenous use	15-APR-2025 to 04-FEB-2025 to	Periodic Report Comments. The patient experienced Diarrhoea, Investigator Causality related to AZD8205, CCA not related to AZD8205; event Neutrophil count decreased Investigator Causality related to AZD8205, CCA not related to AZD8205
Concomitant Medication(s): | Granisetron (C) | Amoxicillin (C) | Clavulanic acid (C) | Ceftazidim (C) | Paracetamol (C) | Metoclopramide (C) | Loperamide (C)									
202503GLO024736NL	NETHERLANDS 64 Years Female	**Diarrhoea (Diarrhoea)***	Recovered	27-Jan-2025 3 months 3 days	AZD8205	Infusion	Intravenous use	25-OCT-2024 to 07-MAR-2025 4 months 11 days	Periodic Report Comments. Patient experienced DIARRHEA. Investigator: related with study therapy. Company physician: Not related.
Concomitant Medication(s): | Metformin (C) | Insulatard (C) | Oxycodone (C) | Enalapril (C) | Ferrous fumarate (C) | Chlorthalidone (C) | Amitriptyline (C) | Metoclopramide (C)									
202507GLO010932AU	AUSTRALIA 57 Years Female	**Colitis (Colitis)***	Not Recovered	13-Jul-2025 nk	AZD2936 AZD8205	Solution Infusion	750 milligram Intravenous use 2.4 milligram/kilogram Intravenous use	to to	Periodic Report Comments. Female Patient with Colitis. Investigator: Related to study therapy AZD2936 and AZD8205. CCA: Not Related to Study therapy AZD2936 and AZD8205. Action taken: No change
Concomitant Medication(s): AZD8205 (S) |									

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

Project ID: D6900

Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
202510GLO010841BE	BELGIUM 69 Years Male	**Gastritis (Gastritis)***	Recovered	05-Oct-2025 nk	AZD8205	Infusion	2.4 milligram/kilogram Unknown	to	
Concomitant Medication(s): | Asaflow (C) | Rosuvastatine (C) | Pantomed (C) | Tramadol (C) | Dafalgan (C)									
202512GLO023735US	UNITED STATES Unknown	**Small intestinal obstruction (Small bowel obstruction)***	Not Recovered	22-Dec-2025 nk	AZD8205	Infusion	Unknown	to	
Concomitant Medication(s):									

SOC:General disorders and administration site conditions

202410GLO024832IT	ITALY 68 Years Female	**Asthenia (Asthenia)*** Neutrophil count decreased (Neutrophil count decreased)*	Not Recovered	24-Oct-2024 1 month 20 days	AZD8205	Infusion Infusion Infusion Infusion	137.6 milligram q3w Intravenous use 206.4 milligram q3w Intravenous use 206.4 milligram q3w Intravenous use 206.4 milligram q3w	28-NOV-2024 to 28-NOV-2024 1 day 05-SEP-2024 to 05-SEP-2024 1 day 17-OCT-2024 to 17-OCT-2024 1 day 26-SEP-2024 to 26-SEP-2024	Periodic Report Comments. The patient Female experienced Asthenia and neutrophil count decreased related to study therapy.CCA:Not related

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

Project ID: D6900

Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
							Intravenous use	1 day	
						Infusion	66.4 milligram q3w	07-FEB-2025 to 07-FEB-2025	
							Intravenous use	1 day	
						Infusion	66.4 milligram q3w	16-JAN-2025 to 16-JAN-2025	
							Intravenous use	1 day	
						Infusion	66.4 milligram q3w	21-MAR-2025 to 21-MAR-2025	
							Intravenous use	1 day	
						Infusion	66.4 milligram q3w	27-DEC-2024 to 27-DEC-2024	
							Intravenous use	1 day	
						Infusion	66.4 milligram q3w	28-FEB-2025 to 28-FEB-2025	
							Intravenous use	1 day	
Concomitant Medication(s): | Eutirox (C) | Ach apixaban (C) | Ferrous (C) | Diosmectal (C) | Codex (C) | Physiological saline solution (C) | Prednisone (C)									
2024A117677	AUSTRALIA 73 Years Female	**Fatigue (Fatigue)***	Recovered	16-May-2024 5 weeks	AZD8205	Infusion	108 milligram q3w	09-MAY-2024 to 09-MAY-2024	Periodic Report Comment. the patient experienced grade three fatigue related to AZD8205 and not related to study procedure , Com causality not related.
							Intravenous use	1 day	
						Infusion	164 milligram q3w	11-APR-2024 to 11-APR-2024	

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

Project ID: D6900

Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
							Intravenous use	1 day	
						Infusion	54 milligram q3w	04-JUL-2024 to 04-JUL-2024	
							Intravenous use	1 day	
						Infusion	54 milligram q3w	13-JUN-2024 to 13-JUN-2024	
							Intravenous use	1 day	
						Infusion	54 milligram q3w	25-JUL-2024 to 25-JUL-2024	
							Intravenous use	1 day	
Concomitant Medication(s): | Atacand (C) | Lipitor (C) | Metoclopramide (C) | Akynzeo (C) | Dexamethasone (C) | Human albumin 20% behring (C) | Cyclizine (C) | Enoxaparin (C) | Magnesium sulphate (C) | Ondansetron (C) | Paracetamol (C) | Potassium chloride (C) | Tazocin (C) | Filgrastim (C) | Sodium dihydrogen phosphate (C) | Human Albumin 5% Octapharma (C) | Gavisconell (C) | Potassium chloride | Sodium chloride | Trometamol (C) | Attapulgite (C) | Furosemide (C) | Amoxicillin trihydrate (C) | Lipegfilgrastim (C)									
2024A204878	UNITED STATES 58 Years Female	**Fatigue (Fatigue)***	Not Recovered	05-Sep-2024 1 month 18 days	AZD2936	Solution	750 milligram q3w	09-AUG-2024 to	Periodic Report Comment. Patient experienced fatigue. The investigator consider a causality assessment for study therapy AZD8205 related, CCA: not related.
							Intravenous use		
						Solution	750 milligram q3w	19-JUL-2024 to	
							Intravenous use		
						Solution	750 milligram q3w	30-AUG-2024 to	
							Intravenous use		

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

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Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
					AZD8205	Infusion	90 milligram q3w	09-AUG-2024 to 09-AUG-2024	
							Intravenous use	1 day	
						Infusion	90 milligram q3w	19-JUL-2024 to 19-JUL-2024	
							Intravenous use	1 day	
						Infusion	90 milligram q3w	30-AUG-2024 to 30-AUG-2024	
							Intravenous use	1 day	
Concomitant Medication(s): | AZD8205 (S) | Lomotil (C) | Imodium (C) | Zofran (C) | Triderm (C) | Flonase (C) | Claritin (C) | Emend (C) | Kytril (C) | Trazodone (C) | Polyethylene glycol (C) | Fluticasone proprionate (C) | Lopermid (C) | Loratadine (C) | Hydrocortisone (C) | Clobex (C) | Compazine (C) | Ritalin (C) | COVID-19 vaccine (C)									
202503GLO018127NL	NETHERLANDS 64 Years Female	**Malaise (Malaise)***	Not Recovered	19-Mar-2025 4 months 20 days	AZD8205	Infusion	123.8 milligram q3w	10-MAR-2025 to 10-MAR-2025	PRC. The patient experienced Malaise. Action Taken: No Change. For Study therapy: Investigator causality: AZD8205 - Related. CC: AZD8205 - Not related. Outcome: Not Recovered.
							Intravenous use	1 day	
						Infusion	123.8 milligram q3w	20-FEB-2025 to 20-FEB-2025	
							Intravenous use	1 day	
						Infusion	150.72 milligram q3w	09-DEC-2024 to 09-DEC-2024	
							Intravenous use	1 day	
						Infusion	150.72 milligram q3w	18-NOV-2024 to 18-NOV-2024	
							Intravenous use	1 day	

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

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Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
						Infusion	150.72 milligram q3w Intravenous use	20-JAN-2025 to 20-JAN-2025 1 day	
						Infusion	150.72 milligram q3w Intravenous use	28-OCT-2024 to 28-OCT-2024 1 day	
						Infusion	150.72 milligram q3w Intravenous use	30-DEC-2024 to 30-DEC-2024 1 day	
Concomitant Medication(s): | Metformin (C) | Insulatard (C) | Oxycodone (C) | Enalapril (C) | Omeprazole (C) | Macrogol (C) | Ferrous fumarate (C) | Chlorthalidone (C) | Amitriptyline (C) | Cholecalciferol (C) | Granisetron (C) | Metoclopramide (C) | Paracetamol (C) | Xylometazoline (C) | Magnesium sulfate (C) | Oxazepam (C) | Enema (C) | Sodium Chloride 0.9% & Dextrose 5% (C) | Potassium chloride (C) | Insulin (C) | Magnesium hydroxide (C) | Fentanyl (C) | Nitrofurantoine (C)									
202506GLO007725AU	AUSTRALIA 49 Years Female	**Fatigue (Fatigue)***	Recovered	09-Jun-2025 11 months 15 days	AZD8205	Infusion	112 milligram q3w Intravenous use	04-SEP-2024 to	The patient experienced FATIGUE, Inv. Causality: related, CCA: not related.
						Infusion	112 milligram q3w Intravenous use	07-NOV-2024 to	
						Infusion	112 milligram q3w Intravenous use	16-OCT-2024 to	
						Infusion	112 milligram q3w	18-DEC-2024 to	

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

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EudraCT No: 2022-502759-70-00

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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
							Intravenous use		
						Infusion	112 milligram q3w	24-AUG-2024 to	
							Intravenous use		
						Infusion	112 milligram q3w	24-JUL-2024 to	
							Intravenous use		
						Infusion	112 milligram q3w	25-SEP-2024 to	
							Intravenous use		
						Infusion	112 milligram q3w	26-JUN-2024 to	
							Intravenous use		
						Infusion	112 milligram q3w	27-NOV-2024 to	
							Intravenous use		
						Infusion	98 milligram q3w	08-JAN-2025 to	
							Intravenous use		
						Infusion	98 milligram q3w	09-APR-2025 to	
							Intravenous use		

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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	98 milligram q3w Intravenous use	19-FEB-2025 to	
						Infusion	98 milligram q3w Intravenous use	19-MAR-2025 to	
						Infusion	98 milligram q3w Intravenous use	28-MAY-2025 to	
						Infusion	98 milligram q3w Intravenous use	30-APR-2025 to	
						Infusion	98 milligram q3w Intravenous use	30-JAN-2025 to	
Concomitant Medication(s): | Codeine phosphate (C) | Loperamide (C)									

SOC:Infections and infestations

2023A218374	UNITED STATES 63 Years Female	**Gastroenteritis viral (Viral gastroenteritis)***	Recovered	21-Sep-2023 16 weeks 1 day	AZD8205	Infusion	181 milligram q3w Intravenous use	06-JUL-2023 to 06-JUL-2023 1 day	Periodic Report Comment. The patient experienced VIRAL GASTROENTERITIS. Investigator-Related. CCA- not related
						Infusion	181 milligram q3w	17-AUG-2023 to 17-AUG-2023	

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

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Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

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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
							Intravenous use	1 day	
						Infusion	181 milligram q3w	31-MAY-2023 to 31-MAY-2023	
							Intravenous use	1 day	
Concomitant Medication(s): | COVID-19 vaccine (C)									
202507GLO005867NL	NETHERLANDS 66 Years Female	**Urinary tract infection (Urinary tract infection)*** Platelet count decreased (Platelet count decreased)*	Recovered	08-Jul-2025 9 days	AZD8205	Infusion	111 milligram q3w	30-JUN-2025 to 30-JUN-2025	
							Intravenous use	1 day	
Concomitant Medication(s):									
202510GLO008203ES	SPAIN 63 Years Male	**Sepsis (Sepsis)*** Febrile neutropenia (Febrile neutropenia)*	Recovered	08-Oct-2025 1 month 20 days	AZD8205	Infusion	238 milligram single	08-SEP-2025 to	
							Intravenous use		
						Infusion	238 milligram single	19-AUG-2025 to	
							Intravenous use		
Concomitant Medication(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
SOC:Investigations									
2023A290895	CHINA 58 Years Female	**Platelet count decreased (Platelet count decreased)*** Anaemia (Anemia aggravated)*	Not Recovered	22-Dec-2023 9 days	AZD8205	Infusion	100 milligram q3w Intravenous use	14-DEC-2023 to	Periodic Report Comment. Inv causality Related to study therapy in response to event aggravation of anaemia. Comp causality not related to study therapy.;Periodic Report Comments. Inv causality Related to study therapy in response to event aggravation of anaemia. Comp causality not related to study therapy.
Concomitant Medication(s): | Potassium chloride (C) | Metoclopramide hydrochloride (C) | Lactulose (C)									
202510GLO007917US	UNITED STATES 43 Years Female	**Platelet count decreased (Platelet count low)***	Not Recovered	08-Oct-2025 nk	AZD2936 AZD8205	Solution Infusion	Intravenous use Intravenous use	to to	
Concomitant Medication(s): AZD8205 (S) |									
SOC:Metabolism and nutrition disorders									
202503GLO019654NL	NETHERLANDS 52 Years Female	**Hyperkalaemia (Hyperkalemia)***	Recovered	18-Mar-2025 1 month 9 days	AZD8205	Infusion	183 milligram q3w Intravenous use	03-MAR-2025 to	PRC. The patient experienced Hyperkalemia. Investigator: related to AZD8205 company physician: not applicable to study therapy.

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

Project ID: D6900

Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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
						Infusion	183 milligram q3w Intravenous use	10-FEB-2025 to	
Concomitant Medication(s): | Zoledronic acid (C) | Movicolon (C)									
202506GLO007696AU	AUSTRALIA 53 Years Female	**Hyperglycaemia (Hyperglycaemia)*** Sepsis (Sepsis)*	Recovered	07-Jun-2025 11 days	AZD8205	Infusion Infusion	180 milligram q3w Intravenous use 216 milligram q3w Intravenous use	25-JUN-2025 to 28-MAY-2025 to	The patient experienced Hyperglycaemia Inv. Causality: related with AZD8250, CCA: not related AZD8250, Inv Causality: related with Dexamethasone, CCA: not applicable with Dexamethasone, and Sepsis, Inv. Causality: related AZD8250, CCA: not related AZD8250, Inv Causality: not related with Dexamethasone, CCA: not applicable with Dexamethasone
Concomitant Medication(s): | Dexamethasone (S) | Duloxetine (C) | Metformin (C) | Paracetamol (C) | Semaglutide (C) | Gliclazide (C) | Metoclopramide (C)									

SOC:Renal and urinary disorders

202502GLO001844NL	NETHERLANDS 64 Years Female	**Haematuria (Hematuria)***	Recovered	29-Jan-2025 nk	AZD8205	Infusion	Intravenous use	to	The patient experienced HEMATURIA. Inv. Causality: related with AZD8250, CCA: not related AZD8250
Concomitant Medication(s): | Metformin (C) | Omeprazole (C) | Enapril (C) | Oxycodone (C) | Macrogol (C) | Ferrous fumarate (C) | Amitriptylene (C) | Granisetron merck (C) | Metoclopramide HCL (C) | San paracetamol (C)									

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

Project ID: D6900

Study ID: D6900C00001

EudraCT No: 2022-502759-70-00

Study Design: Not Blinded

Study Description: Phase 1 Clinical Trial - A Phase I/IIa Multi-center, Open-label Master Protocol to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Antitumor Activity of AZD8205 in Participants with Advanced or Metastatic 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:Respiratory, thoracic and mediastinal disorders									
2023A154957	AUSTRALIA 65 Years Female	**Pneumonitis (Pneumonitis)***	Fatal	04-Jul-2023 3 months 19 days	AZD8205	Infusion	200 milligram q3w Intravenous use	16-MAR-2023 to	Periodic Report Comments. patient experienced pneumonitis. INV: Related to study drug and CCA: unrelated to study drug.
Concomitant Medication(s): | PANADOL OSTEO (C) | TAPENTADOL (C) | FUROSEMIDE (C) | PREGABALIN (C) | Magnesium (C) | Coloxyl c senna (C) | CYCLIZINE (C) | METOCLOPRAMIDE (C) | GASTROSTOP (C) | PARACETAMOL (C) | Mersyndol with codeine (C) | Doxylamine succinate (C) | CLEXANE (C)									
202507GLO008435US	UNITED STATES 78 Years Female	**Dyspnoea (Dyspnea)***	Recovered	09-Jul-2025 4 months 14 days	AZD8205	Infusion	176 milligram q3w Intravenous use	26-FEB-2025 to 21-MAY-2025 2 months 26 days	Periodic Report Comments. Patient experienced dyspnea. Inv: event related to study therapy. CCA: not related.
Concomitant Medication(s): | Allopurinol (C) | Acetaminophen (C) | Ezetimibe (C) | Metformin (C) | Olmesartan (C) | Metoprolol (C) | Prednisone (C) | Denosumab (C) | Rivaroxaban (C) | Oxycodone (C)									
202511GLO021453ES	SPAIN 60 Years Female	**Pulmonary embolism (Pulmonary thromboembolism)***	Not Recovered	18-Nov-2025 23 days 11 hrs 9 min	AZD2936	Solution	750 milligram q3w Intravenous use	25-OCT-2025 12:51 to 25-OCT-2025 13:51 1 hr	
					AZD8205	Infusion	115.6 milligram q3w Intravenous use	24-OCT-2025 11:18 to 24-OCT-2025 12:20 1 hr 2 min	
Concomitant Medication(s): AZD8205 (S) | | Alipza (C) | Flatoril (C) | Ibuprofen (C) | Esomeprazol (C) | Dexamethasone (C) | Paracetamol (C) | Ondansetron (C)									

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

Project ID: D7020

Study ID: D7020C00001

EudraCT No: 2023-508262-15-00

Study Design: Not Blinded

Study Description: D7020C00001 AZD2936 NSCLC MAD/POP Phase I/II study - A Phase I/II, Open-label, Dose Escalation and Dose Expansion Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of AZD2936 Anti-TIGIT/Anti-PD-1 Bispecific Antibody in Participants with Advanced or Metastatic Non-small Cell Lung 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:Gastrointestinal disorders									
202501GLO001950US	UNITED STATES 60 Years Female	**Colitis (Colitis)***	Recovered	27-Dec-2024 1 year 2 months 2 days 11 hrs 5 min	AZD2936	Solution	750 milligram single Intravenous use	24-OCT-2023 12:55 to 24-OCT-2023 14:01 1 hr 6 min	
Concomitant Medication(s): | Acetaminophen (C) | Ascorbic acid (C) | Carvedilol (C) | Cholecalciferol (C) | Diphenhydramine (C) | Losartan (C) | Ferrous sulfate (C) | Omeprazole (C) | Rosuvastatin (C) | Prochlorperazine (C) | Calcium citrate (C) | Premarin (C) | Lidocaine (C) | Mycostatin (C) | Fluconazole (C) | Janssen COVID-19 vaccine (C) | Elasomeran (C) | Pfizer BioNTech COVID-19 vaccine (C)									
SOC:Investigations									
2023A262457	THAILAND 75 Years Female	**Blood creatine phosphokinase increased (Blood creatine phosphokinase increased)***	Recovered	16-Nov-2023 13 weeks	AZD2936	Solution	Intravenous use	17-AUG-2023 to	Periodic Report Comment. patient experienced serious creatinine phosphokinase increased, investigator event not related to study therapy.
Concomitant Medication(s): | ALBUTEROL (C) | Metformin (C)									
2024A130860	BRAZIL 59 Years Female	**Troponin I increased (Troponin I increased)***	Recovered	03-Jun-2024 8 months 15 days	AZD2936	Solution Solution	1500 milligram single Intravenous use 1500 milligram single	08-AUG-2024 to 11-OCT-2024 to	Periodic Report Comment. Patient experienced ultrasensitive troponin i elevation, Inves: related to study therapy com Causality Not Related;periodic report comment. Patient has event : ULTRASENSITIVE TROPONIN I ELEVATION. For study therapy Action Taken: No change, Investigator

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

Project ID: D7020

Study ID: D7020C00001

EudraCT No: 2023-508262-15-00

Study Design: Not Blinded

Study Description: D7020C00001 AZD2936 NSCLC MAD/POP Phase I/II study - A Phase I/II, Open-label, Dose Escalation and Dose Expansion Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of AZD2936 Anti-TIGIT/Anti-PD-1 Bispecific Antibody in Participants with Advanced or Metastatic Non-small Cell Lung 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
							Intravenous use		Causality: Related, CC: Not Related. Outcome: Recovered.
						Solution	1500 milligram single Intravenous use	20-SEP-2023 to	
						Solution	1500 milligram single Intravenous use	30-AUG-2024 to	

Concomitant Medication(s):

SOC:Nervous system disorders

202505GLO001369CN	CHINA 59 Years Male	**Cerebral infarction (Cerebral infarction)***	Not Recovered	03-May-2025 16 days	AZD2936	Solution	750 milligram single Intravenous use	18-APR-2025 to	Periodic Report Comments. Patient has event: Syncope. For study therapy AZD2936 Action Taken: Temporarily Withdrawn. The investigator causality: related and Company causality: not related.

Concomitant Medication(s): | Glimepiride (C) | Miglitol (C) | Citicoline (C) | Rebamipide (C)

SOC:Renal and urinary disorders

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

Project ID: D7020

Study ID: D7020C00001

EudraCT No: 2023-508262-15-00

Study Design: Not Blinded

Study Description: D7020C00001 AZD2936 NSCLC MAD/POP Phase I/II study - A Phase I/II, Open-label, Dose Escalation and Dose Expansion Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of AZD2936 Anti-TIGIT/Anti-PD-1 Bispecific Antibody in Participants with Advanced or Metastatic Non-small Cell Lung 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
202410GLO005865US	UNITED STATES 80 Years Female	**Tubulointerstitial nephritis (Tubulointerstitial nephritis)***	Recovered	05-Oct-2024 6 months 25 days	AZD2936	Solution	1500 milligram Intravenous use	11-MAR-2024 to 17-SEP-2024 6 months 7 days	PRC. Patient experienced Acute kidney injury. Investigator: related with study therapy. Company physician: Not related.

Concomitant Medication(s): | Aspirin (C) | Cholecalciferol (C) | Omeprazole (C) | Vitamin B complex (C) | Fish oil (C) | Calcium polycarbophil (C) | Calcium carbonate (C) | Garlic (C) | Furosemide (C) | Lisinopril (C) | Rosuvastatin (C) | Metoprolol (C) | Albuterol (C) | Magnesium (C) | Cyanocobalamine (C) | Diazepam (C) | Lovastatin (C) | Eliquis (C) | Loperamide (C)

SOC:Skin and subcutaneous tissue disorders

202501GLO018850US	UNITED STATES 60 Years Female	**Pruritus (Pruritus generalised)***	Recovered	20-Jan-2025 1 year 1 month 4 days	AZD2936	Solution	Intravenous use	17-DEC-2023 to 10-OCT-2024 9 months 24 days	

Concomitant Medication(s):

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
202504GLO027617CN	CHINA 71.3 Years Male	**Myelosuppression (Bone marrow suppression)***	Recovered	29-Apr-2025 8 days					
Concomitant Medication(s):									
202506GLO023480TR	TURKEY 75 Years Female	**Lymphopenia (Lymphopenia) ***	Recovered	24-Jun-2025 21 days					
Concomitant Medication(s):									
SOC:Cardiac disorders									
202506GLO011492CA	CANADA 40.4 Years Female	**Pericarditis (Pericarditis)***	Not Recovered	13-Jun-2025 11 months 5 days					
Concomitant Medication(s):									
202507GLO025789CN	CHINA 62 Years Male	**Myocarditis (Myocarditis)***	Recovered	24-Jul-2025 1 month 13 days					
Concomitant Medication(s):									

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO023856CN	CHINA 74.7 Years Male	**Acute coronary syndrome (Acute coronary syndrome)***	Fatal	28-Aug-2025 2 months 12 days					
Concomitant Medication(s):									
202509GLO020950CA	CANADA 38 Years Female	**Pericarditis (Recurrent pericarditis)***	Not Recovered	23-Sep-2025 1 year 2 months 15 days					
Concomitant Medication(s):									
202511GLO020827AU	AUSTRALIA 68.9 Years Female	**Atrioventricular block complete (Complete heart block)***	Not Recovered	19-Nov-2025 nk					
Concomitant Medication(s):									

SOC:Endocrine disorders

202501GLO024850JP	JAPAN 75 Years Female	**Adrenal insufficiency (Adrenal insufficiency)***	Recovering	27-Jan-2025 5 months 29 days					
Concomitant Medication(s):									

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202504GLO027614DE	GERMANY 67 Years Male	**Hypophysitis (Hypophysitis)***	Recovering	28-Apr-2025 2 months 19 days					
Concomitant Medication(s):									
202505GLO013289BE	BELGIUM 31.4 Years Female	**Adrenal insufficiency (Adrenal insufficiency)***	Recovered	13-May-2025 2 months 1 day 13 hrs 30 min					
Concomitant Medication(s):									
202506GLO019848JP	JAPAN 75 Years Female	**Secondary adrenocortical insufficiency (Secondary adrenocortical insufficiency)***	Recovered with Sequelae	20-Jun-2025 nk					
Concomitant Medication(s):									
202507GLO020542ES	SPAIN 71.4 Years Female	**Adrenal insufficiency (Adrenal insufficiency)***	Recovered	22-Jul-2025 1 month 20 days					
Concomitant Medication(s):									
202509GLO008713CN	CHINA 65 Years Male	**Hypopituitarism (Hypopituitarism)*** Hyponatraemia (Hyponatremia)	Not Recovered	08-Sep-2025 6 months 30 days					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR *	Case Outcome Main Event 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):									
202510GLO030334CN	CHINA 64 Years Male	**Hypopituitarism (Hypopituitarism)*** Herpes dermatitis (Herpes dermatitis)*	Recovering	08-Sep-2025 6 months 28 days 8 hrs 50 min					
Concomitant Medication(s):									
202511GLO005507JP	JAPAN 81.9 Years Male	**Adrenal insufficiency (Adrenal insufficiency)***	Recovering	07-Nov-2025 4 months 22 days					
Concomitant Medication(s):									
202512GLO003361US	UNITED STATES 75 Years Female	**Hyperthyroidism (Hyperthyroidism)***	Not Recovered	02-Dec-2025 1 month 11 days 11 hrs 36 min					
Concomitant Medication(s):									

SOC:Eye disorders

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202511GLO019298DE	GERMANY 71.9 Years Female	**Visual impairment (Visual disturbances)***	Recovered	19-Nov-2025 2 months 22 days 10 hrs 15 min					
Concomitant Medication(s):									

SOC:Gastrointestinal disorders

202410GLO016627US	UNITED STATES 59 Years Male	**Colitis (Colitis)***	Recovered	17-Oct-2024 1 month 2 days					
Concomitant Medication(s):									
202411GLO015321NO	NORWAY 64 Years Male	**Colitis (Pancolitis)***	Recovered	03-Oct-2024 23 days					
Concomitant Medication(s):									
202412GLO003002GB	UNITED KINGDOM 78 Years Male	**Enterocolitis (Enterocolitis)***	Recovered	03-Dec-2024 1 month 10 days					
Concomitant Medication(s):									

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A116413	KOREA, REPUBLIC OF 77.4 Years Female	**Intestinal perforation (Intestinal perforation)***	Recovered	15-May-2024 2 months 1 day					
Concomitant Medication(s):									
2024A158751	AUSTRALIA 80 Years Male	**Paraesthesia oral (Paraesthesia tongue)***	Recovered	08-Jul-2024 3 weeks					
Concomitant Medication(s):									
2024A165369	AUSTRALIA 76.5 Years Male	**Enteritis (Ileitis)***	Not Recovered	10-Jul-2024 13 days					
Concomitant Medication(s):									
2024A196524	THAILAND 47 Years Female	**Diarrhoea (Diarrhea)***	Recovered	26-Aug-2024 27 days					
Concomitant Medication(s):									
202501GLO022244IN	INDIA 33.1 Years Female	**Diarrhoea (Diarrhea)***	Recovered	24-Jan-2025 1 month 23 days					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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):									
202503GLO002922US	UNITED STATES 79.2 Years Female	**Diarrhoea (Diarrhea)***	Recovered	02-Mar-2025 2 months 20 days					
Concomitant Medication(s):									
202503GLO024849IT	ITALY 73 Years Male	**Colitis (Colitis)***	Recovered	21-Mar-2025 11 days					
Concomitant Medication(s):									
202504GLO023512US	UNITED STATES 57.3 Years Female	**Enterocolitis (Enterocolitis)***	Recovered	18-Apr-2025 30 days					
Concomitant Medication(s):									
202504GLO026225BE	BELGIUM 30 Years Female	**Diarrhoea (Diarrhea)** Adrenal insufficiency (Adrenal insufficiency)*	Recovered	12-Mar-2025 2 days					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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):									
202505GLO008810CA	CANADA 69.3 Years Female	**Enteritis (Ileitis)***	Recovered	26-Apr-2025 1 month 2 days					
Concomitant Medication(s):									
202505GLO016390AU	AUSTRALIA 70 Years Male	**Diarrhoea (Diarrhoea)***	Recovered	10-May-2025 2 months 13 days					
Concomitant Medication(s):									
202506GLO000632JP	JAPAN 76 Years Male	**Upper gastrointestinal perforation (Upper gastrointestinal perforation)*** Ileus paralytic (Ileus paralytic)*	Recovered with Sequelae	05-Jun-2025 5 months 27 days					
Concomitant Medication(s):									
202506GLO017756FR	FRANCE Male	**Enteritis (Ileitis)***	Recovered	18-Jun-2025 1 month 4 days					
Concomitant Medication(s):									

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202506GLO023978CN	CHINA 74 Years Male	**Diarrhoea (Diarrhoea)***	Not Recovered	21-Jun-2025 11 days					
Concomitant Medication(s):									
202507GLO009812CN	CHINA 54 Years Female	**Intestinal obstruction (Bowel obstruction)***	Recovered	19-Jun-2025 13 days 12 hrs 54 min					
Concomitant Medication(s):									
202507GLO012139JP	JAPAN 81.5 Years Male	**Intestinal obstruction (Intestinal obstruction)***	Recovered	14-Jul-2025 28 days					
Concomitant Medication(s):									
202507GLO022807CN	CHINA 68.5 Years Female	**Gastric dilatation (Distended stomach)***	Not Recovered	18-Jul-2025 29 days					
Concomitant Medication(s):									
202507GLO023354ES	SPAIN 64 Years Male	**Enteritis (Ileitis)***	Recovered	26-Jul-2025 nk					
Concomitant Medication(s):									

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO000039AU	AUSTRALIA 70.5 Years Male	**Diarrhoea (Diarrhoea)***	Recovered	11-Jul-2025 4 months 12 days 8 hrs 40 min					
Concomitant Medication(s):									
202508GLO000262JP	JAPAN 57 Years Female	**Duodenal ulcer (Duodenal ulcer)***	Recovered	09-Jul-2025 nk					
Concomitant Medication(s):									
202508GLO010733BR	BRAZIL 58 Years Female	**Ileal ulcer (Ileal ulcer)***	Recovered	10-Aug-2025 4 months 2 days					
Concomitant Medication(s):									
202508GLO019274DE	GERMANY 61 Years Male	**Immune-mediated enterocolitis (Immune-mediated enterocolitis)***	Not Recovered	24-Aug-2025 3 months 11 days					
Concomitant Medication(s):									
202509GLO007895CN	CHINA 72 Years Female	**Diarrhoea (Diarrhea)***	Recovered	01-Sep-2025 2 months 16 days					
Concomitant Medication(s):									

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202509GLO009178GB	UNITED KINGDOM 75 Years Female	**Pancreatitis (Pancreatitis)***	Recovered	08-Sep-2025 1 month 20 days 11 hrs 14 min					
Concomitant Medication(s):									
202510GLO020524JP	JAPAN 79 Years Male	**Enterocolitis (Enterocolitis)***	Recovered	19-Oct-2025 2 months					
Concomitant Medication(s):									
202511GLO017325GB	UNITED KINGDOM 75 Years Female	**Colitis (Colitis)***	Not Recovered	14-Oct-2025 2 months 27 days					
Concomitant Medication(s):									
202511GLO023252CN	CHINA 71 Years Male	**Pancreatitis (Pancreatitis aggravated)***	Not Recovered	15-Nov-2025 nk					
Concomitant Medication(s):									
202512GLO000908HK	HONG KONG 64 Years Male	**Vomiting (Vomiting)*** Decreased appetite (Appetite lost)* Asthenia (Weakness)* Chromaturia (Urine discolouration)*	Recovering	30-Nov-2025 7 months 7 hrs 25 min					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

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

SOC:General disorders and administration site conditions

202410GLO016292IN	INDIA 70.8 Years Male	**Fatigue (Fatigue)***	Recovered	15-Oct-2024 1 month 14 days					
Concomitant Medication(s):									
202503GLO004142CN	CHINA 67 Years Male	**Chest discomfort (Chest tightness)***	Recovered	02-Mar-2025 11 days					
Concomitant Medication(s):									
202508GLO005150ES	SPAIN 55 Years Female	**Mucosal inflammation (Mucositis)***	Recovered	08-Jul-2025 8 days					
Concomitant Medication(s):									
202508GLO005518ES	SPAIN 51.2 Years Male	**Asthenia (Asthenia)***	Recovering	29-Jul-2025 7 days					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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):									
202511GLO000474DE	GERMANY 57.8 Years Female	**Pyrexia (Fever)***	Recovered	01-Nov-2025 3 months 29 days 13 hrs 40 min					
Concomitant Medication(s):									
202511GLO002463TH	THAILAND 66.6 Years Male	**Fatigue (Fatigue)** Pharyngitis (Pharyngitis)*	Not Recovered	05-Nov-2025 nk					
Concomitant Medication(s):									
202511GLO017030US	UNITED STATES 65 Years Female	**Fatigue (Fatigue)***	Not Recovered	09-Nov-2025 nk					
Concomitant Medication(s):									

SOC:Hepatobiliary disorders

202410GLO027464AU	AUSTRALIA 80 Years Male	**Suspected drug-induced liver injury (Suspected Hy's law case)***	Recovered	26-Oct-2024 4 months 10 days					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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):									
202410GLO027496TW	TAIWAN 55 Years Male	**Suspected drug-induced liver injury (Suspected drug-induced liver injury)***	Recovered	01-Nov-2024 3 months 1 day					
Concomitant Medication(s):									
202503GLO005094IT	ITALY 72 Years Male	**Suspected drug-induced liver injury (Suspected Hy's law case)***	Not Recovered	07-Mar-2025 2 months 24 days					
Concomitant Medication(s):									
202505GLO006051US	UNITED STATES 62 Years Female	**Hepatitis (Hepatitis)***	Recovered with Sequelae	07-May-2025 nk					
Concomitant Medication(s):									
202506GLO026469IN	INDIA 70 Years Female	**Suspected drug-induced liver injury (Suspected Hy's law case)***	Recovered	08-Apr-2025 9 months 6 days					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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):									
202507GLO007293JP	JAPAN 35 Years Male	**Drug-induced liver injury (Hy's law case)***	Recovered	10-Jul-2025 1 month 17 days 12 hrs 25 min					
Concomitant Medication(s):									
202507GLO030147CN	CHINA 69 Years Female	**Suspected drug-induced liver injury (Suspected Hy's law case)***	Recovered	08-Jul-2025 2 months 22 days 9 hrs					
Concomitant Medication(s):									
202510GLO023861CN	CHINA 69 Years Female	**Drug-induced liver injury (Hy's law case)***	Recovered	08-Jul-2025 2 months 22 days 9 hrs					
Concomitant Medication(s):									
202512GLO000271DE	GERMANY 56.9 Years Male	**Cholestasis (Cholestasis)***	Not Recovered	13-Nov-2025 nk					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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:Infections and infestations									
202409GLO006231TW	TAIWAN 81.7 Years Male	**Pneumonia (Pneumonia)***	Fatal	23-Sep-2024 7 months 16 days 10 hrs 20 min					
Concomitant Medication(s):									
202411GLO006137TW	TAIWAN 71.9 Years Female	**Neutropenic sepsis (Neutropenic sepsis)***	Recovered	08-Nov-2024 16 days					
Concomitant Medication(s):									
202503GLO023652CN	CHINA 64.2 Years Male	**Enterocolitis infectious (Enterocolitis infectious)***	Recovered	22-Mar-2025 16 days 8 hrs 2 min					
Concomitant Medication(s):									
202505GLO021624US	UNITED STATES 56 Years Female	**Infection (Infection)** Colitis (Colitis)	Not Recovered	18-May-2025 1 month 29					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
		Norovirus infection (Norovirus infection)*		days					
		Infection (Infection)*	Not Recovered	18-May-2025					
		Colitis (Colitis)* Norovirus infection (Norovirus infection)*		1 month 27 days 8 hrs 52 min					
Concomitant Medication(s):									
202505GLO029606CN	CHINA 50 Years Male	**Biliary tract infection (Biliary tract infection)***	Recovered	23-Jul-2025 2 days					
Concomitant Medication(s):									
202510GLO013674CN	CHINA 56.7 Years Female	**Herpes zoster (Herpes zoster)**	Not Recovered	04-Sep-2025 nk					
		Neuromyelitis optica spectrum disorder (Neuromyelitis optica spectrum disorder)*							
Concomitant Medication(s):									

SOC:Injury, poisoning and procedural complications

202501GLO025909NO	NORWAY 68 Years Male	**Infusion related reaction (Infusion related reaction)***	Recovered	28-Jan-2025 20 days					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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):									
202510GLO006912US	AUSTRALIA 70 Years Male	**Infusion related reaction (Infusion related reaction)***	Recovered	08-Oct-2025 1 day					
Concomitant Medication(s):									
SOC:Investigations									
202410GLO007028GB	UNITED KINGDOM 67 Years Male	**Troponin I increased (Troponin I increased)***	Not Recovered	08-Oct-2024 19 days 11 hrs 24 min					
Concomitant Medication(s):									
202412GLO009412TH	THAILAND 60 Years Female	**Alanine aminotransferase increased (ALT increased)***	Recovered	06-Nov-2024 1 month 9 days 11 hrs 25 min					
Concomitant Medication(s):									
202502GLO022377BR	BRAZIL 54.1 Years Female	**Alanine aminotransferase increased (Alanine aminotransferase increased)***	Recovered	27-Jan-2025 8 months 7 days					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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):									
202504GLO020573US	UNITED STATES 77 Years Male	**Platelet count decreased (Platelet count decreased)*** Pulmonary oedema (Pulmonary edema)	Not Recovered	22-Apr-2025 3 months 16 days					
		Platelet count decreased (Platelet count decreased)* Pulmonary oedema (Pulmonary edema)*	Not Recovered	22-Apr-2025 3 months 16 days					
		Platelet count decreased (Platelet count decreased)* Pulmonary oedema (Pulmonary edema)* Hypoxia (Hypoxemia)*	Not Recovered	22-Apr-2025 nk					
Concomitant Medication(s):									
202505GLO016891US	UNITED STATES 78.4 Years Male	**Platelet count decreased (Platelet count decreased)***	Recovered	19-May-2025 4 months 11 days 10 hrs 3 min					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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):									
202506GLO025726CN	CHINA 74 Years Male	**Platelet count decreased (Platelet count decreased)*** White blood cell count decreased (White blood cell decreased)* Bronchial haemorrhage (Bronchial hemorrhage)*	Fatal	27-Jun-2025 nk					
Concomitant Medication(s):									
202507GLO016370CN	CHINA 50 Years Male	**Platelet count decreased (Reduced platelet count)***	Recovered	17-Jul-2025 5 months 10 days					
Concomitant Medication(s):									
202508GLO016361CN	CHINA 61.6 Years Male	**Globulins decreased (Globulin decreased)***	Recovering	04-Aug-2025 1 month 11 days					
Concomitant Medication(s):									
202509GLO017128CN	CHINA 60.5 Years Female	**Blood bilirubin increased (Bilirubin elevated)***	Not Recovered	16-Jul-2025 22 days					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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):									
202509GLO027275CN	CHINA 50 Years Male	**Liver function test abnormal (Abnormal liver function tests) ***	Not Recovered	24-Apr-2025 2 months 17 days					
Concomitant Medication(s):									
202511GLO012395HK	HONG KONG 56 Years Male	**Neutrophil count decreased (Neutrophil count low)***	Recovered	13-Oct-2025 8 months 29 days					
Concomitant Medication(s):									
202512GLO021081ES	SPAIN 75 Years Male	**Creatinine renal clearance increased (Increased creatinine clearance)***	Not Recovered	22-Dec-2025 8 months 15 days					
Concomitant Medication(s):									

SOC:Metabolism and nutrition disorders

200209GLO000001FR	FRANCE 77.6 Years Male	**Hypertriglyceridaemia (Hypertriglyceridemia)***	Not Recovered	14-Aug-2025 2 months 24 days					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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):									
202507GLO009114CN	CHINA 55 Years Female	**Type 1 diabetes mellitus (Type 1 diabetes mellitus)***	Not Recovered	10-Jul-2025 3 months 7 days 13 hrs 22 min					
Concomitant Medication(s):									
202508GLO017524FR	FRANCE 37 Years Female	**Type 1 diabetes mellitus (Type 1 diabetes mellitus)***	Not Recovered	21-Aug-2025 16 days 12 hrs 45 min					
Concomitant Medication(s):									
SOC:Musculoskeletal and connective tissue disorders									
202412GLO003106GB	UNITED KINGDOM 59 Years Male	**Myalgia (Myalgia)***	Not Recovered	27-Nov-2024 3 months 27 days					
Concomitant Medication(s):									
202504GLO005209TW	TAIWAN 64.2 Years Female	**Systemic lupus erythematosus (Rowell's syndrome)***	Recovered	24-Mar-2025 5 months 3 days					
Concomitant Medication(s):									

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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)									
202505GLO012724JP	JAPAN 67.2 Years Male	**Castleman's disease (Castleman's disease)***	Not Recovered	01-Apr-2025 13 days 11 hrs 35 min					
Concomitant Medication(s):									
SOC:Nervous system disorders									
202409GLO006209TW	TAIWAN 75 Years Female	**Altered state of consciousness (Consciousness abnormal)***	Recovered	14-Sep-2024 2 months 28 days					
Concomitant Medication(s):									
202502GLO023885ES	SPAIN 70 Years Female	**Immune-mediated encephalitis (Immune-mediated encephalitis)***	Recovered with Sequelae	25-Feb-2025 5 months 20 days 12 hrs 20 min					
Concomitant Medication(s):									
202505GLO006041CN	CHINA 69 Years Male	**Headache (Headache)***	Recovered	30-Mar-2025 2 days 7 hrs 15 min					

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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):									
202508GLO024881CN	CHINA 74 Years Female	**Diabetic hyperosmolar coma (Diabetic hyperosmolar coma) ***	Recovered	28-Aug-2025 7 days					
Concomitant Medication(s):									
202510GLO022700CN	CHINA 55 Years Female	**Neuromyelitis optica spectrum disorder (Neuromyelitis optica spectrum disorder)***	Not Recovered	19-Sep-2025 5 months 17 days					
Concomitant Medication(s):									
SOC:Renal and urinary disorders									
202511GLO019160GB	UNITED KINGDOM 66 Years Male	**Acute kidney injury (Acute kidney injury)***	Not Recovered	19-Nov-2025 5 months 14 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: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202409GLO006231TW	TAIWAN 81.7 Years Male	**Pneumonitis (Pneumonitis)***	Fatal	25-Sep-2024 7 months 20 days					
Concomitant Medication(s):									
202502GLO017529IN	INDIA 55.1 Years Female	**Dyspnoea (Shortness of breath)***	Recovered	19-Feb-2025 2 months 8 days					
Concomitant Medication(s):									
202504GLO024878TW	TAIWAN 63 Years Female	**Pneumonitis (Pneumonitis)*** Cytokine release syndrome (Cytokine release syndrome)*	Recovered	22-Apr-2025 6 months 1 day					
Concomitant Medication(s):									
202504GLO029216US	UNITED STATES 78 Years Male	**Pulmonary oedema (Pulmonary edema)*** Hypoxia (Hypoxemia)*	Recovered	22-Apr-2025 3 months 14 days 13 hrs 19 min					
Concomitant Medication(s):									

SOC:Skin and subcutaneous tissue disorders

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202506GLO001763US	UNITED STATES 53 Years Female	**Rash maculo-papular (Rash maculo-papular)***	Not Recovered	14-May-2025 27 days					
Concomitant Medication(s):									
202510GLO007834US	UNITED STATES 75 Years Female	**Onycholysis (Onycholysis)***	Not Recovered	08-Oct-2025 4 months 7 days					
Concomitant Medication(s):									
202510GLO008893DK	DENMARK 80 Years Female	**Pruritus (Pruritus)***	Recovering	09-Sep-2025 1 month 3 days					
Concomitant Medication(s):									
202510GLO012354DK	DENMARK 80 Years Female	**Pruritus (Pruritus)***	Recovering	22-Sep-2025 1 month 16 days					
Concomitant Medication(s):									
202510GLO031385DK	DENMARK 80 Years Female	**Rash maculo-papular (Rash maculo-papular)***	Not Recovered	09-Oct-2025 2 months 3 days					
Concomitant Medication(s):									

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

Project ID: D7025

Study ID: D7025C00001

EudraCT No:

Study Design: Double Blinded

Study Description: D7025C00001 Ph3 rilvegostomig + CTx Adj BTC - A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Global Study of Rilvegostomig in Combination with Chemotherapy as Adjuvant Treatment in Adult Participants After Resection of Biliary Tract Cancer with Curative Intent (ARTEMIDE-Biliary01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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:Vascular disorders									
202502GLO005489CA	CANADA 76 Years Male	**Thrombosis (Thrombus)*** Enterocolitis (Enterocolitis)*	Fatal	07-Feb-2025 3 months 10 days					

Concomitant Medication(s):

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

Project ID: D7029

Study ID: D7029C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Sponsor-blinded, Multicentre Study of Rilvegostomig in Combination with Bevacizumab with or without Tremelimumab as First-lineTreatment in Patients With Advanced 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									
202508GLO004986BR	BRAZIL Female	**Myocarditis (Myocarditis)***	Recovered	05-Aug-2025 nk	RILVEGOSTOMIG	Solution	750 milligram Intravenous use	17-JUL-2025 to	
						Solution	750 milligram Intravenous use	26-JUN-2025 to	
					TREMELIMUMAB	Infusion	300 milligram Intravenous use	26-JUN-2025 to	
Concomitant Medication(s): | TREMELIMUMAB (S) | BEVACIZUMAB (S) | Entresto (C) | Metoprolol (C) | Simvastatin (C) | Spironolactone (C)									
202512GLO023397US	UNITED STATES Female	**Bradycardia (Bradycardia)***	Not Recovered	19-Dec-2025 nk	RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	02-OCT-2025 to	
						Solution	750 milligram q3w Intravenous use	12-NOV-2025 to	
						Solution	750 milligram q3w Intravenous use	12-SEP-2025 to	

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

Project ID: D7029

Study ID: D7029C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Sponsor-blinded, Multicentre Study of Rilvegostomig in Combination with Bevacizumab with or without Tremelimumab as First-lineTreatment in Patients With Advanced 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
						Solution	750 milligram q3w Intravenous use	23-OCT-2025 to	
					TREMELIMUMAB	Infusion	300 milligram Intravenous use	12-SEP-2025 to	
Concomitant Medication(s): | TREMELIMUMAB (S) | BEVACIZUMAB (S) | Amlodipine (C) | Psyllium Husk (C) | Ceftriaxone (C) | Enoxaparin (C) | Famotidine (C) | Metronidazole (C) | Zosyn (C) | Potassium chloride (C)									

SOC:Endocrine disorders

202508GLO014970JP	JAPAN Male	**Hyperthyroidism (Hyperthyroidism)***	Recovered	19-Aug-2025 22 days	RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	09-SEP-2025 to	Periodic Report Comments. Patient experienced event Hyperthyroidism. Investigator states event related to RILVEGOSTOMIG and TREMELIMUMAB and not related with BEVACIZUMAB. Company physician considers event not related to RILVEGOSTOMIG, TREMELIMUMAB and BEVACIZUMAB.
						Solution	750 milligram q3w Intravenous use	29-JUL-2025 to	
						Solution	750 milligram q3w Intravenous use	30-SEP-2025 to	
Concomitant Medication(s): | TREMELIMUMAB (S) | BEVACIZUMAB (S) | Febuxostat (C) | Restamin (C) | Lactec (C) | Propranolol hydrochloride (C) | Soldem 3a (C) | Metoclopramide (C) | Prochlorperazine mesilate (C) | Ursodeoxycholic acid (C) | Hydrocortisone (C) | Levothyroxine sodium hydrate (C) | Antebate (C) | Heparinoid (C)									

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

Project ID: D7029

Study ID: D7029C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Sponsor-blinded, Multicentre Study of Rilvegostomig in Combination with Bevacizumab with or without Tremelimumab as First-lineTreatment in Patients With Advanced 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									
202507GLO002509CN	CHINA 45 Years Male	**Diarrhoea (Diarrhea)***	Recovered	25-Jun-2025 19 days	RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	07-JUN-2025 to	
Concomitant Medication(s): | TREMELIMUMAB (S) | BEVACIZUMAB (S) | Tenofovir alafenamide fumarate (C) | Ceftriaxone sodium (C) | Isepamicin sulfate (C) | Omeprazole (C) | Montmorillonite (C) | Prednisone acetate (C) | Glucose and sodium chloride (C) | Potassium chloride (C) | Methylprednisolone sodium succinate (C) | Vitamin C (C) | Ranitidine hydrochloride (C) | Glutathione (C) | Cefuroxime (C)									
202508GLO018291CN	CHINA Female	**Gastrointestinal haemorrhage (Hemorrhage of digestive tract)***	Recovered	19-Aug-2025 1 month 24 days	RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	06-JUN-2025 to	Periodic Report Comments. Patient experienced digestive tract hemorrhage Related to Bevacizumab, Rilvegostomig and Tremelimumab. Company causality assessment is not related.;Periodic Report Comments. Patient experienced event digestive tract hemorrhage (preferred term: Gastrointestinal haemorrhage). Investigator states event related to Bevacizumab, Rilvegostomig (AZD2936) and Tremelimumab. Company physician considers event unrelated to Bevacizumab, Rilvegostomig (AZD2936) and Tremelimumab.
						Solution	750 milligram q3w Intravenous use	19-JUL-2025 to	
						Solution	750 milligram q3w Intravenous use	27-JUN-2025 to	
					TREMELIMUMAB	Infusion	300 milligram Intravenous use	06-JUN-2025 to	
Concomitant Medication(s): | BEVACIZUMAB (S) | TREMELIMUMAB (S) | Levamlodipine besylate (C) | Fenofibrate (C) | Repaglinide (C) | Amlodipine Benazepril (C) | Dorzagliatin (C) | Ambroxol hydrochloride (C) | Ceftriaxone sodium (C) | Nifedipine (C) | Levofloxacin (C) | Montmorillonite (C) | Leucogen (C) | Human interleukin-11 (C) | Allisartan isoproxil (C) | Amlodipine besylate (C) | Meglumine adenosine cyclophosphate (C) | Recombinant human thrombopoietin (C)									

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

Project ID: D7029

Study ID: D7029C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Sponsor-blinded, Multicentre Study of Rilvegostomig in Combination with Bevacizumab with or without Tremelimumab as First-lineTreatment in Patients With Advanced 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
202509GLO021324TW	TAIWAN Male	**Immune-mediated enterocolitis (Immune-mediated colitis)***	Not Recovered	04-Sep-2025 1 month 7 days	RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	09-SEP-2025 to	
						Solution	750 milligram q3w Intravenous use	19-AUG-2025 to	
						Solution	750 milligram q3w Intravenous use	29-JUL-2025 to	
Concomitant Medication(s): | TREMELIMUMAB (S) | BEVACIZUMAB (S) | Rivotril (C) | Seroquel (C) | Smecta (C) | Loperam (C) | Cefadroxil (C) | Ciprofloxacin (C)									
202512GLO023370US	UNITED STATES Female	**Colitis (Colitis)***	Not Recovered	19-Dec-2025 nk	RILVEGOSTOMIG	Solution	750 milligram Unknown	02-OCT-2025 to	
						Solution	750 milligram Unknown	12-NOV-2025 to	
						Solution	750 milligram Unknown	12-SEP-2025 to	
						Solution	750 milligram Unknown	23-OCT-2025 to	

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

Project ID: D7029

Study ID: D7029C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Sponsor-blinded, Multicentre Study of Rilvegostomig in Combination with Bevacizumab with or without Tremelimumab as First-lineTreatment in Patients With Advanced 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) | BEVACIZUMAB (S) | Amlodipine (C) | Psyllium Husk (C) | Atropine (C) | Lovenox (C)									
SOC:Hepatobiliary disorders									
202506GLO025861CN	CHINA 63 Years Male	**Hepatic function abnormal (Hepatic function abnormal)***	Recovered	25-Jun-2025 6 days	RILVEGOSTOMIG	Solution	Intravenous use	20-JUN-2025 to	
					TREMELIMUMAB	Infusion	Intravenous use	20-JUN-2025 to 20-JUN-2025	
Concomitant Medication(s): TREMELIMUMAB (S) | | BEVACIZUMAB (S) | Amlodipine besylate (C) | Ramipril (C) | Insulin aspart (C) | Ursodeoxycholic acid (C)									
SOC:Investigations									
202509GLO026234JP	JAPAN 67 Years Male	**Aspartate aminotransferase increased (AST increased)***	Recovered	16-Sep-2025 15 days	TREMELIMUMAB	Infusion	300 milligram Every 3 months Intravenous use	02-SEP-2025 to 02-SEP-2025 1 day	
Concomitant Medication(s): RILVEGOSTOMIG (S) | | BEVACIZUMAB (S) | Amlodipine besilate (C) | Atorvastatin calcium trihydrate (C) | Febuxostat (C) | Micatrio (C) | Pemafibrate (C) | Ursodeoxycholic acid (C) | Antebate (C) | Fexofenadine hydrochloride (C) | Heparinoid (C) | Hydroxyzine hydrochloride (C) | Prednisolone sodium succinate (C) | Soldem 3a (C) | Prednisolone (C)									
SOC:Vascular disorders									

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

Project ID: D7029

Study ID: D7029C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Sponsor-blinded, Multicentre Study of Rilvegostomig in Combination with Bevacizumab with or without Tremelimumab as First-lineTreatment in Patients With Advanced 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
202512GLO023384US	UNITED STATES	**Hypotension (Hypotension)***	Recovered with Sequelae	19-Dec-2025 nk	RILVEGOSTOMIG	Solution	750 milligram	02-OCT-2025 to	
	Female						Unknown		
						Solution	750 milligram	12-NOV-2025 to	
							Unknown		
						Solution	750 milligram	12-SEP-2025 to	
							Unknown		
						Solution	750 milligram	23-OCT-2025 to	
							Unknown		
					TREMELIMUMAB	Infusion	300 milligram	12-SEP-2025 to	
							Unknown		

Concomitant Medication(s): | TREMELIMUMAB (S) | BEVACIZUMAB (S) | Amlodipine (C) | Entecavir (C) | Nitrofurantoin (C) | Psyllium Husk (C) | Atropine (C) | Ceftriaxone (C) | Enoxaparin (C) | Famotidine (C) | Metronidazole (C) | Zosyn (C) | Potassium chloride (C)

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
202510GLO022159CN	CHINA 77 Years Male	**Anaemia (Anemia)***	Not Recovered	05-Oct-2025 6 days	RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	30-SEP-2025 to 30-SEP-2025 1 day	Periodic Report Comments. Subject has event: Anemia, Action taken with study drug: Temporarily withdrawn, Investigator causality: related, Company Causality: related
Concomitant Medication(s): | CAPECITABINE (S) | TRASTUZUMAB (S) | OXALIPLATIN (S) | Promethazine (C) | Cimetidine (C) | Dexamethasone sodium phosphate (C) | Netupitant and palonosetron hydrochloride (C) | Iron sucrose injection usp (C) | Sodium potassium magnesium calcium and glucose (C)									
202510GLO032522PL	POLAND Male	**Anaemia (Transfusion dependent anemia)***	Recovered	14-Oct-2025 nk	RILVEGOSTOMIG	Solution	Unknown	to	
Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S)									
202511GLO005736PL	POLAND 69 Years Female	**Anaemia (Anemia)***	Recovering	30-Oct-2025 nk	RILVEGOSTOMIG	Solution	Intravenous use	to	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) |									
202512GLO003076MY	MALAYSIA 64 Years Male	**Anaemia (Anemia)***	Recovered	25-Nov-2025 nk	RILVEGOSTOMIG	Solution	Unknown	to	
Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | PEMBROLIZUMAB (S) | TRASTUZUMAB (S) | 5-FLUOROURACIL (S) | CAPECITABINE (S) | CISPLATIN (S) | OXALIPLATIN (S)									

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
202506GLO006550CA	CANADA 76 Years Male	**Myocarditis (Myocarditis)*** Myositis (Myositis)*	Not Recovered	24-May-2025 1 month 11 days	RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	14-APR-2025 to 14-APR-2025 1 day	Patient experienced myocarditis and myositis Inv causality: RELATED with Rilvegostomig NOT RELATED with Capecitabine, Oxaliplatin, Trastuzumab CCC: NOT RELATED
Concomitant Medication(s): | TRASTUZUMAB (S) | CAPECITABINE (S) | OXALIPLATIN (S) | Telmisartan (C) | Finasteride (C) | Artificial tears (C) | Pantaloc (C) | Magic mouthwash (C) | Ondansetron (C) | Dexamethasone (C) | Lorazepan (C) | Clavulin (C) | Vancomycin (C) | Prednisone (C) | Clopidogrel (C) | Dalteparin (C) | Senokot (C) | Rosuvastatin (C) | Cotrimoxazole (C) | Calcium + vit d (C) | Levothyroxine (C) | Magnesium (C) | Sulfamethoxazole and trimethoprim (C) | Fragmin (C) | Enoxaparin (C)									
202512GLO007255GB	UNITED KINGDOM 79 Years Male	**Myocardial infarction (Myocardial infarction)***	Recovering	17-Nov-2025 3 months 2 days 8 hrs 2 min	CAPECITABINE	Tablet Tablet Tablet	750 milligram/sq. meter Intravenous use 750 milligram/sq. meter bid Intravenous use 750 milligram/sq. meter bid Intravenous use	14-SEP-2025 to 14-SEP-2025 1 day 14-AUG-2025 15:58 to 10-SEP-2025 26 days 8 hrs 2 min 15-SEP-2025 09:30 to 26-SEP-2025 10 days 14 hrs 30 min	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | RILVEGOSTOMIG (S) | Levetiracetam (C) | Rosuvastatin (C)									

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
202506GLO009120TW	TAIWAN Male	**Abdominal pain (Abdominal pain)***	Not Recovered	11-Jun-2025 nk	RILVEGOSTOMIG	Solution	Intravenous use	to	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	Intravenous use	to	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) |									
202511GLO026592KR	KOREA, REPUBLIC OF 62 Years Male	**Pancreatitis (Pancreatitis)***	Not Recovered	28-Nov-2025 3 months 22 days	RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	07-AUG-2025 to 07-AUG-2025 1 day	
						Solution	750 milligram q3w Intravenous use	07-NOV-2025 to 07-NOV-2025 1 day	
						Solution	750 milligram q3w Intravenous use	16-OCT-2025 to 16-OCT-2025 1 day	
						Solution	750 milligram q3w Intravenous use	18-SEP-2025 to 18-SEP-2025 1 day	
						Solution	750 milligram q3w Intravenous use	28-AUG-2025 to 28-AUG-2025 1 day	

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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 (S) | CAPECITABINE (S) | OXALIPLATIN (S) | Feroba u (C) | Algie (C) | Stocure (C) | Husade (C) | Daehwa magnesium oxide (C) | Td rabe (C) | Macperan (C) | Nasea od (C) | Tantum (C) | Lopaine (C) | Magmil s (C) | Zyprexa (C) | Rabiet (C) | Peniramin (C) | Lacticare (C) | Leucostim (C) | Hanomarin (C) | Hartman (C) | Pantoloc (C) | Combiflex peri (C) | K contin (C) | K cab (C) | Tasna (C) | Platelets (C) | Pethidine (C) | Lidocaine (C) | Norvasc (C)

SOC:General disorders and administration site conditions

202512GLO024770CN	CHINA Female	**Pyrexia (Fever)***	Recovered	01-Dec-2025 nk	AZD2936	Solution	750 milligram Unknown	09-SEP-2025 to 09-SEP-2025 1 day	
						Solution	750 milligram Unknown	12-AUG-2025 to 12-AUG-2025 1 day	
						Solution	750 milligram Unknown	18-JUL-2025 to 18-JUL-2025 1 day	
						Solution	750 milligram Unknown	19-JUN-2025 to 19-JUN-2025 1 day	
						Solution	750 milligram Unknown	21-OCT-2025 to 21-OCT-2025 1 day	
						Solution	750 milligram Unknown	28-NOV-2025 to 28-NOV-2025 1 day	

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	29-MAY-2025 to 29-MAY-2025 1 day	
Concomitant Medication(s): | CAPECITABINE (S) | TRASTUZUMAB DERUXTECAN (S)									
202512GLO024798CN	CHINA Female	**Chest discomfort (Chest tightness)***	Recovered	29-Nov-2025 6 months 1 day	RILVEGOS TOMIG	Solution	750 milligram q3w Intravenous use	09-SEP-2025 to 09-SEP-2025 1 day	
						Solution	750 milligram q3w Intravenous use	12-AUG-2025 to 12-AUG-2025 1 day	
						Solution	750 milligram q3w Intravenous use	18-JUL-2025 to 18-JUL-2025 1 day	
						Solution	750 milligram q3w Intravenous use	19-JUN-2025 to 19-JUN-2025 1 day	
						Solution	750 milligram q3w Intravenous use	21-OCT-2025 to 21-OCT-2025 1 day	
						Solution	750 milligram q3w Intravenous use	28-NOV-2025 to	

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	29-MAY-2025 to 29-MAY-2025 1 day	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	09-SEP-2025 to 09-SEP-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	12-AUG-2025 to 12-AUG-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	18-JUL-2025 to 18-JUL-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	21-OCT-2025 to 21-OCT-2025 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	28-NOV-2025 to	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	19-JUN-2025 to 19-JUN-2025 1 day	

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	29-MAY-2025 to 29-MAY-2025 1 day	
Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | CAPECITABINE (S) | Esomeprazole (C) | Polysaccharide iron (C) | Aprepitant (C) | Dexamethasone sodium phosphate (C) | Dolasetron mesylate (C) | Omeprazole sodium (C) | Granisetron hydrochloride (C) | Ondansetron hydrochloride (C) | Megestrol acetate (C) | Pantoprazole sodium (C) | Netupitant | Palonosetron (C) | Glucose and sodium chloride (C) | Sodium potassium magnesium calcium and glucose (C)									
SOC:Hepatobiliary disorders									
202510GLO023774ES	SPAIN 62 Years Female	**Hyperbilirubinaemia (Hyperbilirubinemia)***	Recovered	20-Oct-2025 nk	RILVEGOSTOMIG	Solution	Intravenous use	to	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	Intravenous use	to	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) |									
202511GLO012200BR	BRAZIL 74 Years Male	**Suspected drug-induced liver injury (Suspected Hy's law case)***	Not Recovered	13-Nov-2025 21 days 4 hrs 51 min	RILVEGOSTOMIG	Solution	Unknown	22-OCT-2025 19:09 to 22-OCT-2025 20:09 1 hr	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram	22-OCT-2025 16:39 to 22-OCT-2025 18:09	

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Unknown	1 hr 30 min	
					CAPECITABINE	Tablet	750 milligram/sq. meter bid	22-OCT-2025 to	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | CAPECITABINE (S) | Dipyrone (C) | Morphine (C) | Ondansetron (C) | Dexamethasone (C) | Prednisone (C)									
202511GLO013008BR	BRAZIL 74 Years Male	**Suspected drug-induced liver injury (Suspected Hy's law case)***	Recovered	13-Nov-2025 21 days 4 hrs 51 min	RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	22-OCT-2025 19:09 to 22-OCT-2025 20:09 1 hr	Periodic Report Comments. Patient experienced event - potencial hy's law. Investigator states event related to Rilvegostomig and not related to Trastuzumab Deruxtecan and Capecitabine. Company physician considers event related to Rilvegostomig, Trastuzumab Deruxtecan and Capecitabine.;Periodic Report Comments. Patient experienced Potencial Hy's Law - DILI. Inv: related to AZD2936, CAPECITABINE, not related to TRASTUZUMAB DERUXTECAN;Periodic Report Comments. Patient experienced event - potencial hy's law - dili. Investigator states event not related to Trastuzumab Deruxtecan, Capecitabine and related to Rilvegostomig. Company physician considers event not related to Trastuzumab Deruxtecan, Capecitabine, Rilvegostomig.

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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) | | CAPECITABINE (S) | Dipyrone (C) | Morphine (C) | Dexamethasone (C) | Ondansetron (C) | Prednisone (C) | Metoclopramide (C) | Nystatin (C)									
202511GLO027856FR	FRANCE 43 Years Male	**Hepatitis (Hepatitis)***	Not Recovered	28-Nov-2025 24 days	OXALIPLATIN	Infusion	100 milligram/sq. meter Intravenous use	16-DEC-2025 to 16-DEC-2025 1 day	
						Infusion	130 milligram/sq. meter Intravenous use	05-NOV-2025 to 05-NOV-2025 1 day	
Concomitant Medication(s): CAPECITABINE (S) | TRASTUZUMAB (S) | PEMBROLIZUMAB (S) | | Enalapril (C) | Pravastatine (C)									

SOC:Infections and infestations

202510GLO021537CN	CHINA 61 Years Female	**Septic shock (Septic shock)***	Fatal	20-Oct-2025 25 days	CAPECITABINE	Tablet	750 milligram/sq. meter bid Intravenous use	16-OCT-2025 to 19-OCT-2025 4 days	
						Tablet	750 milligram/sq. meter bid Intravenous use	26-SEP-2025 to 09-OCT-2025 14 days	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w	15-OCT-2025 to 15-OCT-2025 1 day	

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use		
						Powder for solution for infusion	5.4 milligram/kilogram q3w		25-SEP-2025 to 25-SEP-2025 1 day
							Intravenous use		
Concomitant Medication(s): RILVEGOSTOMIG (S) | | TRASTUZUMAB DERUXTECAN (S) | Captopril (C) | Ondansetron hydrochloride (C) | Concentrated sodium chloride (C) | Potassium chloride (C) | Human granulocyte colony stimulating factor (C)									
202512GLO005628CN	CHINA 52 Years Male	**Pneumonia (Pneumonia)***	Not Recovered	26-Nov-2025 5 months 7 days	RILVEGOSTOMIG	Solution	750 milligram q3w	04-NOV-2025 to 04-NOV-2025	Periodic Report Comments. Patient experienced event - pneumonia. Investigator states event related to Rilvegostomig and not related to Capecitabine, Oxaliplatin, Trastuzumab. Company physician considers event not related to Rilvegostomig, Capecitabine, Oxaliplatin, Trastuzumab.
							Intravenous use	1 day	
						Solution	750 milligram q3w	05-AUG-2025 to 05-AUG-2025	
							Intravenous use	1 day	
						Solution	750 milligram q3w	11-JUL-2025 to 11-JUL-2025	
							Intravenous use	1 day	
						Solution	750 milligram q3w	11-OCT-2025 to 11-OCT-2025	
							Intravenous use	1 day	
						Solution	750 milligram q3w	18-SEP-2025 to 18-SEP-2025	
							Intravenous use	1 day	

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	20-JUN-2025 to 20-JUN-2025 1 day	
						Solution	750 milligram q3w Intravenous use	28-AUG-2025 to 28-AUG-2025 1 day	
Concomitant Medication(s): | TRASTUZUMAB (S) | CAPECITABINE (S) | OXALIPLATIN (S) | Fentanyl (C) | Esomeprazole (C) | Aprepitant (C) | Diphenhydramine hydrochloride (C) | Esomeprazole sodium (C) | Metoclopramide (C) | Ondansetron hydrochloride (C) | Vitamin b6 (C) | Vitamin C (C) | Mecapegfilgrastim (C) | Bicyclol (C) | Diammonium glycyrrhizinate (C) | Diphenhydramine hydrochloride (C) | Palonosetron hydrochloride (C) | Tiopronin (C) | Rebamipide (C) | Moxifloxacin (C) | Lactulose (C) | Mucopolysaccharide polysulfuric acid ester (C) | Herombopag Olamine (C) | Caffeic acid (C) | Ethanolamine (C) | Recombinant human thrombopoietin (C) | Levothyroxine sodium (C)									
202512GLO016415CN	CHINA 64 Years Male	**Pulmonary tuberculosis (Pulmonary tuberculosis)*** Pleural effusion (Pleural effusion)	Not Recovered	16-Dec-2025 2 months 24 days	TRASTUZUMAB	Injection	6 milligram/kilogram q3w Intravenous use	04-NOV-2025 to 04-NOV-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	14-OCT-2025 to 14-OCT-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	25-NOV-2025 to 25-NOV-2025 1 day	
						Injection	8 milligram/kilogram q3w	23-SEP-2025 to 23-SEP-2025 1 day	

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use		
		Pulmonary tuberculosis (Pulmonary tuberculosis)* Pleural effusion (Pleural effusion)*	Not Recovered	16-Dec-2025 2 months 24 days	CAPECITABINE	Tablet	1000 milligram/sq. meter bid Oral use	14-OCT-2025 to 14-OCT-2025 1 day	
						Tablet	1000 milligram/sq. meter bid Oral use	24-SEP-2025 to 06-OCT-2025 13 days	
						Tablet	1000 milligram/sq. meter bid Oral use	26-NOV-2025 to 08-DEC-2025 13 days	
						Tablet	1000 milligram/sq. meter bid Oral use	28-OCT-2025 to 28-OCT-2025 1 day	
						Tablet	1000 milligram/sq. meter qd Oral use	04-NOV-2025 to 04-NOV-2025 1 day	
						Tablet	1000 milligram/sq. meter qd Oral use	05-NOV-2025 to 17-NOV-2025 13 days	

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	1000 milligram/sq. meter qd Oral use	07-OCT-2025 to 07-OCT-2025 1 day	
						Tablet	1000 milligram/sq. meter qd Oral use	09-DEC-2025 to 09-DEC-2025 1 day	
						Tablet	1000 milligram/sq. meter qd Oral use	15-OCT-2025 to 27-OCT-2025 13 days	
						Tablet	1000 milligram/sq. meter qd Oral use	18-NOV-2025 to 18-NOV-2025 1 day	
						Tablet	1000 milligram/sq. meter qd Oral use	23-SEP-2025 to 23-SEP-2025 1 day	
						Tablet	1000 milligram/sq. meter qd Oral use	25-NOV-2025 to 25-NOV-2025 1 day	
					OXALIPLATIN	Infusion	130 milligram/sq. meter q3w	04-NOV-2025 to 04-NOV-2025 1 day	

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use		
						Infusion	130 milligram/sq. meter q3w Intravenous use	14-OCT-2025 to 14-OCT-2025 1 day	
						Infusion	130 milligram/sq. meter q3w Intravenous use	23-SEP-2025 to 23-SEP-2025 1 day	
						Infusion	130 milligram/sq. meter q3w Intravenous use	25-NOV-2025 to 25-NOV-2025 1 day	
					RILVEGOS TOMIG	Solution	750 milligram q3w Intravenous use	04-NOV-2025 to 04-NOV-2025 1 day	
						Solution	750 milligram q3w Intravenous use	14-OCT-2025 to 14-OCT-2025 1 day	
						Solution	750 milligram q3w Intravenous use	23-SEP-2025 to 23-SEP-2025 1 day	
						Solution	750 milligram q3w	25-NOV-2025 to 25-NOV-2025	

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use		1 day
Concomitant Medication(s): RILVEGOSTOMIG (S) | | CAPECITABINE (S) | OXALIPLATIN (S) | Nifedipine (C) | Diammonium glycyrrhizinate (C) | Esomeprazole magnesium (C) | Ademetionine (C) | Magnesium Isoglycyrrhizinate (C) | Pantoprazole (C) | Dexamethasone (C) | Omeprazole (C) | Tropisetron hydrochloride (C) | Lafutidine (C) | Platelet (C) | Loperamide hydrochloride (C) | Fosaprepitant (C) | Rabeprazole sodium (C)									
202512GLO023325KR	KOREA, REPUBLIC OF Male	**Pneumocystis jirovecii pneumonia (Pneumocystis pneumonia)***	Not Recovered	12-Dec-2025 2 months 17 days	CAPECITABINE	Tablet	750 milligram/sq. meter bid Oral use	26-SEP-2025 to 12-DEC-2025 2 months 17 days	Periodic Report Comments. Investigator states event PCP pneumonia related to TRASTUZUMAB DERUXTECAN and CAPECITABINE and not related to AZD2936. Company physician considers event PCP pneumonia not related to CAPECITABINE, TRASTUZUMAB DERUXTECAN and AZD2936.
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	26-SEP-2025 to 28-NOV-2025 2 months 3 days	
Concomitant Medication(s): | RILVEGOSTOMIG (S) | TRASTUZUMAB DERUXTECAN (S) | Crostin (C) | Dapamet sr (C) | Fexuclue (C) | Mucosta (C) | Polybutine (C) | Tiropa (C) | Ultracet er (C)									
202512GLO027649CN	CHINA Male	**Pneumonia (Pneumonia)***	Not Recovered	28-Oct-2025 4 months 9 days	RILVEGOSTOMIG	Solution	Unknown	20-JUN-2025 to 04-NOV-2025 4 months 16 days	
Concomitant Medication(s): | TRASTUZUMAB (S) | CAPECITABINE (S) | OXALIPLATIN (S) | Fentanyl (C) | Esomeprazole (C) | Aprepitant (C) | Diphenhydramine hydrochloride (C) | Esomeprazole sodium (C) | Metoclopramide (C) | Ondansetron hydrochloride (C) | Vitamin C (C) | Mucopolysaccharide polysulfuric acid ester (C) | Vitamin b6 (C) | Mecapegfilgrastim (C) | Herombopag Olamine (C) | Bicyclol (C) | Diammonium glycyrrhizinate (C) | Palonosetron hydrochloride (C) | Tiopronin (C) | Caffeic acid (C) | Recombinant human thrombopoietin (C) | Ethanolamine (C) | Levothyroxine sodium (C) | Rebamipide (C) | Moxifloxacin (C) | Lactulose (C)									

SOC:Investigations

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO018811CN	CHINA Female	**Platelet count decreased (Platelet count decreased)***	Recovered	02-Jul-2025 1 month 6 days	RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	27-MAY-2025 to 10-JUL-2025 1 month 14 days	Periodic Report Comments. Patient experienced platelet count decreased. Investigator: related with Study therapy. Company physician: Not related.
						Solution	750 milligram q3w Intravenous use	31-JUL-2025 to 21-AUG-2025 22 days	
					TRASTUZUMAB	Injection	6 milligram/kilogram q3w Intravenous use	19-JUN-2025 to 10-JUL-2025 22 days	
						Injection	6 milligram/kilogram q3w Intravenous use	31-JUL-2025 to 21-AUG-2025 22 days	
						Injection	8 milligram/kilogram q3w Intravenous use	27-MAY-2025 to 27-MAY-2025 1 day	
Concomitant Medication(s): | TRASTUZUMAB (S) | CAPECITABINE (S) | OXALIPLATIN (S) | Palonosetron (C) | Compound methoxyphenamine (C) | Montelukast sodium (C) | Salmeterol (C) | Aprepitant (C) | Cimetidine (C) | Dexamethasone (C) | Diphenhydramine (C) | Ibuprofen (C) | Metoclopramide (C) | Omeprazole (C) | Lactulose (C) | Lidocaine (C) | Ondansetron (C) | Magnesium (C) | Leucogen (C)									
202507GLO027017CN	CHINA Female	**Platelet count decreased (Platelet count decreased)***	Recovering	29-Jul-2025 2 months 13 days	CAPECITABINE	Tablet	Oral use	17-MAY-2025 to	
Concomitant Medication(s): RILVEGOSTOMIG (S) | TRASTUZUMAB DERUXTECAN (S) |									

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202507GLO027940CN	CHINA Unknown	**Aspartate aminotransferase increased (Aspartate aminotransferase increased)***	Recovered	04-Jul-2025 nk	AZD2936	Solution	Intravenous use	to	
					TRASTUZUMAB	Injection	6 milligram/kilogram q3w Intravenous use	11-JUL-2025 to	
						Injection	8 milligram/kilogram q3w Intravenous use	20-JUN-2025 to	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | TRASTUZUMAB (S) | Capecitabine (S) | Oxaliplatin (S)									
202509GLO018865CN	CHINA 53 Years Male	**White blood cell count decreased (White blood cell count decreased)***	Recovered	22-Sep-2025 4 months 9 days	RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	14-MAY-2025 to 15-OCT-2025 5 months 2 days	Periodic Report Comments. Periodic Patient experienced White blood cell count decreased. Inv: related to Blinded AZD2936. CCA: related. Patient experienced White blood cell count decreased. Related to Blinded AZD2936. Not related to AZD2936. CCA: Not related
Concomitant Medication(s): | OXALIPLATIN (S) | TRASTUZUMAB (S) | CAPECITABINE (S) | Clopidogrel bisulfate (C) | Atorvastatin calcium (C) | Isosorbide mononitrate (C) | Folic acid (C) | Vitamin b complex (C) | Iron proteinsuccinylate (C) | Lactulose (C) | Lubiprostone (C) | Calcium gluconate (C) | Sodium chloride (C) | Fat emulsion (C) | Human insulin (C) | Potassium chloride (C) | Trace Element (C) | Vitamin b (C) | Protein (C)									
202510GLO020486CN	CHINA Female	**White blood cell count decreased (White blood cell count decreased)***	Not Recovered	20-Oct-2025 24 days 11 hrs 32 min	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	320 milligram/kilogram	25-SEP-2025 12:28 to 15-OCT-2025 19 days 11 hrs 32	patient has event: Event White blood cell count decreased, Action taken with study drug: No change, Investigator causality: related, Company

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use	min	Causality: Not related
Concomitant Medication(s): RILVEGOSTOMIG (S) | | 5-FLUOROURACIL (S) | CAPECITABINE (S) | Captopril (C)									
202512GLO004794KR	KOREA, REPUBLIC OF 62 Years Male	**Blood creatinine increased (Creatinine increased)***	Not Recovered	28-Nov-2025 3 months 20 days 12 hrs 30 min	RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	07-AUG-2025 11:30 to 07-NOV-2025 13:30 3 months 2 hrs	Periodic Report Comments. Patient experienced event Creatinine increased. Investigator did not assessed causality event to AZD2936 study therapy and not related to capecitabine, trastuzumab, oxaliplatin Company physician considers event unrelated to AZD2936 study therapy and capecitabine, trastuzumab, oxaliplatin.
Concomitant Medication(s): | TRASTUZUMAB (S) | Capecitabine (S) | Oxaliplatin (S) | Feroba you sr (C) | Algie (C) | Stocure (C) | Husade (C) | Td rabe (C) | Nasea od (C) | Sama Tantum gargle (C) | Lopaine (C) | Magmil s (C) | Zyprexa (C) | Rabiet (C) | Peniramin (C) | Lacticare hc (C) | Ulistin (C) | Foipan (C) | Combiflex peri (C) | Hartman (C) | Pantoloc (C)									
202512GLO024780CN	CHINA Female	**Platelet count decreased (Platelet count decreased)***	Recovered	02-Dec-2025 22 days	TRASTUZUMAB	Injection	8 milligram/kilogram Intravenous use	11-NOV-2025 to	
Concomitant Medication(s): CAPECITABINE (S) | | PEMBROLIZUMAB (S) | OXALIPLATIN (S) | Dexamethasone phosphate sodium (C) | Palonosetron hydrochloride (C) | Paracetamol (C) | Promethazine hydrochloride (C) | Bicyclol (C)									

SOC:Metabolism and nutrition disorders

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202508GLO008641CN	CHINA 53 Years Female	**Hypokalaemia (Hypokalemia)***	Recovered	10-Aug-2025 23 days 9 hrs 9 min	TRASTUZUMAB	Injection	8 milligram/kilogram q3w Intravenous use	17-JUL-2025 14:51 to 17-JUL-2025 16:51 2 hrs	
Concomitant Medication(s): | CAPECITABINE (S) | OXALIPLATIN (S) | PEMBROLIZUMAB (S) | Polysaccharide iron (C) | Itopride (C) | Megestrol acetate (C) | Omeprazole (C) | Celecoxib (C) | Tramadol hydrochloride (C) | Concentrated sodium chloride (C) | Esomeprazole magnesium (C) | Dexamethasone (C) | Oxycodone (C) | Lactulose (C) | Glucose and sodium chloride (C) | Human Albumin (C) | Potassium chloride (C) | Potassium chloride (C) | Vitamin C (C) | Ondansetron hydrochloride (C) | Omeprazole sodium (C) | Tropisetron hydrochloride (C) | Glycerine enema (C) | Vitamin b6 (C)									
202510GLO016198CN	CHINA 52 Years Male	**Decreased appetite (Inappetence)***	Recovered	21-Sep-2025 nk	TRASTUZUMAB	Injection	8 milligram/kilogram	20-JUN-2025 to 28-AUG-2025	
					RILVEGOSTOMIG	Solution	750 milligram Intravenous use	20-JUN-2025 to 28-AUG-2025 2 months 9 days	
Concomitant Medication(s): RILVEGOSTOMIG (S) | | CAPECITABINE (S) | OXALIPLATIN (S)									

SOC:Musculoskeletal and connective tissue disorders

202510GLO013594BR	BRAZIL 43 Years Female	**Back pain (Low back pain)*** Nausea (Nausea)*	Recovered	14-Oct-2025 nk	RILVEGOSTOMIG	Solution	Intravenous use	to	
Concomitant Medication(s): | CAPECITABINE (S) | OXALIPLATIN (S) | PEMBROLIZUMAB (S) | TRASTUZUMAB DERUXTECAN (S) | Levothyroxine (C) | Duloxetine (C) | Gabapentin (C) | Tramadol (C) | Amitriptyline (C)									

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
202510GLO023527CN	CHINA 77 Years Male	**Cerebral infarction (Cerebral infarction)***	Not Recovered	23-Oct-2025 22 days 3 hrs 40 min	OXALIPLATIN	Infusion	130 milligram/sq. meter q3w Intravenous use	30-SEP-2025 20:20 to 30-SEP-2025 23:15 2 hrs 55 min	
					TRASTUZUMAB	Injection	8 milligram/kilogram q3w Intravenous use	30-SEP-2025 17:49 to 30-SEP-2025 19:47 1 hr 58 min	
					RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	30-SEP-2025 16:03 to 30-SEP-2025 17:18 1 hr 15 min	
					CAPECITABINE	Tablet	1000 milligram/sq. meter bid Oral use	30-SEP-2025 to	
Concomitant Medication(s): TRASTUZUMAB (S) | RILVEGOSTOMIG (S) | | CAPECITABINE (S) | Promethazine (C) | Iron sucrose (C) | Ranitidine hydrochloride (C) | Nadroparin calcium (C) | Lactulose (C)									
202511GLO009310CN	CHINA 77 Years Male	**Cerebral infarction (Cerebral infarction)***	Not Recovered	23-Oct-2025 24 days	CAPECITABINE	Tablet	1000 milligram/sq. meter bid Oral use	30-SEP-2025 to	
					OXALIPLATIN	Infusion	130 milligram/sq. meter q3w	30-SEP-2025 to 30-SEP-2025	

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
								1 day	
							Intravenous use		
					RILVEGOSTOMIG	Solution	750 milligram q3w	30-SEP-2025 to 30-SEP-2025	
							Intravenous use	1 day	
					TRASTUZUMAB	Injection	8 milligram/kilogram q3w	30-SEP-2025 to 30-SEP-2025	
								1 day	
							Intravenous use		

Concomitant Medication(s): RILVEGOSTOMIG (S) | TRASTUZUMAB (S) | | OXALIPLATIN (S) | Promethazine (C) | Netupitant and palonosetron hydrochloride (C) | Dexamethasone sodium phosphate (C) | Cimetidine (C) | Iron sucrose (C) | Sodium potassium magnesium calcium and glucose (C) | Ranitidine hydrochloride (C)

SOC:Respiratory, thoracic and mediastinal disorders

202512GLO005768CN	CHINA 52 Years Male	**Pneumonitis (Pneumonitis)***	Not Recovered	28-Oct-2025 4 months 7 days 9 hrs 1 min	AZD2936	Solution	750 milligram q3w	04-NOV-2025 11:30 to 04-NOV-2025 12:35	
							Intravenous use	1 hr 5 min	
						Solution	750 milligram q3w	05-AUG-2025 to 05-AUG-2025	
							Intravenous use	1 day	
						Solution	750 milligram q3w	11-JUL-2025 to 11-JUL-2025	
							Intravenous use	1 day	

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

Project ID: D702A

Study ID: D702AC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Randomized, Phase III Study of Rilvegostomig in Combination with Fluoropyrimidine and Trastuzumab Deruxtecan Versus Trastuzumab, Chemotherapy, and Pembrolizumab for the First line Treatment of HER2-positive Gastric Cancer (ARTEMIDE-Gastric01)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	11-OCT-2025 to 11-OCT-2025 1 day	
						Solution	750 milligram q3w Intravenous use	18-SEP-2025 to 18-SEP-2025 1 day	
						Solution	750 milligram q3w Intravenous use	20-JUN-2025 14:59 to 20-JUN-2025 16:15 1 hr 16 min	
						Solution	750 milligram q3w Intravenous use	28-AUG-2025 to 28-AUG-2025 1 day	

Concomitant Medication(s): CAPECITABINE (S) | OXALIPLATIN (S) | | TRASTUZUMAB DERUXTECAN (S) | Fentanyl (C) | Esomeprazole (C) | Aprepitant (C) | Diphenhydramine hydrochloride (C) | Metoclopramide hydrochloride (C) | Ondansetron hydrochloride (C) | Vitamin b6 (C) | Vitamin C (C) | Mecapegfilgrastim (C) | Herombopag Olamine (C) | Bicyclol (C) | Diammonium glycyrrhizinate (C) | Diphenhydramine (C) | Palonosetron hydrochloride (C) | Tiopronin (C) | Magnesium Isoglycyrrhizinate (C) | Caffeic acid (C) | Ethanolamine (C) | Recombinant human thrombopoietin (C) | Glycyrrhizic acid (C) | Levothyroxine (C) | Metoclopramide hydrochloride (C) | Diammonium glycyrrhizinate (C) | Omeprazole (C) | Diphenhydramine hydrochloride (C) | Metoclopramide (C) | Vitamin b (C) | Rebamipide (C) | Yunnan baiyao (C) | Megestrol acetate (C) | Levothyroxine sodium (C) | Hetrombopag olamine (C) | Moxifloxacin (C) | Lactulose (C)

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

Project ID: D702B

Study ID: D702BC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-Lung02)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
202507GLO017599BR	BRAZIL 71 Years Male	**Neutropenia (Neutropenia)***	Recovered	14-Jul-2025 1 month 13 days					
Concomitant Medication(s):									
202507GLO020153AT	AUSTRIA 76 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	21-Jul-2025 6 days					
Concomitant Medication(s):									
202508GLO008776JP	JAPAN 70 Years Male	**Febrile neutropenia (Febrile neutropenia)** Colitis (Colitis)*	Recovered	09-Aug-2025 12 days					
Concomitant Medication(s):									
202508GLO026723BR	BRAZIL Male	**Neutropenia (Neutropenia)***	Recovered	14-Jul-2025 nk					
Concomitant Medication(s):									

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

Project ID: D702B

Study ID: D702BC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-Lung02)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202511GLO014387VN	VIET NAM 49 Years Male	**Bone marrow failure (Bone marrow failure)***	Recovering	15-Nov-2025 2 months 25 days 11 hrs 45 min					

Concomitant Medication(s):

SOC:Cardiac disorders

202507GLO021624AT	AUSTRIA 76 Years Female	**Cardiac arrest (Cardiac arrest)***	Fatal	23-Jul-2025 8 days					

Concomitant Medication(s):

SOC:Gastrointestinal disorders

202507GLO007163KR	KOREA, REPUBLIC OF 68 Years Female	**Enterocolitis (Enterocolitis)***	Recovered	27-Jun-2025 18 days					

Concomitant Medication(s):

202511GLO021195CN	CHINA 68 Years Male	**Gastrointestinal haemorrhage (Gastrointestinal bleeding)***	Recovered	08-Nov-2025 4 months 19 days					

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

Project ID: D702B

Study ID: D702BC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-Lung02)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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:General disorders and administration site conditions									
202510GLO033105US	UNITED STATES Male	**Chest pain (Chest pain)***	Not Recovered	16-Oct-2025 nk					
Concomitant Medication(s):									
SOC:Hepatobiliary disorders									
202508GLO005038JP	JAPAN 50 Years Male	**Autoimmune hepatitis (Autoimmune hepatitis)***	Recovering	07-Aug-2025 1 month 21 days					
Concomitant Medication(s):									
202508GLO010132CN	CHINA 60 Years Male	**Liver injury (Liver damage)***	Not Recovered	12-Aug-2025 21 days					
Concomitant Medication(s):									
SOC:Immune system disorders									

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

Project ID: D702B

Study ID: D702BC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-Lung02)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202506GLO008844CN	CHINA 58 Years Male	**Hypersensitivity (Allergic reaction)***	Recovered	10-Jun-2025 25 days					
Concomitant Medication(s):									
202509GLO000361TR	TURKEY 74 Years Male	**Anaphylactic reaction (Anaphylaxis)***	Recovered	29-Aug-2025 22 days					
Concomitant Medication(s):									
202511GLO023000KR	KOREA, REPUBLIC OF 65 Years Male	**Anaphylactic reaction (Anaphylaxis)***	Recovered	23-Jul-2025 20 days 12 hrs					
Concomitant Medication(s):									

SOC:Infections and infestations

202506GLO000868KR	KOREA, REPUBLIC OF 79 Years Male	**Sepsis (Sepsis)***	Not Recovered	30-May-2025 1 month 27 days					
Concomitant Medication(s):									
202506GLO006241CN	CHINA 76 Years Male	**Klebsiella infection (Klebsiella pneumoniae infection)***	Recovered	05-Jun-2025 28 days					

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

Project ID: D702B

Study ID: D702BC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-Lung02)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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):									
202507GLO012118MY	MALAYSIA 70 Years Male	**Septic shock (Septic shock)** Bacteraemia (Bacteremia)*	Recovered	14-Jul-2025 1 month 5 days					
Concomitant Medication(s):									
202510GLO010894TW	TAIWAN 71 Years Male	**Sepsis (Sepsis)***	Recovered	14-Oct-2025 nk					
Concomitant Medication(s):									
202511GLO010404BR	BRAZIL 66 Years Female	**Abdominal sepsis (Abdominal sepsis)***	Recovered	07-Nov-2025 nk					
Concomitant Medication(s):									
202511GLO027786US	UNITED STATES 61 Years Female	**Sepsis (Sepsis)***	Recovered	21-Nov-2025 10 days					
Concomitant Medication(s):									

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

Project ID: D702B

Study ID: D702BC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-Lung02)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
202511GLO010496BR	BRAZIL 7 Decades Female	**Infusion related reaction (Infusion related reaction)***	Not Recovered	07-Nov-2025 nk					
Concomitant Medication(s):									
SOC:Investigations									
202505GLO008701CN	CHINA 71 Years Male	**Neutrophil count decreased (Neutrophil count decreased)***	Recovered	08-May-2025 8 days					
Concomitant Medication(s):									
202507GLO021546TW	TAIWAN 81 Years Male	**Hepatic enzyme increased (Hepatic enzymes increased)***	Recovered	21-Jul-2025 4 months 3 days					
Concomitant Medication(s):									
202507GLO025818BR	BRAZIL 75 Years Female	**Troponin increased (Troponin increased)***	Not Recovered	28-Jul-2025 3 months 11 days 12 hrs 19 min					

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

Project ID: D702B

Study ID: D702BC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-Lung02)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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):									
202511GLO009941BR	BRAZIL 72 Years Female	**Amylase increased (Amylase increased)***	Recovering	10-Nov-2025 21 days					
Concomitant Medication(s):									
SOC:Metabolism and nutrition disorders									
202507GLO014826CN	CHINA 72 Years Male	**Decreased appetite (Anorexia)*** Fatigue (Fatigue)*	Not Recovered	07-Jul-2025 2 days 5 hrs 9 min					
Concomitant Medication(s):									
SOC:Nervous system disorders									
202508GLO017388CN	CHINA 56 Years Male	**Dizziness (Dizziness)***	Recovered	11-Aug-2025 2 months 15 days					
Concomitant Medication(s):									

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

Project ID: D702B

Study ID: D702BC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-Lung02)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
202503GLO022412TW	TAIWAN 81 Years Male	**Hiccups (Hiccup)***	Recovered	20-Mar-2025 2 days					
Concomitant Medication(s):									
SOC:Skin and subcutaneous tissue disorders									
202511GLO009035BR	BRAZIL 67 Years Male	**Rash (Skin rash)***	Recovered	18-Aug-2025 2 months 21 days					
Concomitant Medication(s):									
SOC:Vascular disorders									
202511GLO010933BR	BRAZIL 66 Years Female	**Hypotension (Hypotension)***	Not Recovered	07-Nov-2025 2 months 1 day 11 hrs 10 min					
Concomitant Medication(s):									

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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									
202505GLO015384CN	CHINA 67 Years Male	**Anaemia (Anemia aggravated)***	Not Recovered	15-May-2025 1 month 11 days 9 hrs 29 min					
Concomitant Medication(s):									
202505GLO029177PL	POLAND Female	**Anaemia (Anemia)***	Recovered	10-Jun-2025 2 months 24 days					
Concomitant Medication(s):									
202507GLO015062FR	FRANCE 62 Years Male	**Bone marrow failure (Aplasia bone marrow)***	Recovered	15-Jul-2025 3 months					
Concomitant Medication(s):									
202509GLO017249JP	JAPAN 61 Years Male	**Neutropenia (Neutropenia)***	Recovered	20-Sep-2025 3 months 2 days					
Concomitant Medication(s):									
202509GLO021550DE	GERMANY	**Neutropenia (Neutropenia)***	Recovered	24-Sep-2025 8 days 10 hrs					

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
	68 Years Male			45 min					
Concomitant Medication(s):									
202509GLO022619DE	GERMANY 64 Years Male	**Thrombocytopenia (Thrombopenia)***	Recovered	22-Sep-2025 1 month 17 days 10 hrs 50 min					
Concomitant Medication(s):									
202510GLO029279DE	GERMANY Male	**Neutropenia (Neutropenia)***	Not Recovered	26-Oct-2025 nk					
Concomitant Medication(s):									
202511GLO005711TR	TURKEY 69 Years Male	**Anaemia (Anemia aggravated)***	Not Recovered	06-Nov-2025 14 days 7 hrs 15 min					
Concomitant Medication(s):									
202511GLO005962TR	TURKEY 69 Years Male	**Thrombocytopenia (Thrombocytopenia)***	Fatal	06-Nov-2025 14 days 7 hrs 15 min					

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
Concomitant Medication(s):									
202511GLO019439VN	VIET NAM 66 Years Male	**Anaemia (Anemia)***	Recovering	17-Nov-2025 4 months 2 days					
Concomitant Medication(s):									
202511GLO023859DE	GERMANY 64 Years Male	**Neutropenia (Neutropenia)***	Not Recovered	19-Nov-2025 3 months 16 days					
Concomitant Medication(s):									
202511GLO026828JP	JAPAN 71 Years Male	**Febrile neutropenia (Febrile neutropenia)***	Not Recovered	27-Nov-2025 29 days 7 hrs 16 min					
Concomitant Medication(s):									
202512GLO009568DE	GERMANY 61 Years Male	**Pancytopenia (Pancytopenia)***	Recovered	08-Dec-2025 3 months 25 days 6 hrs 25 min					

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
Concomitant Medication(s):									
202512GLO012218VN	VIET NAM Male	**Febrile neutropenia (Febrile neutropenia)***	Recovered	12-Dec-2025 5 months 24 days					
Concomitant Medication(s):									
SOC:Cardiac disorders									
202508GLO020381VN	VIET NAM 64 Years Male	**Myocardial infarction (Myocardial infarction)***	Recovered with Sequelae	10-Aug-2025 26 days					
Concomitant Medication(s):									
SOC:Gastrointestinal disorders									
202508GLO021452CN	CHINA 62 Years Male	**Immune-mediated enterocolitis (Immune-mediated colitis)***	Recovered	14-Aug-2025 3 months 1 day					
Concomitant Medication(s):									
202510GLO015898CN	CHINA 71 Years Male	**Abdominal distension (Abdominal distension)***	Recovered	15-Oct-2025 8 hrs					

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
Concomitant Medication(s):									
202510GLO022691CN	CHINA 62 Years Male	**Immune-mediated enterocolitis (Immune-mediated colitis)***	Not Recovered	07-Oct-2025 4 months 24 days					
Concomitant Medication(s):									
202510GLO023991BR	BRAZIL 63 Years Male	**Nausea (Nausea)** Mallory-Weiss syndrome (Mallory Weiss tear)*	Recovered	21-Oct-2025 4 months 4 days					
Concomitant Medication(s):									
202510GLO032566JP	JAPAN 71 Years Male	**Gastroduodenal ulcer (Gastroduodenal ulcer)***	Recovered	01-Nov-2025 3 days 10 hrs 24 min					
Concomitant Medication(s):									
202511GLO004715JP	JAPAN 71 Years Male	**Enterocolitis (Enterocolitis)***	Recovering	04-Nov-2025 6 days 10 hrs 24 min					

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
Concomitant Medication(s):									
202511GLO021138VN	VIET NAM Male	**Enteritis (Enteritis)***	Recovering	21-Nov-2025 1 month 14 days					
Concomitant Medication(s):									
202511GLO021235VN	VIET NAM Unknown	**Enteritis (Enteritis)***	Recovering	21-Nov-2025 nk					
Concomitant Medication(s):									
202511GLO025624BR	BRAZIL 72 Years Male	**Intestinal obstruction (Intestinal obstruction)***	Recovering	25-Nov-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: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
202506GLO002620CN	CHINA Male	**Death (Unknown cause of death)***	Fatal	31-May-2025 17 days					
Concomitant Medication(s):									
202509GLO004814CN	CHINA 78 Years Male	**Malaise (Malaise)***	Recovered	03-Sep-2025 6 days					
Concomitant Medication(s):									
202510GLO019182DE	GERMANY 68 Years Male	**General physical health deterioration (General physical health deterioration)***	Not Recovered	24-Sep-2025 10 days					
Concomitant Medication(s):									
202510GLO020963VN	VIET NAM 66 Years Male	**Fatigue (Fatigue)***	Recovering	26-Sep-2025 3 months 13 days 8 hrs 41 min					
Concomitant Medication(s):									
202510GLO021239DE	GERMANY 68 Years Male	**General physical health deterioration (General physical health deterioration)***	Not Recovered	24-Sep-2025 10 days					
Concomitant Medication(s):									

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
202510GLO023596DE	GERMANY 74 Years Male	**General physical health deterioration (Reduced general condition)***	Not Recovered	01-Oct-2025 1 month 13 days					
Concomitant Medication(s):									
202510GLO023934DE	GERMANY 74 Years Male	**General physical health deterioration (Reduced general condition)***	Not Recovered	01-Oct-2025 1 month 11 days 6 hrs 14 min					
Concomitant Medication(s):									

SOC:Hepatobiliary disorders

202505GLO006238CA	CANADA	**Cholecystitis acute (Acute cholecystitis)***	Not Recovered	nk nk					
Concomitant Medication(s):									
202508GLO018271TW	TAIWAN Male	**Hepatitis (Hepatitis)***	Recovered	22-Aug-2025 17 days					
Concomitant Medication(s):									

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
202512GLO011983ES	SPAIN 65 Years Male	**Hepatotoxicity (Hepatotoxicity)***	Recovering	12-Dec-2025 1 month 12 days 7 hrs 43 min					

Concomitant Medication(s):

SOC:Immune system disorders

202512GLO000206JP	JAPAN 71 Years Male	**Cytokine release syndrome (Cytokine release syndrome)***	Fatal	01-Dec-2025 nk					

Concomitant Medication(s):

SOC:Infections and infestations

202504GLO002756PL	POLAND Male	**Neutropenic sepsis (Neutropenic sepsis)***	Fatal	02-Apr-2025 9 days					

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
Concomitant Medication(s):									
202505GLO000504TH	THAILAND 67 Years Male	**Pneumonia (Lower lobe pneumonia)***	Recovered	30-Apr-2025 28 days					
Concomitant Medication(s):									
202505GLO001446MY	MALAYSIA 63 Years Female	**Sepsis (Sepsis)***	Recovered	02-May-2025 3 days					
Concomitant Medication(s):									
202506GLO024322BR	BRAZIL 75 Years Female	**Clostridium difficile colitis (Clostridium difficile colitis)***	Recovered	20-Jun-2025 1 month 26 days 8 hrs					
Concomitant Medication(s):									
202507GLO013764BR	BRAZIL 64 Years Female	**Bronchitis (Bronchial infection)***	Recovered	15-Jul-2025 1 month 14 days					
Concomitant Medication(s):									

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
202508GLO001983BR	BRAZIL 64 Years Female	**Respiratory tract infection (Respiratory infection)***	Fatal	30-Jul-2025 1 month 29 days					
Concomitant Medication(s):									
202508GLO015038DE	GERMANY 53 Years Female	**Pneumonia (Pneumonia)***	Recovered	18-Aug-2025 11 days					
Concomitant Medication(s):									
202508GLO018289DE	GERMANY 53 Years Female	**Pneumonia (Pneumonia)***	Recovered	18-Aug-2025 11 days					
Concomitant Medication(s):									
202509GLO014698DE	GERMANY 53 Years Female	**Infectious pleural effusion (Pleural empyema)***	Not Recovered	16-Sep-2025 1 month 7 days 10 hrs 10 min					
Concomitant Medication(s):									
202509GLO014926CN	CHINA 64 Years Male	**Pneumonia (Pneumonia)***	Recovered	17-Sep-2025 4 months 5 days					

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
Concomitant Medication(s):									
202509GLO022547DE	GERMANY 74 Years Male	**Sepsis (Sepsis)*** Gastrointestinal haemorrhage (Gastro intestinal bleeding)	Recovered	25-Sep-2025 1 month 7 days					
		Sepsis (Sepsis)* Gastrointestinal haemorrhage (Gastro intestinal bleeding)*	Recovered	25-Sep-2025 1 month 7 days					
Concomitant Medication(s):									
202510GLO003164DE	GERMANY 74 Years Male	**Sepsis (Sepsis)*** Shock (Shock)* Hypervolaemia (Hypervolemia)*	Recovered	25-Sep-2025 1 month 7 days					
Concomitant Medication(s):									
202510GLO023751BR	BRAZIL 66 Years Female	**Gastroenteritis (Gastroenteritis)***	Recovered	24-Oct-2025 2 months 12 days 8 hrs 44 min					
Concomitant Medication(s):									

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
202510GLO031591US	UNITED STATES 57 Years Male	**Sepsis (Sepsis)***	Not Recovered	27-Oct-2025 4 days 11 hrs 42 min					
Concomitant Medication(s):									
202511GLO002448IT	ITALY 68 Years Male	**Septic shock (Septic shock)***	Not Recovered	31-Oct-2025 8 days 6 hrs 50 min					
Concomitant Medication(s):									
202511GLO005702JP	JAPAN 74 Years Male	**Pneumonia (Pneumonia)***	Fatal	04-Nov-2025 28 days 9 hrs 30 min					
Concomitant Medication(s):									
202511GLO016738BR	BRAZIL 66 Years Female	**Gastroenteritis (Gastroenteritis)***	Recovered	17-Nov-2025 3 months 5 days 8 hrs 55 min					

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
Concomitant Medication(s):									
202511GLO016827JP	JAPAN 71 Years Male	**Pneumonia (Pneumonia)***	Unknown	nk nk					
Concomitant Medication(s):									
202511GLO027633JP	JAPAN 71 Years Male	**Sepsis (Sepsis)***	Not Recovered	28-Nov-2025 1 month 10 hrs 24 min					
Concomitant Medication(s):									
202512GLO005741US	UNITED STATES Male	**Pneumonia (Bilateral pneumonia)***	Fatal	18-Nov-2025 nk					
Concomitant Medication(s):									

SOC:Injury, poisoning and procedural complications

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
202505GLO018248MY	MALAYSIA 62 Years Female	**Infusion related reaction (Infusion related reaction)***	Recovered	21-May-2025 20 days 12 hrs					

Concomitant Medication(s):

SOC:Investigations

202506GLO019942TH	THAILAND 68 Years Male	**Acinetobacter test positive (Acinetobacter baumannii test positive)***	Recovered	30-Apr-2025 28 days					

Concomitant Medication(s):

202507GLO006015CA	CANADA Unknown	**Platelet count decreased (Platelet count decreased)***	Unknown	nk nk					

Concomitant Medication(s):

202507GLO025796VN	VIET NAM 43 Years Male	**Hepatic enzyme increased (Elevated liver enzymes)***	Recovering	29-Jul-2025 19 days 10 hrs					

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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
Concomitant Medication(s):									
SOC:Metabolism and nutrition disorders									
202505GLO018640PL	POLAND 70 Years Male	**Hypokalaemia (Hypokalemia)** *	Recovered	29-Apr-2025 1 month 12 days					
Concomitant Medication(s):									
202507GLO010705BR	BRAZIL 73 Years Male	**Hyponatraemia (Hyponatraemia)***	Recovered	13-Jul-2025 3 days					
Concomitant Medication(s):									
202511GLO022479US	UNITED STATES 58 Years Female	**Hyperglycaemia (Hyperglycemia)***	Recovered	26-Jun-2025 1 day					
Concomitant Medication(s):									
202512GLO013740VN	VIET NAM Male	**Hyponatraemia (Hyponatremia)***	Recovering	16-Nov-2025 4 months 15 days					
Concomitant Medication(s):									

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

Project ID: D702F

Study ID: D702FC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab in Combination with Platinum-based Chemotherapy for the First-line Treatment of Patients with Metastatic Non-squamous Non-small Cell Lung Cancer Whose Tumors Express PD-L1 (ARTEMIDE-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:Musculoskeletal and connective tissue disorders									
202507GLO024484FR	FRANCE 66 Years Male	**Myositis (Myositis)***	Recovered	04-Jul-2025 2 months 3 days					
Concomitant Medication(s):									
SOC:Renal and urinary disorders									
202511GLO004772TR	TURKEY 69 Years Male	**Acute kidney injury (Acute kidney injury)***	Fatal	06-Nov-2025 14 days 7 hrs 15 min					
Concomitant Medication(s):									

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

Project ID: D702G

Study ID: D702GC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab Monotherapy for the First-line Treatment of Patients with PD-L1-high Metastatic Non-small Cell Lung Cancer (ARTEMIDE-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:Gastrointestinal disorders									
202510GLO023682GE	GEORGIA 64 Years Male	**Pancreatitis (Pancreatitis)***	Recovered	16-Oct-2025 26 days 10 hrs 20 min					
Concomitant Medication(s):									
SOC:Immune system disorders									
202509GLO010980JP	JAPAN 72 Years Male	**Cytokine release syndrome (Cytokine release syndrome)***	Recovered	11-Sep-2025 1 day					
Concomitant Medication(s):									
SOC:Infections and infestations									
202510GLO025174CN	CHINA 69 Years Male	**Pneumonia (Lung infection)***	Not Recovered	10-Oct-2025 9 days 8 hrs 42 min					
Concomitant Medication(s):									
SOC:Respiratory, thoracic and mediastinal disorders									

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

Project ID: D702G

Study ID: D702GC00001

EudraCT No:

Study Design: Double Blinded

Study Description: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab Monotherapy for the First-line Treatment of Patients with PD-L1-high Metastatic Non-small Cell Lung Cancer (ARTEMIDE-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
202511GLO017897JP	JAPAN 78 Years Male	**Pneumonitis (Pneumonitis)***	Not Recovered	17-Nov-2025 6 days					
Concomitant Medication(s):									
202512GLO017002MY	MALAYSIA 73 Years Male	**Pneumonitis (Pneumonitis)***	Recovering	15-Dec-2025 nk					
Concomitant Medication(s):									
202512GLO020868CN	CHINA 75 Years Male	**Respiratory failure (Respiratory failure)***	Fatal	20-Dec-2025 17 days 12 hrs 29 min					
Concomitant Medication(s):									

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

Project ID: D702N

Study ID: D702NC00001

EudraCT No:

Study Design: Not Blinded

Study Description: Phase III, Randomized, Open-label Sponsor-blind, Global, Multicenter Study of Rilvegostomig or Durvalumab in Combination With Chemotherapy as a First-line Treatment for Patients With Advanced Biliary Tract Cancer (ARTEMIDE-Biliary02)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
202512GLO022958CA	CANADA Female	**Cerebrovascular accident (Stroke)*** Pulmonary embolism (Pulmonary embolism)	Fatal	24-Dec-2025 6 days	CISPLATIN	Infusion	Intravenous use	19-DEC-2025 to	PRC. Patient experienced Bilateral pulmonary embolism. Investigator: Not related with AZD2936 and did not access causality with GEMCITABINE and CISPLATIN. CCA: not related. Patient experienced Stroke. Investigator: did not access causality with AZD2936 , GEMCITABINE and CISPLATIN. CCA: not related.; Periodic Report Comments. Patient experienced Bilateral pulmonary embolism. Investigator: Not related with AZD2936 and did not access causality with GEMCITABINE and CISPLATIN. CCA: not related. Patient experienced Stroke. Investigator: did not access causality with AZD2936 , GEMCITABINE and CISPLATIN. CCA: not related.
		Cerebrovascular accident (Stroke)* Pulmonary embolism (Pulmonary embolism)*	Fatal	24-Dec-2025 6 days	GEMCITABINE	Infusion	Intravenous use	19-DEC-2025 to	

Concomitant Medication(s): RILVEGOSTOMIG (S) | GEMCITABINE (S) | | Rosuvastatin (C) | Dilaudid (C) | Restoralax (C)

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

Project ID: D7632

Study ID: D7632C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
202510GLO026924CN	CHINA 63 Years Male	**Pericardial effusion (Pericardial effusion)***	Fatal	28-Oct-2025 3 months 24 days 13 hrs 45 min	AZD2936	Solution	750 milligram q3w Unknown	03-JUL-2025 10:15 to 03-JUL-2025 11:37 1 hr 22 min	Periodic Report Comments. Patient experienced Pericardial effusion, investigator assessed causality with Rilvegostomig (AZD2936) as related, CCA: not related with study therapy, Rilvegostomig (AZD2936).
						Solution	750 milligram q3w Unknown	04-SEP-2025 to 04-SEP-2025 1 day	
						Solution	750 milligram q3w Unknown	14-AUG-2025 11:29 to 14-AUG-2025 12:36 1 hr 7 min	
						Solution	750 milligram q3w Unknown	24-JUL-2025 11:27 to 24-JUL-2025 12:31 1 hr 4 min	

Concomitant Medication(s): | Reserpine (C) | Nadroparin calcium (C) | Rivaroxaban (C) | Dexamethasone sodium phosphate (C) | Denosumab (C) | Promethazine (C) | Oxybuprocaine (C) | Sodium chloride (C) | Compound glycyrrhiza (C) | Cefuroxime axetil (C) | Ceftriaxone sodium (C) | Pantoprazole sodium (C) | Ambroxol hydrochloride (C) | Furosemide (C) | Lansoprazole (C) | Esomeprazole magnesium (C) | Methylprednisolone sodium succinate (C) | Vitamin d3 (C) | Calcium carbonate and vitamin d3 (C)

SOC:Endocrine disorders

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

Project ID: D7632

Study ID: D7632C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202505GLO007245KR	KOREA, REPUBLIC OF 70 Years Male	**Adrenal insufficiency (Adrenal insufficiency)***	Recovering	08-May-2025 5 months 17 days	RILVEGOSTOMIG	Solution	750 milligram Intravenous use	02-JAN-2025 to 02-JAN-2025 1 day	
						Solution	750 milligram Intravenous use	06-MAR-2025 to 06-MAR-2025 1 day	
						Solution	750 milligram Intravenous use	07-JUL-2025 to 07-JUL-2025 1 day	
						Solution	750 milligram Intravenous use	08-SEP-2025 to 08-SEP-2025 1 day	
						Solution	750 milligram Intravenous use	10-NOV-2025 to 10-NOV-2025 1 day	
						Solution	750 milligram Intravenous use	12-DEC-2024 to 12-DEC-2024 1 day	
						Solution	750 milligram Intravenous use	13-FEB-2025 to 13-FEB-2025 1 day	
						Solution	750 milligram Intravenous use	15-APR-2025 to 15-APR-2025 1 day	

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

Project ID: D7632

Study ID: D7632C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	16-JUN-2025 to 16-JUN-2025	
							Intravenous use	1 day	
						Solution	750 milligram	18-AUG-2025 to 18-AUG-2025	
							Intravenous use	1 day	
						Solution	750 milligram	20-OCT-2025 to 20-OCT-2025	
							Intravenous use	1 day	
						Solution	750 milligram	21-JAN-2025 to 21-JAN-2025	
							Intravenous use	1 day	
						Solution	750 milligram	22-NOV-2024 to 22-NOV-2024	
							Intravenous use	1 day	
						Solution	750 milligram	26-MAY-2025 to 26-MAY-2025	
							Intravenous use	1 day	
						Solution	750 milligram	27-MAR-2025 to 27-MAR-2025	
							Intravenous use	1 day	
						Solution	750 milligram	28-JUL-2025 to 28-JUL-2025	
							Intravenous use	1 day	

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

Project ID: D7632

Study ID: D7632C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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 Intravenous use	29-SEP-2025 to 29-SEP-2025 1 day	

Concomitant Medication(s): DATO-DXD (S) | | Carvedilol (C) | Trimetazidine (C) | Valsartan (C) | Rosuvamibe (C) | Nifedipine (C) | Clopidogrel (C) | Cough syrup (C) | Anoro (C) | Ezetimibe (C) | Acetaminophen (C) | Akynzeo (C) | Dexamethasone (C) | Celestone (C) | Fexuprazan hydrochloride (C) | Hydroxyzine hydrochloride (C) | Levocetrizine hydrochloride (C) | Prednisolone (C) | Sodium hyaluronate (C) | Benzydamine hydrochloride (C) | Acetylcysteine (C) | Chlorhexidine gluconate (C) | Chlorpromazine hydrochloride (C) | Smoflipid (C) | Itopride hydrochloride (C) | Cefepime hydrochloride (C) | Propacetamol hydrochloride (C) | Complex phazyme (C)

SOC:Gastrointestinal disorders

202510GLO021022BR	BRAZIL 61 Years Male	**Nausea (Nausea)*** Vomiting (Vomiting)	Recovering	15-Oct-2025 1 month 12 days 14 hrs	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Unknown	02-SEP-2025 10:00 to	Periodic Report Comment : Event Nausea, Action taken with study drug: Not Applicable, Investigator causality: related, Company Causality: Not related;Periodic Report Comments. Patient experienced event nausea and vomiting Investigator states event related to DATOPOTAMAB DERUXTECAN, AZD2936 Company physician considers event not related to DATOPOTAMAB DERUXTECAN, AZD2936.

Concomitant Medication(s): | AZD2936 (S) | Methadone (C) | Omeprazole (C) | Fluoxetine (C) | Quetiapine (C) | Rivaroxaban (C) | Nicotine (C) | Bisacodyl (C) | Salbutamol (C) | Lactulose (C) | Atorvastatin (C) | Ciprofloxacin (C) | Ivermectin (C) | Methylprednisolone (C) | Enoxaparin (C) | Potassium chloride (C) | Dexamethasone (C) | Captopril (C) | Losartan (C) | Cimetidine (C)

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

Project ID: D7632

Study ID: D7632C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202510GLO023689CN	CHINA 73 Years Female	**Stomatitis (Mucositis oral)***	Not Recovered	20-Oct-2025 4 months 19 days 10 hrs 8 min	DATOPOTAMAB DERUXTECAN	Injection	Unknown	30-MAY-2025 13:52 to 31-OCT-2025 12:05 5 months 22 hrs 13 min	Periodic Report Comments. Patient experienced event Oral mucositis. Investigator states that, the event related to DATOPOTAMAB DERUXTECAN and RILVEGOSTOMIG. Company physician considers that, the event not related to DATOPOTAMAB DERUXTECAN and RILVEGOSTOMIG.;Patient has event: Event: Mucositis oral, Action taken with study drug: No Change, Investigator causality: related, Company Causality: Not related
					RILVEGOSTOMIG	Solution	Unknown	30-MAY-2025 16:00 to 31-OCT-2025 12:37 5 months 20 hrs 37 min	

Concomitant Medication(s): | RILVEGOSTOMIG (S) | Felodipine (C) | Clopidogrel bisulfate (C) | Estazolam (C) | Simvastatin (C) | Lactulose (C) | Loxoprofen (C) | Dexamethasone (C)

SOC:General disorders and administration site conditions

202506GLO007438IN	INDIA 60 Years Female	**Death (Unknown cause of death)***	Fatal	03-Jun-2025 28 days	AZD2936	Solution	750 milligram q3w Intravenous use	07-MAY-2025 to 30-MAY-2025 24 days	

Concomitant Medication(s): | Domperidone (C) | Lactulose (C) | Metoclopramide (C) | Ondansetron (C) | Palonosetron (C) | Pantoprazole (C) | Ranitine (C) | Vitamin d3 (C) | Calcium citrate malate (C) | Calcium citrate (C) | Folic acid (C) | Becosules (C)

SOC:Hepatobiliary disorders

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

Project ID: D7632

Study ID: D7632C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202509GLO008565JP	JAPAN 63 Years Male	**Drug-induced liver injury (Drug-induced liver injury)***	Recovered	09-Sep-2025 21 days	AZD2936	Solution	Intravenous use	20-AUG-2025 to 20-AUG-2025 1 day	
					DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	20-AUG-2025 to 20-AUG-2025 1 day	

Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Empagliflozin (C) | Lansoprazole (C) | Magnesium oxide (C) | Naldemedine tosilate (C) | Mirogabalin besilate (C) | Prochlorperazine mesilate (C) | Aprepitant (C) | Dexamethasone sodium phosphate (C) | Palonosetron hydrochloride (C) | Dexamethasone (C) | Eszopiclone (C) | White petrolatum (C) | Clostridium butyricum (C) | Loperamide hydrochloride (C) | Sennoside (C) | Oxycodone hydrochloride (C)

SOC:Infections and infestations

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202506GLO006355KR	KOREA, REPUBLIC OF 55 Years Male	**Pneumocystis jirovecii pneumonia (Pneumocystis jirovecii pneumonia)***	Recovered	05-Jun-2025 1 month 8 days	AZD2936	Solution	750 milligram q3w Intravenous use	29-APR-2025 to 30-SEP-2025 5 months 2 days	Patient experienced PCP (Pneumocystis jirovecii) Pneumonia investigator causality related to Dato-dxt and AZD2936, cca not related.
					DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	21-AUG-2025 to 30-SEP-2025 1 month 10 days	
						Injection	6 milligram/kilogram q3w Intravenous use	29-APR-2025 to 24-JUN-2025 1 month 27 days	

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

Project ID: D7632

Study ID: D7632C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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) | | Lasix (C) | Naxen (C) | Spiracton (C) | Septrin (C) | Twynsta (C) | Tylenol (C) | Prednisol (C) | Trison (C) | Levofloxacin (C) | Stilnox (C) | Ceprax (C) | Solondo (C) | Paramacet SEMI (C) | Akynzeo (C) | Yuhan dexamethasone (C) | Acetphen premix (C) | Gaster (C) | Methylon (C) | Pantoloc (C) | Levotuss (C) | Cough (C) | Normal saline (C) | Ventolin (C) | Atrovent (C) | Nadoxol (C) | Muteran (C) | Tabactam (C) | Predisol (C) | Caldolor (C) | Roxol (C) | Lanston lfdt (C) | Dulackhan (C)									
202507GLO000749IN	INDIA 73 Years Female	**Gastroenteritis (Acute gastroenteritis)***	Recovered	01-Jul-2025 2 months 13 days	PEMBROLIZUMAB	Solution for infusion	200 milligram Intravenous use	19-APR-2025 to 27-JUN-2025 2 months 9 days	Periodic Report Comments. Patient experienced Acute gastroenteritis. Inv: related. CCA:not related.
Concomitant Medication(s): | Insulin (C) | Diamicron (C) | Istamet (C) | Tazloc (C) | Met xl (C) | Rosuvastatin (C) | Optive (C) | Budamate (C) | Duolin (C) | Cifran (C) | Domperidone | Pantoprazole (C) | Emeset (C) | Ondansetron (C) | Ceftriaxone (C) | Cefixime (C) | Para (C) | Fexofenadine hydrochloride (C) | Pan D (C)									
202508GLO024992AU	AUSTRALIA 61 Years Female	**Pneumonia (Pneumonia)***	Recovered	22-Aug-2025 1 month 6 days	AZD2936	Solution	750 milligram Intravenous use	17-JUL-2025 to 18-SEP-2025 2 months 2 days	
					DATOPOTAMAB DERUXTECAN	Injection	330 milligram/kilogram Intravenous use	17-JUN-2025 to 18-SEP-2025 3 months 2 days	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) |									
202510GLO005474CN	CHINA 63 Years Male	**Pneumonia (Lung infection)***	Not Recovered	23-Sep-2025 2 months 19 days 13 hrs 45 min	AZD2936	Solution	750 milligram q3w Intravenous use	03-JUL-2025 10:15 to 04-SEP-2025 12:10 2 months 1 day 1 hr 55 min	

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

Project ID: D7632

Study ID: D7632C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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): | Compound reserpine (C) | Nadroparin calcium (C) | Rivaroxaban (C) | Dexamethasone sodium phosphate (C) | Denosumab (C) | Promethazine (C) | Oxybuprocaine (C) | Sodium chloride (C) | Methylprednisolone sodium succinate (C) | Calcium carbonate and vitamin d3 (C) | Compound glycyrrhiza (C) | Cefuroxime axetil (C) | Ceftriaxone sodium (C) | Pantoprazole sodium (C) | Ambroxol hydrochloride (C) | Moxifloxacin hydrochloride and sodium chloride (C) | Furosemide (C) | Lansoprazole (C) | Prednisone (C)									
202511GLO008874CN	CHINA 69 Years Male	**Pneumonia bacterial (Bacterial pneumonia, unspecified)***	Not Recovered	26-Oct-2025 3 months 14 days 11 hrs 3 min	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	11-JUL-2025 12:57 to 21-OCT-2025 3 months 9 days 11 hrs 3 min	Periodic Report Comments. Patient has event: cough with outcome: not recovered, action taken for study therapy was temporary withdrawn, investigator causality: related, company causality: not related.
					AZD2936	Solution	750 milligram q3w Intravenous use	11-JUL-2025 15:13 to 21-OCT-2025 3 months 9 days 8 hrs 47 min	
Concomitant Medication(s): | AZD2936 (S) | Multivitamin (C) | Dexamethasone sodium phosphate (C) | Ilaprazole sodium (C) | Netupitant and palonosetron hydrochloride (C) | Promethazine hydrochloride (C) | Paracetamol/caffeine (C) | Loratadine (C) | Live combined bifidobacterium and lactobacillus (C) | Posterior pituitary (C) | Biapenem (C) | Benzylpenicillin sodium (C) | Carbazochrome sodium sulfonate (C) | Ticarcillin disodium (C) | Ciprofol (C) | Compound sodium acetate (C) | Compound sulfamethoxazole (C) | Sevoflurane (C) | Dezocine (C) | Esomeprazole sodium (C) | Hydrocortisone (C) | Mivacurium (C) | Penehyclidine hydrochloride (C) | Potassium chloride (C) | Remifentanil hydrochloride (C) | Remimazolam tosilate (C) | Sufentanil citrate (C) | Thymalfasin (C) | Sitafloxacin (C)									
SOC:Investigations									
202505GLO006122JP	JAPAN 54 Years Female	**Liver function test increased (Liver function test increased)***	Recovered	03-May-2025 24 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	10-APR-2025 to 23-JUL-2025 3 months 14 days	

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

Project ID: D7632

Study ID: D7632C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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-AUG-2025 to 13-AUG-2025 1 day	
Concomitant Medication(s): | Amlodipine od (C) | Calonal (C) | Loxoprofen na (C) | Takecab (C) | Oxinorm (C) | Oxycontin tr (C) | Symproic (C) | Codeine phosphate (C) | Neophagen (C) | Restamin kowa (C)									
202510GLO021103BR	BRAZIL Male	**Blood creatinine abnormal (Creatinine abnormal NOS)***	Recovering	21-Sep-2025 20 days	RILVEGOS TOMIG	Solution	750 milligram q3w	13-OCT-2025 to 13-OCT-2025 1 day	
						Solution	750 milligram q3w Intravenous use	02-SEP-2025 to 02-SEP-2025 1 day	
						Solution	750 milligram q3w Intravenous use	22-SEP-2025 to 22-SEP-2025 1 day	
Concomitant Medication(s): DATO-DXD (S) | | Methadone (C) | Omeprazole (C) | Fluoxetine (C) | Quetiapine (C) | Rivaroxaban (C) | Nicotine (C) | Bisacodyl (C)									

SOC:Metabolism and nutrition disorders

202506GLO013067KR	KOREA, REPUBLIC OF 79 Years Male	**Hyponatraemia (Hyponatremia)***	Recovered	16-Jun-2025 7 days	AZD2936	Solution	6 milligram/kilogram 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: D7632

Study ID: D7632C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	6 milligram/kilogram Intravenous use	10-JUN-2025 to 10-JUN-2025 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Duodart (C) | Olmetec (C) | Dulackhan (C) | Atozet (C) | Codeine (C) | Phazyme complex (C) | Serenzal (C) | Fexuclue (C)									

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

202506GLO024730IT	ITALY 70 Years Male	**Tumour associated fever (Tumour associated fever)***	Recovered	15-Jun-2025 nk	AZD2936 DATOPOTAMAB DERUXTECAN	Solution Injection	Unknown Unknown	to to	Periodic Report Comments. Patient has event: FEVER. Action Taken with study therapy was Unknown. Investigator Causality: Not reported CC: not Related.; Periodic Report Comments. Patient has event: paraneoplastic fever. Action Taken with study therapy was Not applicable. Investigator Causality: Not reported CC: Not applicable.
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | No Drug (S)									
202510GLO005390IT	ITALY 70 Years Female	**Tumour hyperprogression (Tumor hyperprogression)***	Fatal	04-Oct-2025 17 days 7 hrs 50 min	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	16-SEP-2025 16:10 to 16-SEP-2025 17:10 1 hr	Periodic Report Comments. Patient experienced event - progression disease to liver, spleen and lymph nodes. Investigator states event related to pembrolizumab. Company physician considers event not related to pembrolizumab.

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

Project ID: D7632

Study ID: D7632C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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): | Acetylsalicylic acid (C) | Olmesartan medoxomil (C) | Rosuvastatin (C) | Augmentin (C) | Norepinephrine (C) | Tramadole (C) | Morphine (C) | Eparin (C)									
202510GLO023656PL	POLAND 71 Years Female	**Metastases to central nervous system (Brain metastases)***	Recovering	21-Oct-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	to	
					PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	to	
					RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	to	
Concomitant Medication(s): | RILVEGOSTOMIG (S) | PEMBROLIZUMAB (S)									

SOC:Nervous system disorders

202410GLO004200JP	JAPAN 63 Years Male	**Phrenic nerve paralysis (Phrenic nerve paralysis)***	Recovering	05-Oct-2024 2 months 24 days	PEMBROLIZUMAB	Solution for infusion	Intravenous use	15-NOV-2024 to 15-NOV-2024 1 day	Periodic Report Comments. Patient experienced phrenic nerve paralysis. Inv: event related to PEMBROLIZUMAB, CCA: not related.
						Solution for infusion	200 milligram Intravenous use	12-JUL-2024 to 22-AUG-2024 1 month 11 days	

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

Project ID: D7632

Study ID: D7632C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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): | Denosumab (C) | Omeprazole (C) | Acetaminophen (C) | Crotamiton (C) | Linagliptin (C) | Magnesium oxide (C) | Rosuvastatin calcium (C) | Rebamipide (C) | Vantelin (C) | White petrolatum (C) | Panthenol (C) | Soldem (C) | Bacitracin (C) | Bisoprolol (C) | Salivent (C) | Levofloxacin Hydrate (C) | Insulin human (C)									
2024A209475	JAPAN 63 Years Male	**Paralysis recurrent laryngeal nerve (Paralysis recurrent laryngeal nerve)***	Recovering	12-Sep-2024 2 months 1 day	PEMBROLIZUMAB	Solution for infusion	q3w Intravenous use	15-NOV-2024 to 15-NOV-2024 1 day	The patient experienced Paralysis recurrent laryngeal nerve. Investigator: related to PEMBROLIZUMAB Company physician: Not related to study therapy.
						Solution for infusion	200 milligram q3w Intravenous use	12-JUL-2024 to 22-AUG-2024 1 month 11 days	
Concomitant Medication(s): | Vantelinkowa ex (C) | Denosumab (C) | Omeprazole (C) | Acetaminophen (C) | Crotamiton (C) | Bisoprolol (C) | Levofloxacin Hydrate (C) | Sulbacillin (C) | White petrolatum (C) | Panthenol (C) | Soldem (C) | Bacitracin (C) | Salivent (C) | Silodosin (C)									
202508GLO022376JP	JAPAN 63 Years Male	**IIIrd nerve paralysis (Oculomotor nerve paralysis)***	Recovering	26-Aug-2025 1 year 1 month 15 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	12-JUL-2024 to 22-AUG-2024 1 month 11 days	
Concomitant Medication(s): | Vantelin (C) | Denosumab (C) | Omeprazole (C) | Panthenol (C) | Bisoprolol (C) | Soldem (C) | Hydroxyzine hydrochloride (C) | Insulin human (C) | Dermosol g (C)									
202512GLO015817CA	CANADA 71 Years Female	**Dysgeusia (Dysgeusia)***	Not Recovered	30-Jul-2025 2 months 10 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	19-NOV-2025 to 19-NOV-2025 1 day	
						Injection	6 milligram/kilogram q3w	21-MAY-2025 to 29-OCT-2025	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

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

Project ID: D7632

Study ID: D7632C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use	5 months 9 days	
Concomitant Medication(s): AZD2936 (S) | | Fluticasone (C) | Rabeprazole (C) | Hydromorphone (C) | Salbutamol (C) | Omega-3 fish oil (C) | Acetaminophen (C) | Vitamin b12 (C) | Vitamin d3 (C) | Dexamethasone (C) | Prochlorperazine (C)									
202512GLO025677TR	TURKEY 60 Years Male	**Headache (Headache)***	Recovering	24-Dec-2025 nk	AZD2936	Solution	Unknown	to	
					DATOPOTAMAB DERUXTECAN	Injection	Unknown	to	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | PEMBROLIZUMAB (S)									

SOC:Renal and urinary disorders

202501GLO004203JP	JAPAN 64 Years Male	**Acute kidney injury (Acute renal failure)*** Pulmonary toxicity (Drug-induced lung injury)*	Recovered	07-Jan-2025 4 months 23 days	AZD2936	Solution	750 milligram q3w Intravenous use	06-SEP-2024 to 06-SEP-2024 1 day	PRC. Patient experienced Drug-induced lung injury and Acute renal failure Investigator: related to study therapy for both the events , CCA: not related to study therapy for both the events.;Patient has event: Event: Acute renal failure, Action taken with study drug: Withdrawn, Investigator causality: related, Company Causality: Not related Patient has event: Event: Acute renal failure, Action taken with
						Solution	750 milligram q3w Intravenous use	08-NOV-2024 to 08-NOV-2024 1 day	
						Solution	750 milligram q3w	16-AUG-2024 to 16-AUG-2024	

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Study ID: D7632C00001

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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
							Intravenous use	1 day	study drug: No Change, Investigator causality: related, Company Causality: Not related
						Solution	750 milligram q3w	18-OCT-2024 to 18-OCT-2024	
							Intravenous use	1 day	
						Solution	750 milligram q3w	20-DEC-2024 to 20-DEC-2024	
							Intravenous use	1 day	
						Solution	750 milligram q3w	27-SEP-2024 to 27-SEP-2024	
							Intravenous use	1 day	
						Solution	750 milligram q3w	29-NOV-2024 to 29-NOV-2024	
							Intravenous use	1 day	
					DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	06-SEP-2024 to 06-SEP-2024	
								1 day	
						Injection	Intravenous use	08-NOV-2024 to 08-NOV-2024	
								1 day	
						Injection	Intravenous use	16-AUG-2024 to 16-AUG-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	Intravenous use	18-OCT-2024 to 18-OCT-2024 1 day	
						Injection	Intravenous use	20-DEC-2024 to 20-DEC-2024 1 day	
						Injection	Intravenous use	27-SEP-2024 to 27-SEP-2024 1 day	
						Injection	Intravenous use	29-NOV-2024 to 29-NOV-2024 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Sodium hyaluronate (C) | Ketoprofen (C) | Vonoprazan fumarate (C)									
202510GLO023562BR	BRAZIL 61 Years Male	**Renal impairment (Renal function aggravated)***	Recovering	23-Oct-2025 1 month 22 days	RILVEGOS TOMIG	Solution Intravenous use	750 milligram	02-SEP-2025 to 02-SEP-2025 1 day	Periodic Report Comments. Patient experienced event Renal impairment. Investigator and company physician states that, the event not related to DATOPOTAMAB DERUXTECAN and related to RILVEGOSTOMIG.
						Solution Intravenous use	750 milligram	13-OCT-2025 to	
						Solution Intravenous use	750 milligram	22-SEP-2025 to 22-SEP-2025 1 day	

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Project ID: D7632

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EudraCT No:

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Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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): DATO-DXD (S) | | Rivaroxaban (C) | Methadone (C) | Omeprazole (C) | Fluoxetine (C) | Quetiapine (C) | Nicotine (C) | Bisacodyl (C) | Salbutamol (C) | Lactulose (C) | Atorvastatin (C) | Acetylsalicylic acid (C) | Enoxaparin (C) | Potassium chloride (C) | Morphine (C) | Bromopride (C)									
SOC:Respiratory, thoracic and mediastinal disorders									
202501GLO020421GB	UNITED KINGDOM 70 Years Male	**Dyspnoea (Dyspnoea)***	Not Recovered	05-Jan-2025 26 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	11-DEC-2024 to 11-DEC-2024 1 day	
						Solution for infusion	200 milligram q3w Intravenous use	31-DEC-2024 to 31-DEC-2024 1 day	
Concomitant Medication(s): | Salamol (C) | Trimbow (C) | Senna (C) | Dexamethasone (C) | Naproxen (C) | Omeprazole (C) | Oramorph (C) | Paracetamol (C) | Laxido (C) | Oxycodone (C) | Dalteparin sodium (C) | Thealoz (C) | Difflam (C) | Ipratropium bromide (C) | Salbutamol (C)									
202501GLO023330BR	BRAZIL 69 Years Female	**Pneumonitis (Pneumonitis)***	Recovered with Sequelae	25-Jan-2025 12 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	14-JAN-2025 to 14-JAN-2025 1 day	Periodic Report Comments. The patient experienced pneumonitis. Investigator causality and CCA related for Dato-DXd. Investigator causality and company causality not related to AZD2936.
Concomitant Medication(s): | AZD2936 (S) | Citalopram (C) | Codeine (C) | Dexamethasone (C) | Acetaminophen (C) | Ketoprofen (C) | Diphenhydramine (C) | Loratadine (C) | Dexmedetomidine (T) | Tranexamic (T)									
202510206023837JP	JAPAN 54 Years Male	**Pneumonitis (Pneumonitis)***	Recovering	08-Sep-2025 2 months 22	AZD2936	Solution	750 milligram q3w	16-JUN-2025 14:50 to 19-AUG-	

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Study ID: D7632C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations (TROPION-Lung10)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
				days 19 hrs 11 min			Intravenous use	2025 16:10 2 months 3 days 1 hr 20 min	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Tamsulosin (C) | Candesartan (C) | Febuxostat (C) | Loxoprofen na (C) | Rebamipide (C) | Loxoprofen na (C) | Lansoprazole (C) | Sodium hyaluronate (C) | Acetaminophen (C) | Codeine phosphate (C) | Lemborexant (C) | Sodium bicarbonate | Sodium gualenate (C) | Panvitan (C) | Palonosetron (C) | Fosnetupitant (C) | Chlorpheniramine (C) | Dexamethasone (C) | Hydrocortisone (C) | Magnesium oxide (C) | Posterisan (C) | Prednisolone (C) | Sodium succinate (C) | Sulfamethoxazole (C) | Infliximab (C) | Oxygen (C)									
202510GLO001926JP	JAPAN 58 Years Female	**Pneumonitis (Pneumonitis)***	Recovering	01-Oct-2025 2 months 15 days 11 hrs 21 min	AZD2936	Solution	750 milligram q3w Intravenous use	05-AUG-2025 13:05 to 05-AUG-2025 14:09 1 hr 4 min	Periodic Report Comments. Patient experienced event Pneumonitis. Investigator states that, the event related to DATOPOTAMAB DERUXTECAN and RILVEGOSTOMIG. Company physician considers that, the event not related to DATOPOTAMAB DERUXTECAN and RILVEGOSTOMIG.
						Solution	750 milligram q3w Intravenous use	15-JUL-2025 12:39 to 15-JUL-2025 13:42 1 hr 3 min	
						Solution	750 milligram q3w Intravenous use	17-SEP-2025 12:37 to 17-SEP-2025 13:40 1 hr 3 min	
						Solution	750 milligram q3w Intravenous use	25-AUG-2025 14:20 to 25-AUG-2025 15:23 1 hr 3 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
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Dimemorfan phosphate (C) | Loxoprofen sodium hydrate (C) | Rebamipide (C) | Codeine phosphate (C) | Retinol (C) | Ergocalciferol (C) | Nicorette (C) | Acetaminophen (C) | Aprepitant (C) | Boric acid (C) | D chlorpheniramine maleate nissin (C) | Dexamethasone sodium phosphate (C) | Vonoprazan fumarate (C) | Dexamethasone (C) | Ursodeoxycholic acid (C) | Metoclopramide (C) | Augmentin (C) | Amoxicillin hydrate (C) | Clostridium butyricum (C) | Palonosetron hydrochloride (C) | Magnesium oxide (C) | Granisetron hydrochloride (C) | Heparinoid (C) | Hydrocortisone butyrate (C) | Fexofenadine hydrochloride (C) | Prednisolone sodium succinate (C) | Prednisolone (C) | Sulfamethoxazole (C) | Alendronate sodium hydrate (C) | Atovaquone (C)									
202510GLO009686CN	CHINA 63 Years Male	**Pneumonitis (Pneumonitis)***	Not Recovered	12-Oct-2025 3 months 10 days	AZD2936	Solution Intravenous use	750 milligram q3w 1 day	03-JUL-2025 to 03-JUL-2025	Periodic Report Comments. Patient experienced event Interstitial pneumonia. Investigator states event related to AZD2936. CCC- not related.
						Solution Intravenous use	750 milligram q3w 1 day	04-SEP-2025 to 04-SEP-2025	
						Solution Intravenous use	750 milligram q3w 1 day	14-AUG-2025 to 14-AUG-2025	
						Solution Intravenous use	750 milligram q3w 1 day	24-JUL-2025 to 24-JUL-2025	
Concomitant Medication(s): | Rivaroxaban (C) | Reserpine (C) | Nadroparin calcium (C) | Dexamethasone sodium phosphate (C) | Calcium carbonate (C) | Denosumab (C) | Promethazine (C) | Oxybuprocaine (C) | Sodium chloride (C) | Glycyrrhiza (C) | Cefuroxime axetil (C) | Ceftriaxone sodium (C) | Methylprednisolone sodium succinate (C) | Pantoprazole (C) | Ambroxol hydrochloride (C) | Moxifloxacin hydrochloride (C) | Esomeprazole magnesium (C) | Piperacillin sodium (C)									
202511GLO016815CN	CHINA 75 Years Male	**Interstitial lung disease (Interstitial lung disease)***	Not Recovered	12-Nov-2025 4 months 3 days 7 hrs 38	RILVEGOSTOMIG	Solution	750 milligram q3w	08-JUL-2025 16:22 to 08-JUL-2025 17:21	

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Study ID: D7632C00001

EudraCT No:

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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
				min			Intravenous use	59 min	
						Solution	750 milligram q3w Intravenous use	09-SEP-2025 12:24 to 09-SEP-2025 13:29 1 hr 5 min	
						Solution	750 milligram q3w Intravenous use	19-AUG-2025 12:53 to 19-AUG-2025 14:16 1 hr 23 min	
						Solution	750 milligram q3w Intravenous use	28-OCT-2025 17:46 to 28-OCT-2025 19:11 1 hr 25 min	
						Solution	750 milligram q3w Intravenous use	29-JUL-2025 11:32 to 29-JUL-2025 12:40 1 hr 8 min	
Concomitant Medication(s): DATO-DXD (S) | | Compound sodium lactate and glucose (C) | Diphenhydramine hydrochloride (C) | Fosaprepitant dimeglumine (C) | Levothyroxine sodium (C) | Loxoprofen (C) | Omeprazole sodium (C) | Polyene phosphatidylcholine (C) | Tropisetron (C) | Metoclopramide dihydrochloride (C) | Ondansetron hydrochloride (C) | Meropenem (C) | Methylprednisolone sodium succinate (C) | Lactulose (C) | Prednisone acetate (C)									
202511GLO026952CN	CHINA 67 Years Male	**Pleural effusion (Pleural effusion)***	Not Recovered	26-Nov-2025 20 days 4 hrs 33 min	AZD2936	Solution	750 milligram q3w Intravenous use	06-NOV-2025 10:30 to 06-NOV-2025 11:45 1 hr 15 min	

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EudraCT No:

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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): | Denosumab (C)									
202511GLO027021CN	CHINA Male	**Pleural effusion (Pleural effusion)***	Not Recovered	26-Nov-2025 21 days	AZD2936	Solution	750 milligram q3w Intravenous use	06-NOV-2025 to 06-NOV-2025 1 day	Periodic Report Comments. Subject has event: Pleural effusion, Action taken: Temporarily Withdrawn, Investigator causality for Study drug: related, and CCA: related.
Concomitant Medication(s): | Denosumab (C)									
202512GLO019557CN	CHINA Male	**Interstitial lung disease (Interstitial lung disease)***	Not Recovered	12-Nov-2025 3 months 13 days	AZD2936	Solution	750 milligram q3w Intravenous use	31-JUL-2025 to 23-OCT-2025 2 months 23 days	Periodic Report Comments. Patient experienced event - ILD. Investigator states event related to AZD2936. Company physician considers event not related to AZD2936.
Concomitant Medication(s): | Fluticasone Furoate (C) | Xgeva (C) | Calcium carbonate (C) | Caltrate (C) | Compound codeine phosphate and ibuprofen (C) | Tramadol (C) | Pantoprazole sodium (C)									
SOC:Vascular disorders									
202508GLO018305CN	CHINA 66 Years Male	**Deep vein thrombosis (Thrombosis of leg deep venous)*** Pulmonary embolism (Pulmonary embolism)*	Not Recovered	21-Aug-2025 1 month 9 days 10 hrs 56 min	DATOPOTAMAB DERUXTECAN	Injection Injection	6 milligram/kilogram Intravenous use 6 milligram/kilogram	01-AUG-2025 12:27 to 01-AUG-2025 13:35 1 hr 8 min 05-SEP-2025 11:43 to 05-SEP-2025 13:00	Periodic Report Comments. Patient experienced event Thrombosis of leg deep venous and Pulmonary embolism. Investigator states that events related to RILVEGOSTOMIG and DATOPOTAMAB DERUXTECAN. Company physician considers events not related to RILVEGOSTOMIG

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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
							Intravenous use	1 hr 17 min	and DATOPOTAMAB DERUXTECAN.
						Injection	6 milligram/kilogram Intravenous use	11-JUL-2025 13:04 to 11-JUL-2025 14:37 1 hr 33 min	
						Injection	6 milligram/kilogram Intravenous use	17-OCT-2025 12:31 to 17-OCT-2025 13:38 1 hr 7 min	
						Injection	6 milligram/kilogram Intravenous use	26-SEP-2025 11:01 to 26-SEP-2025 13:22 2 hrs 21 min	
					AZD2936	Solution	750 milligram Intravenous use	01-AUG-2025 14:16 to 01-AUG-2025 15:14 58 min	
						Solution	750 milligram Intravenous use	05-SEP-2025 13:35 to 05-SEP-2025 14:36 1 hr 1 min	
						Solution	750 milligram Intravenous use	11-JUL-2025 15:12 to 11-JUL-2025 16:15 1 hr 3 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
						Solution	750 milligram Intravenous use	17-OCT-2025 14:05 to 17-OCT-2025 14:58 53 min	
						Solution	750 milligram Intravenous use	26-SEP-2025 14:01 to 26-SEP-2025 14:57 56 min	
Concomitant Medication(s): AZD2936 (S) | | Ambroxol hydrochloride (C) | Methoxyphenamine (C) | Dexamethasone sodium phosphate (C) | Diphenhydramine hydrochloride (C) | Doxofylline (C) | Fosaprepitant dimeglumine (C) | Esomeprazole (C) | Loxoprofen sodium (C) | Tropisetron (C) | Aprepitant (C) | Metoclopramide dihydrochloride (C) | Ondansetron hydrochloride (C) | Enoxaparin sodium (C) | Ibuprofen and codeine phosphate (C)									
202510GLO024496AU	AUSTRALIA 64 Years Female	**Superior vena cava occlusion (Superior vena caval obstruction)***	Not Recovered	21-Oct-2025 nk	AZD2936	Solution	Unknown	to	
					DATOPOTAMAB DERUXTECAN	Injection	Unknown	to	
					PEMBROLIZUMAB	Solution for infusion	Intravenous use	to	
Concomitant Medication(s): | DATOPOTAMAB DERUXTECAN (S) | PEMBROLIZUMAB (S)									

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

Project ID: D781D

Study ID: D781DC00001

EudraCT No:

Study Design: Not Blinded

Study Description: An Open-Label, Sponsor-Blinded, Randomized, Controlled, Multicenter, Phase III Study of Trastuzumab Deruxtecan (T-DXd) Plus Rilvegostomig or Pembrolizumab vs Chemotherapy Plus Pembrolizumab as First-Line Therapy of HER2-Expressing (IHC 3+/2+), Mismatch Repair Proficient (pMMR), Primary Advanced or Recurrent Endometrial 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									
202510GLO031085CN	CHINA 70 Years Female	**Myelosuppression (Bone marrow suppression)***	Not Recovered	29-Aug-2025 nk	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram Intravenous use	to	
					AZD2936	Solution	750 milligram Intravenous use	20-AUG-2025 to 20-AUG-2025 1 day	
Concomitant Medication(s): AZD2936 (S) | | Enoxaparin sodium (C) | Insulin (C) | Omeprazole sodium (C) | Bicyclol (C) | Dexamethasone sodium phosphate (C) | Lansoprazole (C) | Insulin glargine (C) | Clopidogrel hydrogen sulphate (C) | Aspirin (C) | Felodipine (C) | Metoprolol tartrate (C) | Mecobalamin (C) | Potassium chloride (C) | Calcium gluconate (C) | Ibuprofen (C) | Meropenem (C) | Octreotide acetate (C) | Sucralose (C) | Tramadol hydrochloride (C) | Fentanyl citrate (C) | Heparin sodium (C) | Magnesium Isoglycyrrhizinate (C) | Magnesium sulfate (C) | Methylprednisolone acetate (C) | Noradrenaline bitartrate (C) | Rocuronium bromide (C) | Tathion (C) | Teicoplanin (C) | Polymyxin b sulfate (C) | Hydrocortisone sodium succinate (C) | Human Albumin (C) | Dextrose (C) | Cryoprecipitate (C) | Glutamine (C) | Cefoperazone sodium (C) | Sodium bicarbonate (C) | Ibuprofen (C) | Polymyxin b sulfate (C) | Glucose (C) | Voglibose (C)									
SOC:Infections and infestations									
202509GLO000673CN	CHINA 70 Years Female	**Septic shock (Septic shock)*** Myelosuppression (Bone marrow suppression)* Enterocolitis (Enterocolitis)* Multiple organ dysfunction syndrome (Multiple organ failure)*	Fatal	29-Aug-2025 8 days 10 hrs 7 min	AZD2936	Solution	750 milligram q3w Intravenous use	20-AUG-2025 13:53 to 20-AUG-2025 15:14 1 hr 21 min	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w	20-AUG-2025 11:41 to 20-AUG-2025 13:14	

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

Project ID: D781D

Study ID: D781DC00001

EudraCT No:

Study Design: Not Blinded

Study Description: An Open-Label, Sponsor-Blinded, Randomized, Controlled, Multicenter, Phase III Study of Trastuzumab Deruxtecan (T-DXd) Plus Rilvegostomig or Pembrolizumab vs Chemotherapy Plus Pembrolizumab as First-Line Therapy of HER2-Expressing (IHC 3+/2+), Mismatch Repair Proficient (pMMR), Primary Advanced or Recurrent Endometrial 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
							Intravenous use	1 hr 33 min	

Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Lansoprazole (C) | Voglibose (C) | Felodipine (C) | Aspirin (C) | Enoxaparin (C) | Insulin glargine (C) | Clopidogrel (C) | Metoprolol tartrate (C) | Mecobalamin (C) | Enoxaparin sodium (C) | Insulin (C) | Omeprazole sodium (C) | Bicyclol (C) | Dexamethasone sodium phosphate (C) | Potassium chloride (C) | Meropenem (C) | Noradrenaline bitartrate (C) | Octreotide acetate (C) | Polymyxin b sulfate (C)

SOC:Investigations

202506GLO002769TW	TAIWAN 59 Years Female	**Neutrophil count decreased (Absolute neutrophil count decreased)*** White blood cell count decreased (White blood cell decreased)*	Recovered	03-Jun-2025 14 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	02-JUL-2025 to 21-AUG-2025 1 month 20 days	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	21-MAY-2025 to 21-MAY-2025 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	23-SEP-2025 to	

Concomitant Medication(s): | PEMBROLIZUMAB (S) | Sennoside (C) | Nimicor (C) | Nebivolol (C) | Zepnap (C) | Folic acid (C) | Sodium ferrous citrate (C) | Silymarin (C)

SOC:Skin and subcutaneous tissue disorders

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

Project ID: D781D

Study ID: D781DC00001

EudraCT No:

Study Design: Not Blinded

Study Description: An Open-Label, Sponsor-Blinded, Randomized, Controlled, Multicenter, Phase III Study of Trastuzumab Deruxtecan (T-DXd) Plus Rilvegostomig or Pembrolizumab vs Chemotherapy Plus Pembrolizumab as First-Line Therapy of HER2-Expressing (IHC 3+/2+), Mismatch Repair Proficient (pMMR), Primary Advanced or Recurrent Endometrial 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
202508GLO017460CN	CHINA 66 Years Female	**Dermatitis (Dermatitis)***	Recovered	17-Aug-2025 11 days	CARBOPLATIN	Infusion	5 dosage form q3w Intravenous use	05-SEP-2025 to 05-SEP-2025 1 day	
						Infusion	5 dosage form q3w Intravenous use	07-AUG-2025 to 07-AUG-2025 1 day	
						Infusion	5 dosage form q3w Intravenous use	30-SEP-2025 to 30-SEP-2025 1 day	
					PACLITAXEL	Infusion	175 milligram/sq. meter q3w Intravenous use	05-SEP-2025 to 05-SEP-2025 1 day	
						Infusion	175 milligram/sq. meter q3w Intravenous use	07-AUG-2025 to 07-AUG-2025 1 day	
						Infusion	175 milligram/sq. meter q3w Intravenous use	30-SEP-2025 to 30-SEP-2025 1 day	

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

Project ID: D781D

Study ID: D781DC00001

EudraCT No:

Study Design: Not Blinded

Study Description: An Open-Label, Sponsor-Blinded, Randomized, Controlled, Multicenter, Phase III Study of Trastuzumab Deruxtecan (T-DXd) Plus Rilvegostomig or Pembrolizumab vs Chemotherapy Plus Pembrolizumab as First-Line Therapy of HER2-Expressing (IHC 3+/2+), Mismatch Repair Proficient (pMMR), Primary Advanced or Recurrent Endometrial 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): PEMBROLIZUMAB (S) | PACLITAXEL (S) | | Cimetidine (C) | Rivaroxaban (C) | Compound sodium chloride (C) | Dexamethasone sodium phosphate (C) | Diphenhydramine hydrochloride (C) | Furosemide (C) | Netupitant and palonosetron hydrochloride (C) | Nifedipine (C) | Omeprazole sodium (C) | Compound glycyrrhizin (C) | Alfacalcidol (C) | Calcium carbonate and vitamin d3 (C) | Ranitidine hydrochloride (C) | Vitamin C (C) | Methylprednisolone (C) | Ebastine (C) | Triamcinolone acetonide acetate (C) | Aluminum (C)									
SOC:Vascular disorders									
202511GLO029548CN	CHINA Female	**Deep vein thrombosis (Deep vein thrombosis)***	Recovered	22-Nov-2025 nk	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	Intravenous use	to	
Concomitant Medication(s):									
202512GLO025634AU	AUSTRALIA 75 Years Female	**Hypotension (Hypotension)***	Not Recovered	28-Dec-2025 4 months 7 days	AZD2936	Solution	750 milligram Intravenous use	22-AUG-2025 to	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram Intravenous use	22-AUG-2025 to	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Rosuvastatin (C) | Esomeprazole (C) | Metformin (C) | Metoprolol succinate (C) | Levothyroxine (C)									

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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:Blood and lymphatic system disorders									
202410GLO030556BR	BRAZIL 68 Years Female	**Thrombocytopenia (Thrombocytopenia)*** Cholangitis (Cholangitis)* Pancytopenia (Pancytopenia)*	Recovered	21-Oct-2024 1 month 17 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	05-SEP-2024 to 14-OCT-2024 1 month 10 days	Periodic Report Comments. Patient experienced events Thrombocytopenia, Cholangitis and Pancytopenia. Investigator states events related toTrastuzumab deruxtecan and not related to AZD2936. CCC-not related.
Concomitant Medication(s): | AZD2936 (S) | Rivaroxaban (C) | Amlodipine (C) | Losartan (C) | Levothyroxine (C) | Naproxen (C)									
202510GLO016176VN	VIET NAM 62 Years Male	**Anaemia (Anemia)***	Recovering	29-Sep-2025 22 days	AZD2936	Solution	750 milligram q3w Unknown	08-SEP-2025 to	Periodic Report Comments. The patient experienced Hemoglobin test indicates grade 2 anemia. Investigator causality related to study therapy and AZD2936. CCA not related.
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Amlodipine (C) | Valsartan (C) | Silymarin (C) | Tenofovir (C) | Dexamethason (C) | Granisetron kabi (C) | Lysin (C) | Ondansetron (C) | Ursode (C) | Methylprednisolone (C)									
202510GLO023832VN	VIET NAM Female	**Bone marrow failure (Bone marrow failure)***	Recovered	17-Oct-2025 6 days 12 hrs 14 min	RILVEGOSTOMIG	Solution Solution	750 milligram q3w Unknown 750 milligram q3w Unknown	10-OCT-2025 11:46 to 10-OCT-2025 12:58 1 hr 12 min 21-NOV-2025 09:09 to 21-NOV-2025 10:14 1 hr 5 min	Periodic Report Comments. Patient experienced Bone marrow failure, investigator assessed causality with Blinded AZD2936 as related, with TRASTUZUMAB DERUXTECAN and RILVEGOSTOMIG as not related. CCA: related with study therapy, TRASTUZUMAB DERUXTECAN and

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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
									RILVEGOSTOMIG.
						Solution	750 milligram q3w Unknown	31-OCT-2025 11:46 to 31-OCT-2025 12:51 1 hr 5 min	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	4.4 milligram/kilogram q3w Unknown	21-NOV-2025 10:44 to 21-NOV-2025 11:24 40 min	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Unknown	31-OCT-2025 13:21 to 31-OCT-2025 14:01 40 min	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Unknown	10-OCT-2025 14:01 to 10-OCT-2025 15:35 1 hr 34 min	

Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Esomeprazole (C)

SOC:Gastrointestinal disorders

202501GLO004103TW	TAIWAN 69 Years Female	**Diarrhoea (Diarrhea)***	Recovered	03-Jan-2025 2 months 5 days	AZD2936	Solution	750 milligram Intravenous use	02-JAN-2025 to 02-JAN-2025 1 day	
						Solution	750 milligram	12-DEC-2024 to 12-DEC-2024	

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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
							Intravenous use	1 day	
						Solution	750 milligram Intravenous use	21-NOV-2024 to 21-NOV-2024 1 day	
						Solution	750 milligram Intravenous use	30-OCT-2024 to 30-OCT-2024 1 day	
Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | Linagliptin (C) | Pitavastatin (C) | Acetylcysteine (C) | Glycyrrhiza (C) | Dextromethorphan (C) | Metformin (C) | Glucose (C) | Dexamethasone phosphate (C) | Diphenhydramine HCL (C) | Acetaminophen (C) | Celecoxib (C) | Lansoprazole (C) | Cefixime (C) | Akynzeo (C) | Loperamide (C)									
202507GLO020166MY	MALAYSIA 74 Years Female	**Abdominal distension (Abdominal bloating)***	Not Recovered	22-Jul-2025 nk	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	q3w Unknown	to	
Concomitant Medication(s):									
202508GLO024880CN	CHINA 58 Years Male	**Vomiting (Vomiting)** Renal impairment (Renal function abnormal)*	Recovered	28-Aug-2025 1 month 12 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion Powder for solution for infusion	4.4 milligram/kilogram q3w Unknown 5.4 milligram/kilogram q3w Unknown	26-SEP-2025 to 17-OCT-2025 22 days 17-JUL-2025 to 28-AUG-2025 1 month 12 days	Periodic Report Comments. The patient experienced vomiting and Renal function abnormal. Investigator causality related to AZD2936 and Trastuzumab deruxtecan. CCA not related.

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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
					AZD2936	Solution	750 milligram q3w Unknown	17-JUL-2025 to 17-OCT-2025 3 months 1 day	
Concomitant Medication(s): AZD2936 (S) | | Amlodipine (C) | Dexamethasone (C) | Ondansetron (C) | Aprepitant (C) | Fat emulsion (C)									
202509GLO004467CN	CHINA 58 Years Male	**Diarrhoea (Diarrhea)***	Recovered	04-Sep-2025 1 month 19 days	AZD2936	Solution	750 milligram q3w Intravenous use	17-JUL-2025 to 28-AUG-2025 1 month 12 days	Periodic Report Comments. Patient experienced delayed-onset diarrhea, Investigator: related with Azd2936 and not related with Trastuzumab Deruxtecan. CCA: not related.; Patient experienced Diarrhea. Inv: related with Rilvegostomig Not related with Trastuzumab Deruxtecan. CCA: Not related
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Amlodipine besylate (C) | Dexamethasone sodium phosphate (C) | Enema (C) | Celecoxib (C) | Aprepitant (C) | Insulin injection (C) | Potassium chloride (C) | Omeprazole (C) | Diclofenac sodium (C) | Lidocaine (C) | Ondansetron hydrochloride (C) | Lactulose (C) | Sodium lactate ringer's (C) | Tramadol hydrochloride (C) | Loperamide hydrochloride (C) | Concentrated sodium chloride (C) | Esomeprazole (C) | Bicyclol (C)									
202511GLO014775CN	CHINA 55 Years Female	**Intestinal obstruction (Intestinal obstruction)***	Recovered	15-Nov-2025 nk	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Unknown	to	
Concomitant Medication(s):									
202511GLO016257CN	CHINA 40 Years Male	**Vomiting (Vomiting)***	Not Recovered	15-Nov-2025 1 month 15 days 11 hrs 25 min	AZD2936	Solution	750 milligram Unknown	22-OCT-2025 11:05 to	

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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
						Solution	750 milligram Unknown	30-SEP-2025 12:35 to 30-SEP-2025 13:55 1 hr 20 min	

Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | Repaglinide (C) | Entecavir (C) | Estazolam (C) | Amino acid (C) | Omeprazole (C) | Tramadol hydrochloride (C) | Bucinnazine hydrochloride (C) | Flurbiprofen axetil (C) | Dexamethasone sodium phosphate (C) | Ondansetron hydrochloride (C) | Morphine sulfate (C) | Carbohydrate and electrolyte (C)

SOC:General disorders and administration site conditions

202411GLO021311CA	CANADA 60 Years Male	**Death (Death NOS)***	Fatal	22-Nov-2024 nk	AZD2936	Solution	Unknown	to	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	Unknown	to	

Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | No Drug (S)

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	

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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
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)									
202510GLO026925IN	INDIA 67 Years Male	**Pyrexia (Fever)***	Recovered	27-Oct-2025 8 days 12 hrs 35 min	AZD2936	Solution	750 milligram q3w Unknown	18-OCT-2025 11:25 to 18-OCT-2025 12:25 1 hr	
Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | Glycomet (C) | Amlong (C)									
202511GLO009189VN	VIET NAM 53 Years Female	**Fatigue (Fatigue)***	Recovered	08-Nov-2025 30 days	AZD2936	Solution Solution Solution	750 milligram q3w Intravenous use 750 milligram q3w Intravenous use 750 milligram q3w Intravenous use	10-OCT-2025 to 10-OCT-2025 1 day 21-NOV-2025 to 21-NOV-2025 1 day 31-OCT-2025 to 31-OCT-2025 1 day	Periodic Report Comments. Patient experienced Fatigue. Inv: related to TRASTUZUMAB DERUXTECAN, AZD2936
Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | Morphine sulphate (C) | Sorbitol (C) | Famotidin (C) | Natri clorid (C) | Dexamethason (C) | Diphenhydramin (C) | Palonosetron hydrochloride (C) | Fegamed (C) | Opezimin (C) | Filgrastim (C)									
202511GLO015041IN	INDIA 62 Years Male	**Pyrexia (Fever)***	Recovered	16-Nov-2025 nk	AZD2936	Solution	750 milligram q3w Unknown	to	Periodic Report Comments. Patient experienced event fever. Investigator states event did not report causality AZD2936. Company physician considers

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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
									event related AZD2936
Concomitant Medication(s): | Heptral (C) | Emset (C) | Meropenem (C) | Pantocid (C) | Udiliv (C) | Amlokind (C) | Concor (C) | Lipirose (C) | Azithromycin (C) | Albumin (C) | A to z (C) | Cefixime (C) | Cremaffin (C) | Emeset (C) | Linid (C) | Pantoprazole (C)									

SOC:Hepatobiliary disorders

202507GLO021576TW	TAIWAN 72 Years Female	**Biliary dilatation (Biliary dilatation)***	Recovered	22-Jul-2025 nk	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	Intravenous use	to	
Concomitant Medication(s):									
202509GLO014621VN	VIET NAM Male	**Biliary obstruction (Biliary obstruction)***	Recovering	12-Sep-2025 nk	AZD2936 TRASTUZUMAB DERUXTECAN	Solution Powder for solution for infusion	Unknown Unknown	to to	Periodic Report Comments. Patient has event biliary obstruction. Action taken with study therapy was Unknown. Investigator Causality: Not Reported, CC: Not Related
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Silimarin (C) | Vihacaps (C)									
202510GLO032631TH	THAILAND 66 Years Female	**Cholangitis (Cholangitis)***	Recovered	25-Oct-2025 nk	AZD2936	Solution	750 milligram q3w Unknown	to	

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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
Concomitant Medication(s):									
202511GLO004770TH	THAILAND 66 Years Female	**Cholangitis acute (Cholangitis acute)***	Not Recovered	03-Nov-2025 nk	AZD2936	Solution	Unknown	to	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	Unknown	to	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) |									
202512GLO018215VN	VIET NAM 60 Years Male	**Drug-induced liver injury (Hy's law case)***	Not Recovered	26-Nov-2025 20 days 7 hrs 10 min	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Unknown	05-NOV-2025 16:50 to	
Concomitant Medication(s): | Entecavir stella (C) | Amlodipin (C)									
SOC:Infections and infestations									
202502GLO020621CN	CHINA 55 Years Female	**Septic shock (Septic shock)*** Febrile neutropenia (Febrile neutropenia)*	Fatal	23-Feb-2025 12 days	AZD2936	Solution	750 milligram q3w Intravenous use	12-FEB-2025 to 12-FEB-2025 1 day	Periodic Report Comments. Periodic comment: Patient experience Septic shock and Febrile Neutropenia . Investigator: Related to study therapy. CCA: Not related to Study therapy.. Action taken : Withdrawn for Both study Drugs
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	248.4 milligram/kilogram q3w Intravenous use	12-FEB-2025 to 12-FEB-2025 1 day	

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Lidocaine (C) | Oxycodone (C) | Sodium phosphate (C) | Drotaverine hydrochloride (C) | Protein (C)									
202503GLO021067US	UNITED STATES 80 Years Female	**Septic shock (Septic shock)***	Recovered	23-Mar-2025 10 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	14-MAR-2025 to 07-AUG-2025 4 months 25 days	Periodic Report Comments. Patient has event Diarrhea. Action taken for TRASTUZUMAB DERUXTECAN, AZD2936 was No change. Investigator Causality: Related, CC: Not Related for TRASTUZUMAB DERUXTECAN, AZD2936.; Periodic Report Comments. Patient has event Septic shock . Action taken for TRASTUZUMAB DERUXTECAN, AZD2936 was No change. Investigator Causality: Related, CC: Not Related for TRASTUZUMAB DERUXTECAN, AZD2936.
Concomitant Medication(s): | AZD2936 (S) | Omeprazole (C) | Pantoprazole (C) | Paroxetine (C) | Vancomycin (C) | Cefepime (C) | Piperacillin (C) | Metronidazole (C) | Ceftriaxone (C)									
202510GLO014587CN	CHINA 45 Years Male	**Biliary tract infection (Biliary tract infection)***	Recovered	30-Sep-2025 1 month 9 days 9 hrs 8 min	CISPLATIN	Infusion Infusion	25 milligram/sq. meter Intravenous use 25 milligram/sq. meter Intravenous use	06-NOV-2025 11:46 to 27-NOV-2025 20 days 12 hrs 14 min 10-OCT-2025 15:34 to 10-OCT-2025 17:31 1 hr 57 min	Patient has event: Event: Biliary tract infection Action taken with study drug: , No Change , Investigator causality: related, Company Causality: Not related

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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
						Infusion	25 milligram/sq. meter	11-SEP-2025 14:35 to 11-SEP-2025 16:09	
							Intravenous use	1 hr 34 min	
						Infusion	25 milligram/sq. meter	17-SEP-2025 12:10 to 17-SEP-2025 14:57	
							Intravenous use	2 hrs 47 min	
						Infusion	25 milligram/sq. meter	20-AUG-2025 14:52 to 20-AUG-2025 15:20	
							Intravenous use	28 min	
						Infusion	25 milligram/sq. meter	29-AUG-2025 12:36 to 29-AUG-2025 15:38	
							Intravenous use	3 hrs 2 min	
						Infusion	25 milligram/sq. meter	29-OCT-2025 13:38 to 29-OCT-2025 15:40	
							Intravenous use	2 hrs 2 min	
						Infusion	25 milligram/sq. meter	29-SEP-2025 17:11 to 29-SEP-2025 18:34	
							Intravenous use	1 hr 23 min	
					GEMCITABINE	Infusion	100 milligram/sq. meter	29-OCT-2025 12:59 to 29-OCT-2025 13:31	

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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
							Unknown		32 min
						Infusion	1000 milligram/sq. meter Unknown	06-NOV-2025 11:18 to 27-NOV-2025 20 days 12 hrs 42 min	
						Infusion	1000 milligram/sq. meter Unknown	10-OCT-2025 15:03 to 10-OCT-2025 15:33 30 min	
						Infusion	1000 milligram/sq. meter Unknown	11-SEP-2025 14:03 to 11-SEP-2025 14:43 40 min	
						Infusion	1000 milligram/sq. meter Unknown	17-SEP-2025 11:34 to 17-SEP-2025 12:09 35 min	
						Infusion	1000 milligram/sq. meter Unknown	20-AUG-2025 14:52 to 20-AUG-2025 15:20 28 min	
						Infusion	1000 milligram/sq. meter Unknown	29-AUG-2025 11:59 to 29-AUG-2025 12:23 24 min	

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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
						Infusion	1000 milligram/sq. meter Unknown		29-SEP-2025 16:23 to 29-SEP-2025 17:10 47 min
Concomitant Medication(s): DURVALUMAB (S) | GEMCITABINE (S) | | Ademetionine (C) | Diammonium glycyrrhizinate (C) | Polyene phosphatidylcholine (C) | Bicyclol (C) | Glutathione (C) | Glycyrrhizin (C) | Ademetionine 1,4-butanedisulfonate (C) | Halometasone (C) | Aprepitant (C) | Dexamethasone (C) | Difenhydramin (C) | Esomeprazole magnesium (C) | Magnesium Isoglycyrrhizinate (C) | Palonosteron bidiphar (C) | Itopride hydrochloride (C) | Pancreatin (C) | Filgrastim (C) | Polyene phosphatidylcholine (C) | Bifid triple viable (C) | Montmorillonite (C) | Phloroglucinol (C) | Saccharomyces boulardii (C) | Azithromycin (C) | Loperamide hydrochloride (C) | Megestrol acetate (C) | Gui pi (C) | Probiotics (C) | Dexamethasone sodium phosphate (C) | Jian wei xiao shi (C) | Palonosetron ascendis (C) | Norfloxacin (C) | Ceftazidime (C) | Celecoxib (C) | Compound amionprine and antipyrine (C) | Ertapenem (C) | Ibuprofen (C) | Yu ping feng (C) | Moxifloxacin hydrochloride (C) | Moxifloxacin (C) | Dexamethasone phosphate (C) | Kang ai (C) | Adenosylmethionine (C) | Diphenhydramine (C)									
202510GLO031590CN	CHINA 62 Years Female	**Sepsis (Pyemia)***	Recovered	28-Oct-2025 1 month 10 days	DURVALUMAB	Infusion Infusion	1500 milligram q3w Intravenous use 1500 milligram q3w Intravenous use	10-OCT-2025 to 10-OCT-2025 1 day 19-SEP-2025 to 19-SEP-2025 1 day	
Concomitant Medication(s): | CISPLATIN (S) | GEMCITABINE (S) | Tramadol hydrochloride (C) | Compound clobetasol propionate (C) | Compound lactic acid (C) | Metoclopramide hydrochloride (C) | Netupitant and palonosetron hydrochloride (C) | Ranitidine hydrochloride (C) | Sodium chloride (C) | Tropisetron hydrochloride (C) | Clopidogrel hydrogen sulphate (C) | Isosorbide mononitrate (C) | Rosuvastatin calcium (C) | Glycerol (C) | Polyene phosphatidylcholine (C) | Compound sodium chloride (C) | Iron Polysaccharide complex (C) | Metoclopramide dihydrochloride (C) | Megestrol acetate (C) | Human erythropoietin (C) | Potassium chloride (C)									
202511GLO007596IN	INDIA 67 Years Male	**Lower respiratory tract infection (Lower respiratory tract infection)*** Proctalgia (Perianal pain)*	Recovered	06-Nov-2025 18 days 12 hrs 35 min	AZD2936 TRASTUZUMAB	Solution Powder for solution for	750 milligram q3w Unknown 5.4 milligram/kilog	18-OCT-2025 11:25 to 18-OCT-2025 14:45 to	Periodic Report Comments. Patient experienced event Lower respiratory tract infection. Investigator states event related to Rilvegostomig and Trastuzumab deruxtecan. CCC-not related.

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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
					DERUXTECAN	infusion	ram q3w Unknown		
Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | Amlong mt (C) | Glycomet (C)									

SOC:Investigations

202508GLO023774CN	CHINA 45 Years Male	**Transaminases increased (Transaminases increased)***	Recovered	26-Aug-2025 7 days	CISPLATIN	Infusion	25 milligram/sq. meter Intravenous use	20-AUG-2025 to 10-OCT-2025 1 month 21 days	
Concomitant Medication(s): DURVALUMAB (S) | GEMCITABINE (S) | | Halometasone (C) | Glutathione (C)									
202509GLO024561CN	CHINA 65 Years Female	**Weight decreased (Loss of weight)***	Not Recovered	25-Sep-2025 2 months 23 days	AZD2936	Solution	750 milligram Intravenous use	03-JUL-2025 to 25-SEP-2025 2 months 23 days	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram Intravenous use	03-JUL-2025 to 25-SEP-2025 2 months 23 days	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) |									

SOC:Metabolism and nutrition disorders

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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
202509GLO002570CN	CHINA 56 Years Female	**Hypokalaemia (Hypokalemia)***	Recovered	27-Aug-2025 nk	AZD2936	Solution	 Unknown	to	Periodic Report Comments. Patient has event Hypokalemia. Action taken with study therapy was No change. Investigator Causality: Related, CC: Not Related
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) |									
202512GLO018451MY	MALAYSIA 38 Years Female	**Hypokalaemia (Hypokalemia)***	Recovering	18-Dec-2025 15 days	RILVEGOSTOMIG	Solution	750 milligram q3w Unknown	04-DEC-2025 to 04-DEC-2025 1 day	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) |									

SOC:Psychiatric disorders

202510GLO002045JP	JAPAN 72 Years Male	**Anorexia nervosa (Anorexia nervosa)***	Not Recovered	26-Jul-2025 4 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion Powder for solution for infusion	4.4 milligram/kilogram Unknown 5.4 milligram/kilogram Unknown	21-AUG-2025 to 10-SEP-2025 21 days 23-JUL-2025 to 23-JUL-2025 1 day	Periodic Report Comments. Patient has event Anorexia. Action taken with study therapy was Dose decreased. Investigator Causality: Related, CC: Not Related
Concomitant Medication(s): | AZD2936 (S) | Denosumab (C) | Lansoprazole (C) | Celecoxib (C)									

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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:Respiratory, thoracic and mediastinal disorders									
202502GLO016244TW	TAIWAN 63 Years Male	**Pneumonitis (Pneumonitis)***	Fatal	19-Feb-2025 3 months	AZD2936	Solution	750 milligram q3w Intravenous use	20-NOV-2024 to 12-FEB-2025 2 months 24 days	Patient experienced suspect pneumonitis. Investigator: related. Company: not related. Patient experienced septic shock. Investigator: not related. Company: not related.;PRC. The Patient Experienced Pneumonitis and Septic Shock. Investigator: Related To TRASTUZUMAB DERUXTECAN And AZD2936 For Event Pneumonitis And Not Related To Septic Shock. Company Physician: Not Related to Study Therapy.
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	11-DEC-2024 to 12-FEB-2025 2 months 2 days	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	20-NOV-2024 to 20-NOV-2024 1 day	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Benzydamine HCL (C) | Loperamide (C) | Dioctahedral smectite (C) | Megestrol (C) | Prochlorperazine (C) | Zinc oxide (C) | Fludiazepam (C) | Levofloxacin (C) | Esomeprazole (C) | Piperacilline (C) | Pantoprazole (C) | Norepinephrine (C) | Teicoplanine bradex (C) | Acetaminophen (C) | Sennoside a+b calcium (C) | Methylprednisolone (C) | Cotrimoxazole (C)									
202509GLO028730MY	MALAYSIA Male	**Pulmonary embolism (Pulmonary embolism)***	Recovered	25-Sep-2025 nk	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	Unknown	to	
Concomitant Medication(s): | Axcel paracetamol (C) | Celebrex (C) | Eliquis (C) | Motilium (C) | Nexium (C) | Zinnat (C)									
202511GLO003281VN	VIET NAM 73 Years Male	**Pulmonary thrombosis (Pulmonary thrombosis)*** Cerebral thrombosis (Thrombosis cerebral)*	Recovering	30-Oct-2025 nk	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	Intravenous use	to	periodic report comment. Investigators causality not reported and MAH causality as not related;Periodic Report Comments. Patient experienced events – cerebral thrombosis,

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

Project ID: D781P

Study ID: D781PC00001

EudraCT No:

Study Design: Not Blinded

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
		Biliary tract infection (Biliary tract infection)*							infection thought to be from the biliary tract and pulmonary thrombosis. Investigator did not report a causality between cerebral thrombosis, infection thought to be from the biliary tract and pulmonary thrombosis and Trastuzumab Deruxtecan. Company physician considers event cerebral thrombosis, infection thought to be from the biliary tract and pulmonary thrombosis not related to Trastuzumab Deruxtecan.
Concomitant Medication(s): | Antivic (C) | Gemapaxane (C)									

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
202504GLO011904CN	CHINA 75 Years Male	**Anaemia (Anemia)***	Recovering	09-Apr-2025 5 months 6 days	AZD0901	Infusion Infusion Infusion Infusion Infusion Infusion Infusion Infusion	Intravenous use Intravenous use Intravenous use Intravenous use Intravenous use Intravenous use Intravenous use 1.8 milligram q3w Intravenous use	04-NOV-2024 to 06-JAN-2025 to 10-MAR-2025 to 14-FEB-2025 to 18-DEC-2024 to 25-JAN-2025 to 26-NOV-2024 to 04-NOV-2024 to 10-MAR-2025 4 months 7 days	Periodic Report Comments. The patient experienced serious severe anemia related to AZD0901 and CAPECITABINE. CCA:Not related.

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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) | CAPECITABINE (S) | L-glutamine and sodium gualenate (C) | Pantoprazole sodium (C) | Sucralfate (C) | Dexamethasone (C) | Enteral (C) | Lidocaine hydrochloride (C) | Lidocaine (C) | Olanzapine (C) | Palonosetron (C) | Esomeprazole sodium (C) | Megestrol acetate (C) | Aprepitant (C) | Compound ketoconazole (C) | Mupirocin (C) | Povidone (C)

SOC:Cardiac disorders

2023A212514	UNITED STATES 79 Years Male	**Acute coronary syndrome (Acute coronary syndrome)***	Recovering	15-Sep-2023 2 weeks 2 days	5-FLUOROURACIL	Infusion	2400 milligram/sq. meter q3w Intravenous use	13-SEP-2024 to	Periodic Report Comment. 78 y. o. male patient event: Acute coronary syndrome. Inv causality Not related to AZD2936, oxaliplatin and leuocovorin. Related to 5-fluorouracil. Comp causality not related to study therapy.
						Infusion	2400 milligram/sq. meter q3w Intravenous use	27-SEP-2023 to	
						Infusion	2400 milligram/sq. meter q3w Intravenous use	30-AUG-2023 to	
						Infusion	400 milligram/sq. meter q3w Intravenous use	13-SEP-2024 to	
						Infusion	400 milligram/sq. meter q3w Intravenous use	27-SEP-2023 to	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	400 milligram/sq. meter q3w Intravenous use	30-AUG-2023 to	
Concomitant Medication(s): | AZD 2936 (S) | LEUCOVORIN (S) | OXALIPLATIN (S) | ASPIRIN (C) | AVODART (C) | FIBER (C) | Vitamin C (C) | ATORVASTIN (C) | Premier protein (C) | IRON (C) | DEXAMETHASONE (C) | PALONOSETRON (C) | Laxative stool softener with senna (C) | Prochlorperazine maleate (C) | ZOFRAN (C) | ATIVAN (C) | HEPARIN (C) | NITROGLYCERIN (C) | Atorvastatin calcium (C)									
202502GLO005618CN	CHINA 69 Years Male	**Myocardial ischaemia (Myocardial ischemia)***	Not Recovered	05-Feb-2025 21 days	AZD2936	Solution	750 milligram q3w Intravenous use	01-APR-2025 to	Patient experienced MYOCARDIAL ISCHEMIA. Inv: event related to AZD2936, not related to Azd0901 and Capecitabine. CCA not related.
						Solution	750 milligram q3w Intravenous use	04-JUN-2025 to	
						Solution	750 milligram q3w Intravenous use	04-SEP-2025 to	
						Solution	750 milligram q3w Intravenous use	10-MAR-2025 to	
						Solution	750 milligram q3w Intravenous use	13-MAY-2025 to	
						Solution	750 milligram q3w Intravenous use	14-AUG-2025 to	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	16-JAN-2025 to 1 day	
						Solution	750 milligram q3w Intravenous use	17-FEB-2025 to	
						Solution	750 milligram q3w Intravenous use	21-APR-2025 to	
						Solution	750 milligram q3w Intravenous use	24-JUL-2025 to	
						Solution	750 milligram q3w Intravenous use	25-JUN-2025 to	
Concomitant Medication(s): | AZD0901 (S) | CAPECITABINE (S) | Moxifloxacin hydrochloride (C) | Ibuprofen (C) | Ondansetron (C) | Mosapride (C) | Palonosetron (C) | Olanzapine (C) | Dexamethasone sodium phosphate (C) | Omeprazole (C) | Indobufen (C) | Rosuvastatin (C) | Nifedipine (C) | Aprepitant (C) | Dexamethasone sodium phosphate (C) | Magnesium Isoglycyrrhizinate (C) | Xiao chai hu (C) | Ondansetron hydrochloride (C) | Pegylated recombinant human granulocyte colony-stimulating factor (C)									
202504GLO011935GB	UNITED KINGDOM 77 Years Male	**Myocarditis (Myocarditis)***	Not Recovered	12-Apr-2025 9 months 4 days	AZD2936	Solution	750 milligram q3w Intravenous use	09-JUL-2024 to 04-FEB-2025 6 months 27 days	patient experienced CTC 3 suspected myocarditis, inv. causality: related- AZD2936, not related to-AZD0901, CCA: Not related.

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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): | AZD0901 (S) | 5-FLUOROURACIL (S) | Amlodipine (C) | Lansoprazole (C) | Ondansetron (C) | Docusate (C) | Bisoprolol (C) | Ramipril (C) | Enoxaparin (C) | Buscopan (C) | Piriton (C) | Hydrocortisone (C)									
SOC:Gastrointestinal disorders									
202412GLO001933GB	UNITED KINGDOM 58 Years Male	**Gastritis (Gastritis)***	Recovered	02-Dec-2024 1 month 25 days	AZD0901	Infusion	Intravenous use	08-OCT-2024 to 08-OCT-2024 1 day	
						Infusion	53 milligram q3w Intravenous use	15-JAN-2025 to 07-FEB-2025 24 days	
						Infusion	53 milligram q3w Intravenous use	29-OCT-2024 to 19-NOV-2024 22 days	
Concomitant Medication(s): AZD2936 (S) | | CAPECITABINE (S) | Cod liver oil (C) | Omeprazole (C) | Cholecalciferol (C) | Metoclopramide (C) | Ondansetron (C) | Normal saline (C) | Dalteparin (C) | Aprepitant (C) | Hyoscine butylbromide (C) | Olanzapine (C) | Dexamethasone (C)									
202501GLO000853TW	TAIWAN 55 Years Male	**Colitis (Colitis)***	Recovered	20-Dec-2024 2 months 6 days	AZD2936	Solution	750 milligram q3w Intravenous use	09-JAN-2025 to 08-MAY-2025 4 months	
						Solution	750 milligram q3w Intravenous use	15-OCT-2024 to 19-DEC-2024 2 months 5 days	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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): | AZD0901 (S) | CAPECITABINE (S) | Dimethicone (C) | Esomeprazole magnesium (C) | Alprazolam (C) | Diphenhydramine HCL (C) | Esomelone (C) | Fosaprepitant dimeglumine (C) | Granisetron (C) | Metoclopramide (C) | Palonosetron (C) | Urea (C) | Loperamide HCL (C) | Micro co-trimoxazole (C) | Prednisolone (C)									
202502GLO001835TW	TAIWAN 55 Years Male	**Gastritis (Gastritis)***	Not Recovered	27-Jan-2025 nk	AZD0901	Infusion	1.8 milligram/kilogram q3w Intravenous use	15-OCT-2024 to 27-MAR-2025 5 months 13 days	
Concomitant Medication(s): | AZD2936 (S) | CAPECITABINE (S) | Dimethicone (C) | Esomeprazole magnesium (C) | Alprazolam (C) | Diphenhydramine HCL (C) | Esomelone (C) | Fosaprepitant Meglumine (C) | Granisetron (C) | Metoclopramide (C) | Palonosetron (C) | Urea (C) | Loperamide (C) | Bisacodyl (C) | Niflec (C) | Dextrose monohydrate (C) | Methylprednisolone sodium succinate (C) | Baktar (C) | Prednisolone (C) | Valganciclovir HCL (C)									
202504GLO004093TW	TAIWAN 76 Years Male	**Ileus (Ileus)***	Recovered	05-Apr-2025 2 months 17 days	AZD0901	Infusion	1.2 milligram/kilogram q3w Intravenous use	24-APR-2025 to 24-APR-2025 1 day	PRC. The patient experienced Abdominal pain. Investigator: related to 5-FLUOROURACIL and Not related to AZD2936 and AZD0901 Company physician: Not related to study therapy.;Periodic Report Comments. Patient experienced the event "ILEUS" . INV related to AZD0901 and not related to AZD2936 & 5-FLUOROURACIL. Company causality not related to AZD2936 & AZD0901 & 5-FLUOROURACIL.
						Infusion	1.8 milligram/kilogram q3w Intravenous use	03-MAR-2025 to 03-MAR-2025 1 day	
						Infusion	1.8 milligram/kilogram q3w Intravenous use	10-FEB-2025 to 10-FEB-2025 1 day	
						Infusion	1.8 milligram/kilogram q3w Intravenous use	20-JAN-2025 to 20-JAN-2025 1 day	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	1.8 milligram/kilogram q3w Intravenous use	24-MAR-2025 to 24-MAR-2025 1 day	
Concomitant Medication(s): AZD2936 (S) | | 5-FLUOROURACIL (S) | Dutasteride (C) | Silodosin (C) | Spersin (C)									
202505GLO002411TW	TAIWAN 76 Years Male	**Ileus (Ileus)***	Recovered	01-May-2025 3 months 12 days	AZD0901	Infusion	1.2 milligram/kilogram Intravenous use	24-APR-2025 to 24-APR-2025 1 day	
						Infusion	1.8 milligram/kilogram Intravenous use	20-JAN-2025 to 24-MAR-2025 2 months 5 days	
Concomitant Medication(s): | AZD2936 (S) | 5-fluorouracil (C) | Dutasteride (C) | Silodosin (C) | Lansoprazole (C)									
202506GLO005432CN	CHINA 68 Years Male	**Abdominal pain upper (Epigastric pain)***	Recovering	03-Jun-2025 6 months 24 days	AZD0901	Infusion	Intravenous use	11-NOV-2024 to 16-MAY-2025 6 months 6 days	Periodic Report Comments. Patient experienced event Epigastric pain. Action taken with study therapy was Temporarily withdrawn. Investigator Causality: Related, CC: Related for AZD0901.
						Infusion	Intravenous use	24-JUN-2025 to	
Concomitant Medication(s): | AZD2936 (S) | CAPECITABINE (S) | Dexamethasone (C) | Bicyclol (C) | L-glutamine and sodium gualenate (C) | Aprepitant (C) | Esomeprazole sodium (C) | Olanzapine (C) | Palonosetron (C) | Enteral (C) | Adenosylmethionine (C) | Esomeprazole (C)									

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
2023A065713	KOREA, REPUBLIC OF 59 Years Male	**Death (Unknown cause of death)***	Fatal	15-Mar-2023 nk	CAPECITABINE	Tablet	1000 milligram/sq. meter bid Oral use	27-FEB-2023 10:55 to 01-MAR-2023 1 day 13 hrs 5 min	Periodic Report Comment. Patient Ex: Unknown cause of death. Investigator causality related to Medi5752, Oxaliplatin and Capecitabine.
					MEDI5752	Infusion	750 milligram q3w Intravenous use	27-FEB-2023 10:55 to 27-FEB-2023 10:55	
					OXALIPLATIN	Infusion	130 milligram/sq. meter q3w Intravenous use	27-FEB-2023 10:55 to 27-FEB-2023 10:55	
Concomitant Medication(s): MEDI5752 (S) | | OXALIPLATIN (S) | Aloxi (C) | Dexamethasone (C) | Fotagel (C) | Peniramin (C) | Tagamet (C) | Combif ar (C) | Macperan (C) | Lopmin (C)									
2024A183962	SPAIN 81 Years Female	**Pyrexia (Fever)***	Recovered	08-Aug-2024 5 months 13 days	MEDI5752	Infusion	250 milligram q3w Intravenous use	11-JUL-2024 to 01-AUG-2024 22 days	Periodic Report Comment. Patient experienced thyroid disorder,Inves: related to study therapy
						Infusion	500 milligram q3w Intravenous use	27-FEB-2024 to 14-MAY-2024 2 months 18 days	
Concomitant Medication(s): | OXALIPLATIN (S) | 5-FLUOROURACIL (S) | LEUCOVORIN CALCIUM (S) | Amitriptilin (C) | Levothyroxine (C) | Dexamethasone (C) | Prednisone (C) | Atorvastatin (C) | Ezetimibe (C) | Omeprazole (C) | Dexchlorpheniramine (C) | Granisetron (C)									

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
202502GLO016226CN	CHINA 67 Years Male	**Fatigue (Fatigue aggravated)***	Recovering	20-Jan-2025 2 months 10 days	AZD0901	Infusion	1.2 milligram/kilogram q3w Intravenous use	04-MAR-2025 to 16-MAY-2025 2 months 13 days	
						Infusion	97 milligram/kilogram q3w Intravenous use	04-MAR-2025 to 16-MAY-2025 2 months 13 days	
						Infusion	97 milligram/kilogram q3w Intravenous use	11-NOV-2024 to 07-FEB-2025 2 months 28 days	
Concomitant Medication(s): | AZD2936 (S) | CAPECITABINE (S) | Magnesium Isoglycyrrhizinate (C) | Glycerine enema (C) | Roxatidine (C) | Esomeprazole sodium (C) | Vitamin b6 (C) | Dexamethasone (C)									
202502GLO024850CN	CHINA 54 Years Male	**Asthenia (Asthenia)***	Recovered	22-Feb-2025 2 days	AZD0901	Infusion	Intravenous use	07-APR-2025 to	Periodic Report Comments. Patient experienced ASTHENIA, Inv, not related to AZD2936, and not related to AZD0901: the sponsor did not find evidence to suggest a causal relationship between the event and the study therapy.
						Infusion	Intravenous use	09-JUL-2025 to	
						Infusion	Intravenous use	12-JUN-2025 to	
						Infusion	Intravenous use	17-MAR-2025 to	
						Infusion	Intravenous use	21-FEB-2025 to	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	21-MAY-2025 to	
						Infusion	Intravenous use	28-APR-2025 to	
						Infusion	2.2 milligram/kilogram q3w Intravenous use	21-FEB-2025 to 28-APR-2025 2 months 8 days	
					AZD2936	Solution	750 milligram q3w Intravenous use	07-APR-2025 to 22 days	
						Solution	750 milligram q3w Intravenous use	09-JUL-2025 to	
						Solution	750 milligram q3w Intravenous use	12-JUN-2025 to	
						Solution	750 milligram q3w Intravenous use	17-MAR-2025 to 1 day	
						Solution	750 milligram q3w Intravenous use	21-FEB-2025 to 1 day	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	21-MAY-2025 to	
						Solution	750 milligram q3w Intravenous use	28-APR-2025 to	

Concomitant Medication(s): | AZD2936 (S) | CAPECITABINE (S) | Glycerol (C) | Esomeprazole magnesium (C) | Albumen (C) | Ensure (C) | Vitamin B1 (C) | Vitamin b2 (C) | Vitamin b6 (C) | Vitamin C (C) | Aprepitant (C) | Olanzapine (C) | Potassium chloride (C) | Verapamil hydrochloride (C) | Ibuprofen (C) | Dexamethasone (C) | Ilaprazole sodium (C)

SOC:Hepatobiliary disorders

2023A091950	KOREA, REPUBLIC OF 52 Years Female	**Drug-induced liver injury (Hy's law case)***	Recovered	05-Apr-2023 2 months 5 days	MEDI5752	Infusion	750 milligram q3w Intravenous use	01-FEB-2023 to 01-FEB-2023 1 day	Periodic Report Comment. Patient experienced HY'S LAW, Inv, Related to MEDI5752, CAPECITABINE and OXALIPLATIN, and not related to STUDY PROCEDURE. Comp: Related to MEDI5752, CAPECITABINE and OXALIPLATIN, and not related to STUDY PROCEDURE.; Periodic Report Comments. Patient experienced HY'S LAW, Inv, Related to MEDI5752, CAPECITABINE and OXALIPLATIN, and not related to STUDY PROCEDURE. Comp: Related to MEDI5752, CAPECITABINE and OXALIPLATIN, and not related to STUDY PROCEDURE.
						Infusion	750 milligram q3w Intravenous use	06-APR-2023 to 06-APR-2023 1 day	
						Infusion	750 milligram q3w Intravenous use	15-MAR-2023 to 15-MAR-2023 1 day	
						Infusion	750 milligram q3w Intravenous use	23-FEB-2023 to 23-FEB-2023 1 day	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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) | Oxaliplatin (S) | CAMOSTATUM (C) | GRANISEL (C) | GENTAMICIN (C) | METRONIDAZOLE (C) | CAFSOL (C) | Camostat (C) | Motilitone (C) | Rosuvastatin (C) | Dexamethasone (C) | Palonosetron (C) | Chlorpheniramine (C) | Epinephrine (C) | Hydrocortisone (C) | Lorazepam (C) | Udca (C) | Godex (C) | Methylprednisolone (C) | Metoclopramide (C) | L-Ornithine (C) | Pantoprazole (C) | Albumin 20 trcs (C) | Furosemide (C) | Almagel-f (C) | Rabeprazole (C) | Magnesium (C) | Lactose (C) | Silymarin (C) | Mycophenolate mofetil (C) | Sulfamethoxazole (C) | Tazoferan (C) | Fresh frozen plasma (C) | Atropine (C) | Famotidine (C) | Kalimate (C) | Calcium gluconate (C) | Phosten (C) | Esomeprazole (C)									
2023A144205	TAIWAN 59 Years Male	**Drug-induced liver injury (Drug-induced hepatitis)*** Cholecystitis (Cholecystitis)*	Recovered	21-Jun-2023 1 month 13 days	MEDI5752	Infusion	750 milligram q3w Intravenous use	09-MAY-2023 to 11-JUL-2023 6 weeks 1 day	Periodic Report Comment. patient experience serious hy's law (hepatitis) and cholecystitis.. Inv related to study drug.
Concomitant Medication(s): | 5-FLUOROURACIL (S) | CAPECITABINE (S) | OXALIPLATIN (S) | LEUCOVORIN CALCIUM (S) | Losartan (C) | Xanax (C) | Ulcertin (C) | Aloxi (C) | Sennapur (C)									
2023A161555	CHINA 61 Years Male	**Drug-induced liver injury (Hy's law case)***	Not Recovered	13-Jul-2023 2 months 1 day 23 hrs 44 min	5-FLUOROURACIL	Infusion Intravenous use Infusion Intravenous use Infusion Intravenous use	1000 milligram/sq. meter q2w 1000 milligram/sq. meter q2w 1200 milligram/sq. meter q2w	08-JUN-2023 20:54 to 10-JUN-2023 18:30 1 day 54 hr 23-AUG-2023 23:10 to 25-AUG-2023 21:00 2 days 11-MAY-2023 00:26 to 11-MAY-2023 22:29 22 hrs 3 min 22-JUN-2023 18:10 to 24-JUN-2023 15:50	Periodic Report Comment. Pt exp Hy's law and macule. Inv: events related to MEDI5752. Comp: Hy's law related to MEDI5752.

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use	1 day 54 hrs	
						Infusion	1200 milligram/sq. meter q2w	24-MAY-2023 21: 58 to 26-MAY-2023 19:43	
							Intravenous use	1 day 55 hr	
						Infusion	320 milligram/sq. meter q2w	08-JUN-2023 20: 45 to 08-JUN-2023 20:53	
							Intravenous use	8 min	
						Infusion	320 milligram/sq. meter q2w	23-AUG-2023 23: 01 to 23-AUG-2023 23:09	
							Intravenous use	8 min	
						Infusion	400 milligram/sq. meter q2w	11-MAY-2023 00: 16 to 11-MAY-2023 00:25	
							Intravenous use	9 min	
						Infusion	400 milligram/sq. meter q2w	22-JUN-2023 17: 50 to 22-JUN-2023 17:58	
							Intravenous use	8 min	
						Infusion	400 milligram/sq. meter q2w	24-MAY-2023 21: 49 to 24-MAY-2023 21:56	
							Intravenous use	7 min	

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

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EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
					OXALIPLATIN	Infusion	67 milligram/sq. meter q2w	08-JUN-2023 17:11 to 08-JUN-2023 19:02	
							Intravenous use	1 hr 51 min	
						Infusion	70 milligram/sq. meter q2w	07-SEP-2023 18:03 to 07-SEP-2023 21:00	
							Intravenous use	2 hrs 57 min	
						Infusion	70 milligram/sq. meter q2w	23-AUG-2023 18:12 to 23-AUG-2023 21:09	
							Intravenous use	3 hr 4 min	
						Infusion	85 milligram/sq. meter q2w	10-MAY-2023 19:20 to 10-MAY-2023 22:26	
							Intravenous use	3 hrs 16 min	
						Infusion	85 milligram/sq. meter q2w	22-JUN-2023 13:45 to 22-JUN-2023 15:51	
							Intravenous use	2 hrs 6 min	
						Infusion	85 milligram/sq. meter q2w	24-MAY-2023 17:06 to 24-MAY-2023 19:51	
							Intravenous use	2 hrs 11 min	
					LEUCOVORIN CALCIUM	Infusion	320 milligram/sq. meter q2w	08-JUN-2023 19:23 to 08-JUN-2023 20:36	

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

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EudraCT No: 2024-510977-27-00

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Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use		1 hr 13 min
						Infusion	320 milligram/sq. meter q2w Intravenous use		23-AUG-2023 21:30 to 23-AUG-2023 22:49 1 hr 19 min
						Infusion	400 milligram/sq. meter q2w Intravenous use		10-MAY-2023 22:06 to 11-MAY-2023 00:15 2 hr 9 min
						Infusion	400 milligram/sq. meter q2w Intravenous use		22-JUN-2023 16:09 to 22-JUN-2023 17:42 1 hr 33 min
						Infusion	400 milligram/sq. meter q2w Intravenous use		24-MAY-2023 20:16 to 24-MAY-2023 21:32 1 hr 16 min
		Drug-induced liver injury (Hy's law case)* Macule (Macule)*	Not Recovered	13-Jul-2023 2 months 2 days 7 hrs 8 min	MEDI5752	Infusion	750 milligram q3w Intravenous use		10-MAY-2023 16:52 to 22-JUN-2023 13:02 1 month 11 days 20 hrs 10 min
Concomitant Medication(s): MEDI5752 (S) | OXALIPLATIN (S) | | LEUCOVORIN CALCIUM (S) | TATHION (C) | Magnesium Isoglycyrrhizinate (C) | Polyene phosphatidylcholine (C)									
2024A070978	TAIWAN	**Hepatitis acute (Hepatitis acute)***	Recovered	22-Mar-2024 16 days	MEDI5752	Infusion	500 milligram q3w	07-MAR-2024 to 07-MAR-2024	Periodic Report Comment. Patient received Medi5752, Capecitabine and Oxaliplatin,

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
	76 Years Male	Stevens-Johnson syndrome (Stevens-Johnson syndrome)*					Intravenous use	1 day	Patient exp:acute hepatitis and suspect early steven's-johnson syndrome. Inv: Related with Medi5752. Company: Not related. Seriousness: Yes.
Concomitant Medication(s): | CAPECITABINE (S) | OXALIPLATIN (S) | Acetaminophen (C) | Esomeprazole (C) | Megestrol (C) | Mosapride citrate (C) | METOCLOPRAMIDE (C) | Simethicone (C) | Spironolactone (C) | Dexamethasone phosphate (C) | FOSAPREPITANT (C) | PALONOSETRON (C) | NACL (C) | BETAMETHASONE (C) | CEFTRIAXONE (C) | DEXCHLORPHENIRAMINE (C) | Diphenhydramine HCL (C) | LEVOCETIRIZINE (C) | METHYLPREDNISOLONE (C) | Tetracycline HCL (C) | Esomeprazole (C) | NaCl (C) | Betamethasone (C) | Dexchlorpheniramine maleate (C) | Tetracycline HCL (C) | Etanercept (C) | Neomycin (C) | Silymarin (C) | Fluorometholone (C) | Fresh frozen plasma (C) | Fexofenadine (C) | Zinc gluconate (C) | Albumin 20 trcs (C) | Bisacodyl (C) | Furosemide (C) | Amino acid (C) | Lactulose (C) | Mycophenolate mofetil (C) | Acetylcysteine (C) | Ambroxol HCL (C) | Benzydamine HCL (C) | Piperacillin (C) | Quetiapine (C) | Haloperidol (C) | Cefepime (C) | Tranexamic acid (C) | Vitamin K1 (C) | Amino acid (C) | Meropenem trihydrate (C) | Morphine HCL (C) | Teicoplanin (C) | Ketorolac tromethamine (C)									
2024A075274	KOREA, REPUBLIC OF 62 Years Female	**Drug-induced liver injury (Hy's law case)***	Recovered	26-Mar-2024 5 weeks	CAPECITABINE	Tablet	1000 milligram/sq. meter bid Intravenous use	13-MAR-2024 to 25-MAR-2024 1 week 6 days	Periodic Report Comment. Female pt experienced serious event related to study drug Volrustomig, not related to Capecitabine, Oxaliplatin, CCA: related
						Tablet	1000 milligram/sq. meter bid Intravenous use	20-FEB-2024 to 05-MAR-2024 2 weeks 1 day	
					OXALIPLATIN	Infusion	130 milligram/sq. meter q3w Intravenous use	13-MAR-2024 to 13-MAR-2024 1 day	
						Infusion	130 milligram/sq. meter q3w Intravenous use	20-FEB-2024 to 20-FEB-2024 1 day	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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): | MEDI5752 (S) | OXALIPLATIN (S) | ADOCHLORIN (C) | ALOXI (C) | DEXAMETHASONE (C) | KLENZO (C) | LOPAINE (C) | MACPERAN (C) | PENIRAMIN (C) | PORTALAC (C) | Sodium bicarbonate (C) | TAGENON (C) | VALSAONE (C) | DULACKHAN (C) | ENCOVER (C) | MEGACE (C) | AKYNZEO (C) | LYRICA (C) | NORZYME (C) | COMBIFLEX (C) | Combiflex peri (C) | RhoGAM Ultra Filtered (C) | GODEX (C) | HEPA (C) | MEDISOLU (C) | NACL (C) | NEXIUM (C) | URSA (C) | Morphine sulfate (C) | Stilnox cr (C) | Viti c (C) | K CAB (C) | NORVASC (C) | ROMIPLATE (C) | MOTILITONE (C) | DENOGAN (C) | SEPTRIN (C) | ALMAGEL (C) | GAMMA (C) | CYNACTEN (C) | PETHIDINE (C) | SOLONDO (C) | PALOSET (C) | KLENZ (C)									
2024A102251	TAIWAN 77 Years Male	**Hepatitis acute (Hepatitis acute)***	Not Recovered	15-Apr-2024 1 month 9 days	MEDI5752	Infusion Infusion	500 milligram q3w Intravenous use 500 milligram q3w Intravenous use	07-MAR-2024 to 29-MAR-2024 to	Periodic Report Comment. Patient experienced acute hepatitis and weakness. Inves: ae acute hepatitis related to Medi5752, not related to Capecitabine and Oxaliplatin. CCA not related.
Concomitant Medication(s): | CAPECITABINE (S) | OXALIPLATIN (S) | Acetaminophen (C) | Acetylsalicylic acid (C) | Bc megestrol (C) | Metoclopramide (C) | Spironolactone (C) | Adco betamethasone (C) | Human albumin 20% behring (C) | Aig esomeprazole (C) | Ag quetiapine (C) | Haloperidol (C) | Meropenem trihydrate (C) | Diamorphine HCL (C) | Berhgen (C) | Alcaftadine (C) | Megestrol (C) | Mosapride citrate (C) | Simethicone (C) | Fosaprepitant (C) | NaCl (C) | Tranexamic acid (C) | Morphine HCL (C) | Ketorolac tromethamine (C) | Esomeprazole (C) | Betamethasone benzoate | Gentamicin sulfate (C) | Dexchlorpheniramine maleate (C) | Diphenhydramine HCL (C) | Levocetirizine (C) | Methylprednisolone (C) | Tetracycline HCL (C) | Etanercept (C) | Bacitracin zinc | Neomycin sulfate | Tyrothricin (C) | Silymarin (C) | Fluorometholone (C) | Albumin (C) | Calcium polystyrene sulfonate (C) | Fexofenadine (C) | Zinc gluconate (C)									
2024A106292	SPAIN 54 Years Male	**Cholecystitis (Cholecystitis)***	Recovered	30-Apr-2024 12 weeks	LEUCOVORIN	Infusion Infusion Infusion	q3w Intravenous use q3w Intravenous use 300 milligram/sq. meter qw	05-MAR-2024 to 05-MAR-2024 1 day 20-MAY-2024 to 16-APR-2024 to 30-APR-2024	Periodic Report Comment. Patient experienced cholecystitis., Inves: related to study therapy, comp causality: not related to study therapy; Periodic Report Comments. Patient has event: Event: Cholecystitis, Action taken with study drug: Withdrawn, Investigator causality: related, Company Causality: Not related

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use	15 days	
						Infusion	400 milligram/sq. meter qw Intravenous use	06-FEB-2024 to 26-MAR-2024 1 month 21 days	
					MEDI5752	Infusion	qw Intravenous use	20-MAY-2024 to	
						Infusion	qw Intravenous use	27-FEB-2024 to 27-FEB-2024 1 day	
						Infusion	500 milligram qw Intravenous use	06-FEB-2024 to 30-APR-2024 2 months 25 days	
					OXALIPLATIN	Infusion	Intravenous use	05-MAR-2024 to 05-MAR-2024 1 day	
						Infusion	Intravenous use	20-MAY-2024 to	
						Infusion	70 milligram/sq. meter qw Intravenous use	16-APR-2024 to 30-APR-2024 15 days	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	85 milligram/sq. meter qw Intravenous use	06-FEB-2024 to 20-FEB-2024 15 days	
						Infusion	85 milligram/sq. meter qw Intravenous use	13-MAR-2024 to 26-MAR-2024 14 days	
Concomitant Medication(s): MEDI5752 (S) | OXALIPLATIN (S) | 5-FLUOROURACIL (S) | | Aig esomeprazole (C) | Dexamethasone (C) | Granisetron (C) | Zarzio (C) | Fortasec (C)									
2024A117437	SPAIN 72 Years Female	**Hepatitis acute (Hepatitis acute)***	Recovered	13-May-2024 10 weeks 6 days	MEDI5752	Infusion	500 milligram qw Intravenous use	07-MAY-2024 to	Periodic Report Comment. Patient experienced ACUTE HEPATITIS event, Inves: related to study therapy:CCA: Not related.;Patient experienced ACUTE HEPATITIS event, Investigator related, and company Not related.
						Infusion	500 milligram qw Intravenous use	09-APR-2024 to	
						Infusion	500 milligram qw Intravenous use	14-MAY-2024 to	
						Infusion	500 milligram qw Intravenous use	19-MAR-2024 to	
						Infusion	500 milligram qw Intravenous use	27-FEB-2024 to	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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): | 5-FLUOROURACIL (S) | LEUCOVORIN (S) | OXALIPLATIN (S) | AMITRIPTILINA DASANTI (C) | LEVOTHYROXINE (C) | ADCO-OMEPRAZOLE (C) | DEXAMETHASONE (C) | Dexchlorpheniramine (C) | Granisetron aft (C) | PREDNISONE (C) | Septrin (C)									
2024A135966	TAIWAN 70 Years Male	**Drug-induced liver injury (Hy's law case)***	Recovered	11-Jun-2024 15 weeks	5-FLUOROURACIL	Infusion	1600 milligram/sq. meter qw Intravenous use	02-OCT-2024 to 04-OCT-2024 3 days	Periodic Report Comment. Patient experienced hy's law. Inves: related to MEDI5752 , study procedure and not related to 5-fluorouracil, Leucovorin and Oxaliplatin. CCA: related to study therapy and study procedure.
						Infusion	2000 milligram/sq. meter qw Intravenous use	07-AUG-2024 to 02-OCT-2024 1 month 26 days	
						Infusion	2000 milligram/sq. meter qw Intravenous use	08-MAY-2024 to	
						Infusion	2000 milligram/sq. meter qw Intravenous use	10-APR-2024 to 10-APR-2024 1 day	
						Infusion	2000 milligram/sq. meter qw Intravenous use	27-MAY-2024 to	
						Infusion	2400 milligram/sq. meter qw Intravenous use	13-MAR-2024 to 13-MAR-2024 1 day	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	2400 milligram/sq. meter qw Intravenous use	27-FEB-2024 to 27-FEB-2024 1 day	
						Infusion	300 milligram/sq. meter qw Intravenous use	08-MAY-2024 to 08-MAY-2024 1 day	
						Infusion	300 milligram/sq. meter qw Intravenous use	10-APR-2024 to 10-APR-2024 1 day	
						Infusion	300 milligram/sq. meter qw Intravenous use	15-JUL-2024 to	
						Infusion	300 milligram/sq. meter qw Intravenous use	27-MAY-2024 to	
						Infusion	400 milligram/sq. meter qw Intravenous use	13-MAR-2024 to 13-MAR-2024 1 day	
						Infusion	400 milligram/sq. meter qw	27-FEB-2024 to	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use		
					LEUCOVORIN	Infusion	300 milligram/sq. meter qw Intravenous use	02-OCT-2024 to 25-DEC-2024 2 months 24 days	
						Infusion	300 milligram/sq. meter qw Intravenous use	07-AUG-2024 to 07-AUG-2024 1 day	
						Infusion	300 milligram/sq. meter qw Intravenous use	08-MAY-2024 to 08-MAY-2024 1 day	
						Infusion	300 milligram/sq. meter qw Intravenous use	10-APR-2024 to 10-APR-2024 1 day	
						Infusion	300 milligram/sq. meter qw Intravenous use	15-JUN-2024 to 15-JUN-2024 1 day	
						Infusion	300 milligram/sq. meter qw Intravenous use	27-MAY-2024 to 27-MAY-2024 1 day	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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/sq. meter qw Intravenous use	28-AUG-2024 to 28-AUG-2024 1 day	
						Infusion	400 milligram/sq. meter qw Intravenous use	13-MAR-2024 to 13-MAR-2024 1 day	
						Infusion	400 milligram/sq. meter qw Intravenous use	27-FEB-2024 to 27-FEB-2024 1 day	
					OXALIPLATIN	Infusion	70 milligram/sq. meter qw Intravenous use	07-AUG-2024 to 25-DEC-2024 4 months 19 days	
						Infusion	70 milligram/sq. meter qw Intravenous use	08-MAY-2024 to 08-MAY-2024 1 day	
						Infusion	70 milligram/sq. meter qw Intravenous use	10-APR-2024 to 10-APR-2024 1 day	
						Infusion	70 milligram/sq. meter qw	15-JUL-2024 to 15-JUL-2024 1 day	

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use		
						Infusion	70 milligram/sq. meter qw Intravenous use	27-MAY-2024 to 27-MAY-2024 1 day	
						Infusion	85 milligram/sq. meter qw Intravenous use	13-MAR-2024 to 13-MAR-2024 1 day	
						Infusion	85 milligram/sq. meter qw Intravenous use	27-FEB-2024 to	
Concomitant Medication(s): MEDI5752 (S) | OXALIPLATIN (S) | | LEUCOVORIN (S) | Ag bisoprolol (C) | CLOPIDOGREL (C) | SENNOSIDES (C) | Diphenhydramine HCL (C) | PALONOSETRON (C) | Megestrol acetate (C) | NYSTATIN (C) | Adenosine (C) | LEVOCETIRIZINE (C) | METHYLPREDNISOLONE (C) | Chlorpromazine HCL (C) | CEREGULART (C) | Mycophenolate mofetil (C) | SULAMPI (C) | BAKTAR (C) | PREDNISOLONE (C) | LOPERAMIDE (C)									
SOC:Immune system disorders									
2023A194629	KOREA, REPUBLIC OF 52 Years Male	**Cytokine release syndrome (Cytokine release syndrome)***	Recovered	23-Aug-2023 6 months 2 days	MEDI5752	Infusion	500 milligram q3w Intravenous use	23-AUG-2023 to 21-FEB-2024 5 months 30 days	Periodic Report Comment. the patient experienced cytokin release syndrome,Inv.related to MEDI5752 .
						Infusion	750 milligram q3w	22-FEB-2023 to 12-JUL-2023	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use	4 months 21 days	

Concomitant Medication(s): CAPECITABINE (S) | | OXALIPLATIN (S) | AMOSARTAN (C) | PITAVAS (C) | HUMEGA (C) | MACPERAN (C) | BAMBUSCOT (C) | Paramacet SEMI (C) | CETIZAL (C) | LYRICA (C) | IRCODON (C) | SOLONDO (C) | LACIDOFIL (C) | DENOGAN (C) | MGO (C) | GLUPA (C) | ZEMIGLO (C) | TRESIBA (C) | Apetrol es (C) | ACETPHEN PREMIX (C) | ACTEMRA (C) | Chlorpheniramine maleate (C) | METHYSOL (C) | NUTRIFLEX (C) | NORPIN (C)

SOC:Infections and infestations

2023A096198	TAIWAN 57 Years Female	**Sepsis (Sepsis NOS)***	Recovered	21-Apr-2023 12 weeks 2 days	MEDI5752	Infusion	750 milligram q3w Intravenous use	09-MAR-2023 to	Periodic Report Comment. Patient experienced Sepsis, Investigator related to MEDI5752, Oxaliplatin and not related to 5-Fluorouracil, Leucovorin.Az company: not related
						Infusion	750 milligram q3w Intravenous use	12-MAY-2023 to 12-MAY-2023 1 day	
						Infusion	750 milligram q3w Intravenous use	16-FEB-2023 to	
						Infusion	750 milligram q3w Intravenous use	21-APR-2023 to 12-MAY-2023 22 days	
						Infusion	750 milligram q3w Intravenous use	25-JAN-2023 to	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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 q3w Intravenous use	30-MAR-2023 to	
					OXALIPLATIN	Infusion	85 milligram/sq. meter q2w Intravenous use	07-APR-2023 to	
						Infusion	85 milligram/sq. meter q2w Intravenous use	08-FEB-2023 to	
						Infusion	85 milligram/sq. meter q2w Intravenous use	09-MAR-2023 to	
						Infusion	85 milligram/sq. meter q2w Intravenous use	21-APR-2023 to 05-MAY-2023 15 days	
						Infusion	85 milligram/sq. meter q2w Intravenous use	23-FEB-2023 to	
						Infusion	85 milligram/sq. meter q2w Intravenous use	23-MAR-2023 to	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	85 milligram/sq. meter q2w Intravenous use	25-JAN-2023 to	
Concomitant Medication(s): | OXALIPLATIN (S) | 5-FLUOROURACIL (S) | LEUCOVORIN (S) | Alprazolam (C) | Triazolam (C) | Venlafaxine (C) | Furosemide (C) | Tramadol (C) | Dexlansoprazole (C) | Piperacillin (C) | Spironolactone (C) | Sennosides a&b (C) | Tranexamic acid (C) | Acetaminophen (C) | Ceftazidime (C) | Acetylcysteine (C) | Potassium chloride (C)									
2023A203458	KOREA, REPUBLIC OF 55 Years Female	**Pneumonia klebsiella (Klebsiella pneumonia)***	Recovered	02-Sep-2023 nk	OXALIPLATIN	Infusion	85 milligram/sq. meter qw Intravenous use	02-AUG-2023 to	Periodic Report Comment. The patient experienced klebsiella pneumonia. . Inv:related to Oxaliplatin, 5-fluorouracil,CCA not related to IP.
						Infusion	85 milligram/sq. meter qw Intravenous use	05-JUL-2023 to	
						Infusion	85 milligram/sq. meter qw Intravenous use	07-JUN-2023 to	
						Infusion	85 milligram/sq. meter qw Intravenous use	10-MAY-2023 to	
						Infusion	85 milligram/sq. meter qw Intravenous use	19-APR-2023 to	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	85 milligram/sq. meter qw Intravenous use	19-JUL-2023 to	
						Infusion	85 milligram/sq. meter qw Intravenous use	20-SEP-2023 to	
						Infusion	85 milligram/sq. meter qw Intravenous use	21-JUN-2023 to	
						Infusion	85 milligram/sq. meter qw Intravenous use	22-MAR-2023 to	
						Infusion	85 milligram/sq. meter qw Intravenous use	24-MAY-2023 to	
						Infusion	85 milligram/sq. meter qw Intravenous use	30-AUG-2023 to	
						Infusion	85 milligram/sq. meter qw Intravenous use	30-AUG-2023 to	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use		
					5-FLUOROURACIL	Infusion	2000 milligram/sq. meter qw	30-AUG-2023 to	
							Intravenous use		
						Infusion	2400 milligram/sq. meter qw	05-JUL-2023 to	
							Intravenous use		
						Infusion	2400 milligram/sq. meter qw	07-JUN-2023 to	
							Intravenous use		
						Infusion	2400 milligram/sq. meter qw	10-MAY-2023 to	
							Intravenous use		
						Infusion	2400 milligram/sq. meter qw	19-APR-2023 to	
							Intravenous use		
						Infusion	2400 milligram/sq. meter qw	19-JUL-2023 to	
							Intravenous use		

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	2400 milligram/sq. meter qw Intravenous use	21-JUN-2023 to	
						Infusion	2400 milligram/sq. meter qw Intravenous use	22-MAR-2023 to	
						Infusion	2400 milligram/sq. meter qw Intravenous use	24-MAY-2023 to	
						Infusion	400 milligram/sq. meter qw Intravenous use	05-JUL-2023 to	
						Infusion	400 milligram/sq. meter qw Intravenous use	07-JUN-2023 to	
						Infusion	400 milligram/sq. meter qw Intravenous use	10-MAY-2023 to	
						Infusion	400 milligram/sq. meter qw	19-APR-2023 to	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use		
						Infusion	400 milligram/sq. meter qw	19-JUL-2023 to	
							Intravenous use		
						Infusion	400 milligram/sq. meter qw	21-JUN-2023 to	
							Intravenous use		
						Infusion	400 milligram/sq. meter qw	22-MAR-2023 to	
							Intravenous use		
						Infusion	400 milligram/sq. meter qw	24-MAY-2023 to	
							Intravenous use		
						Infusion	400 milligram/sq. meter qw	02-AUG-2023 to	
							Intravenous use		
						Infusion	400 milligram/sq. meter qw	20-SEP-2023 to	
							Intravenous use		

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	400 milligram/sq. meter qw Intravenous use	30-AUG-2023 to	
Concomitant Medication(s): 5-FLUOROURACIL (S) | AZD 2936 (S) | LEUCOVORIN (S) | | CAROL-F (C) | MACPERAN (C) | MAG-OX (C) | Sama Tantum gargle (C) | LEUCOSTIM (C) | ITOMED (C) | DULACKHAN EASY (C) | GASTER (C) | Phazyme complex (C) | GRASIN (C) | LYRICA (C) | AMBROXOL (C) | CEFTRIAXONE (C) | KETORAC (C)									
202409GLO009447CN	CHINA 64 Years Male	**Cystitis (Cystitis)***	Not Recovered	17-Sep-2024 3 months 26 days 7 hrs 24 min	AZD2936	Solution	750 milligram q3w Intravenous use	21-MAY-2024 16: 36 to 14-NOV-2025 1 year 5 months 23 days 7 hrs 24 min	Periodic Report Comments. The patient experienced urethralgia and Cystitis. Investigator causality related for suspect AZD2936 and not related for AZD0901,CAPECITABINE. CCA not related.
Concomitant Medication(s): | CAPECITABINE (S) | AZD0901 (S) | Insulin aspart (C) | Insulin degludec (C) | Ilaprazole sodium (C) | Palonosetron hydrochloride (C) | Dexamethasone sodium phosphate (C) | Diphenhydramine hydrochloride (C) | Dexamethasone acetate (C) | Albumin (C) | Glycerol (C) | Esomeprazole magnesium (C) | Tramadol hydrochloride (C) | Olanzapine (C) | Ceftriaxone sodium (C) | Phloroglucinol (C) | Daglizin (C) | Lidocaine hydrochloride (C) | Aprepitant (C) | Raceanisodamine hydrochloride (C) | Ondansetron hydrochloride (C) | Amino acid (C) | Glucose (C) | Granisetron hydrochloride (C) | Metoclopramide hydrochloride (C) | Omeprazole sodium (C) | Potassium chloride (C) | Vitamin b6 (C) | Vitamin C (C) | Sodium chloride (C) | Lactulose (C) | Pantoprazole sodium (C) | Water-soluble vitamin (C) | Magnesium Isoglycyrrhizinate (C) | Glycerine (C) | Mosapride citrate (C) | Ilaprazole (C)									
202504GLO001790JP	JAPAN 74 Years Male	**Pneumonia (Pneumonia)***	Fatal	31-Mar-2025 19 days	CAPECITABINE	Tablet	1000 milligram/sq. meter qd Intravenous use	13-MAR-2025 to 13-MAR-2025 1 day	periodic report comment. patient experienced PNEUMONIA: investigator: related to Azd0901, Capecitabine, not related to Azd2936, cca: not related to Azd2936, Azd0901, Capecitabine.;PRC. patient experienced PNEUMONIA: investigator: related to Azd0901, Capecitabine, not related to Azd2936, cca: not
						Tablet	1000 milligram/sq. meter qd Intravenous use	14-MAR-2025 to 21-MAR-2025 8 days	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	1000 milligram/sq. meter qd Intravenous use	22-MAR-2025 to 22-MAR-2025 1 day	related to Azd2936, Azd0901, Capecitabine.;periodic report comment. Patient has event : PNEUMONIA. For study therapy Action Taken: drug interrupted, Investigator Causality: Related, CC: Not Related. Outcome: Fatal.

Concomitant Medication(s): AZD2936 (S) | AZD0901 (S) | | Mitiglinide calcium hydrate (C) | Telmisartan (C) | Silodosin (C) | Levothyroxine sodium (C) | Vonoprazan fumarate (C) | Sodium ferrous citrate (C) | Acetaminophen (C) | Dexamethasone sodium phosphate (C) | Guaiazulene (C) | Filgrastim (C) | Glycerin (C) | Lactec (C) | Lidocaine (C) | Meropenem (C) | Pegfilgrastim (C) | Sodium chloride (C) | Sodium gualenate hydrate (C) | Solace (C) | Vancomycin hydrochloride (C) | Vitamin d (C) | Noradrenaline (C) | Plasma (C) | Heparin sodium (C) | Human serum albumin (C) | Lidocaine hydrochloride (C) | Menatetrenone (C) | Octreotide acetate (C) | White petrolatum (C) | Sodium (C) | Sodium phosphate (C) | Bactramin (C) | Furosemide (C) | Potassium canrenoate (C) | Potassium chloride (C) | Glucose (C) | Soldem 3a (C) | Human red blood cells (C) | Venoglobulin (C) | Dexmedetomidine hydrochloride (C) | Insulin human (C) | Midazolam (C)

SOC:Injury, poisoning and procedural complications

2023A119766	KOREA, REPUBLIC OF 45 Years Male	**Infusion related reaction (Infusion related reaction)***	Recovered	22-May-2023 3 months 17 days	OXALIPLATIN	Infusion	130 milligram/sq. meter q3w Intravenous use	06-FEB-2023 to 06-FEB-2023 1 day	Periodic Report Comment. Patient experienced Infusion related reaction, Investigator : related to study therapy Oxaliplatin and not related to MEDI5752, Capecitabine.
						Infusion	130 milligram/sq. meter q3w Intravenous use	28-FEB-2023 to 20-MAR-2023 21 days	
						Infusion	98 milligram/sq. meter q3w Intravenous use	22-MAY-2023 to 22-MAY-2023 1 day	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	98 milligram/sq. meter q3w Intravenous use	24-APR-2023 to 24-APR-2023 1 day	

Concomitant Medication(s): MEDI5752 (S) | CAPECITABINE (S) | | ALMAGEL-F (C) | Tegoprazan (C) | Fentanyl (C) | LACTICARE (C) | LEVODROPROPIZINE (C) | PRIVITUSS (C) | EPINEPHRINE (C) | HYDROCORTISONE (C) | MEROPENEM (C) | ETHYLNOREPINEPHRINE (C) | PETHIDINE (C) | TAZOFERAN (C) | Fexuprazan (C) | Palonosetron (C) | Prednisolone (C) | Udca (C) | Albumin 20 trcs (C) | Heparin (C) | Tpn (C) | Fluconazole (C) | Hyaluronate (C) | Dexamethazone (C) | Esomeprazole (C) | Tramadol (C) | Loperamide (C) | Magnesium oxide (C) | Metoclopramide (C) | Phosphate (C) | Chlorpheniramine (C) | Ammonium chloride (C) | Levocetirizine (C) | Levodropropizine (C) | Novorapid (C) | Tazoferan (C) | Tresiba (C) | Benoxinate (C) | Cimetropium (C) | Midazolam (C) | Pethidine (C) | Simethicone (C) | Acetaminophen (C) | Gabapentin (C) | KCl (C) | Pregabalin (C) | Thioctic acid (C) | Moxifloxacin (C) | Irinotecan (C) | Pitavastatin (C) | Ganciclovir (C) | Homatropine (C) | Levofloxacin (C) | Prednisolone acetate (C) | Proparacaine (C) | Tropherine (C)

SOC:Investigations

2023A142549	KOREA, REPUBLIC OF 57 Years Male	**Liver function test increased (Liver function test increased)** *	Recovered	19-Jun-2023 4 months 4 days	MEDI5752	Infusion	500 milligram q3w Intravenous use	05-OCT-2023 to	Periodic Report Comment. Patient had Liver Function Test Increased (OTPT, Total Bilirubin), Investigator: related to MEDI5752. CCA: Not related to study therapies.;Patient has event: Event: Liver function test increased, Action taken with study drug: No Change, Investigator causality: related, Company Causality: Not related
						Infusion	500 milligram q3w Intravenous use	07-SEP-2023 to	
						Infusion	750 milligram q3w Intravenous use	01-JUN-2023 to	
						Infusion	750 milligram q3w Intravenous use	08-MAY-2023 to	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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 q3w Intravenous use	09-MAR-2023 to	
						Infusion	750 milligram q3w Intravenous use	16-FEB-2023 to	
Concomitant Medication(s): | CAPECITABINE (S) | OXALIPLATIN (S) | ULTRACET (C) | Lacticare (C) | PARAMACET (C) | LANSTON (C) | LYRICA (C) | GALVUS (C) | Glupa (C) | DIAMICRON MR (C) | Apetrol (C) | Synthyroid (C)									
202504GLO015669JP	JAPAN 74 Years Male	**Blood creatine phosphokinase increased (CPK increased)***	Recovered	05-Apr-2025 24 days	CAPECITABINE	Tablet	1000 milligram/sq. meter Oral use	13-MAR-2025 to 22-MAR-2025 10 days	
Concomitant Medication(s): AZD2936 (S) | AZD0901 (S) | | Silodosin (C) | Levothyroxine sodium hydrate (C) | Mitiglinide calcium hydrate (C) | Telmisartan (C) | Vonoprazan fumarate (C)									
SOC:Metabolism and nutrition disorders									
2024A198826	CHINA 43 Years Male	**Ketoacidosis (Ketoacidosis)***	Recovered	26-Aug-2024 5 months 8 days	MEDI5752	Infusion	500 milligram q3w Intravenous use	09-APR-2024 to 09-APR-2024 1 day	Periodic Report Comment. the patient experienced ketoacidosis, related to Medi5752, not related to Capecitabine and Oxaliplatin. Com causality not related.
						Infusion	500 milligram q3w Intravenous use	14-APR-2024 to 14-APR-2024 1 day	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	15-APR-2024 to 15-APR-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	19-MAR-2024 to 19-MAR-2024 1 day	

Concomitant Medication(s): CAPECITABINE (S) | | OXALIPLATIN (S) | Dexamethasone (C) | Glimepiride (C) | Magnesium glycerophosphate (C) | Palonosetron (C)

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
2023A161719	KOREA, REPUBLIC OF 52 Years Male	**Myalgia (Myalgia)***	Recovered	22-Jun-2023 4 months 1 day	MEDI5752	Infusion	500 milligram q3w Intravenous use	08-NOV-2023 to	Periodic Report Comment. Pt exp. wholebody myalgia. Inv: event related to MEDI5752, unrelated to Capecitabine and Oxaliplatin.
						Infusion	500 milligram q3w Intravenous use	10-JAN-2024 to	
						Infusion	500 milligram q3w Intravenous use	20-DEC-2023 to	
						Infusion	500 milligram q3w Intravenous use	21-FEB-2024 to	
						Infusion	500 milligram q3w	23-AUG-2023 to	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use		
						Infusion	500 milligram q3w	29-NOV-2023 to	
							Intravenous use		
						Infusion	500 milligram q3w	31-JAN-2024 to	
							Intravenous use		
						Infusion	750 milligram q3w	05-APR-2023 to	
							Intravenous use		
						Infusion	750 milligram q3w	12-JUL-2023 to	
							Intravenous use		
						Infusion	750 milligram q3w	15-MAR-2023 to	
							Intravenous use		
						Infusion	750 milligram q3w	22-FEB-2023 to	
							Intravenous use		
						Infusion	750 milligram q3w	24-MAY-2023 to	
							Intravenous use		

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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) | | OXALIPLATIN (S) | AMOSARTAN (C) | PITAVAS (C) | HUMEGA (C) | Glucophage xr (C) | ALOXI (C) | MACPERAN (C) | BUSCOPAN (C) | Paramacet SEMI (C) | ADIPAM (C) | CETIZAL (C) | LYRICA (C) | NEXIUM (C) | IRCODON (C) | GASTER (C) | SEPTRIN (C) | SOLONDO (C) | LACIDOFIL (C) | CENOVA-L (C) | DEXAMETHASONE (C) | CHLORPHENIRAMINE (C) | DENOGAN (C) | Humalog (C) | Tramadol HCL (C) | MGO (C) | Diabex xr (C) | GLIMEL (C)									
202511GLO016238ES	SPAIN 81 Years Male	**Arthritis (Arthritis)***	Not Recovered	17-Nov-2025 nk	RILVEGOS TOMIG	Solution Intravenous use	750 milligram q3w	02-OCT-2025 to	Patient has event: Event: Arthritis, Action taken with study drug: No Change, Investigator causality: related, Company Causality: Not related
						Solution Intravenous use	750 milligram q3w	06-JUN-2025 to	
						Solution Intravenous use	750 milligram q3w	10-SEP-2025 to	
						Solution Intravenous use	750 milligram q3w	22-AUG-2025 to	
						Solution Intravenous use	750 milligram q3w	27-JUN-2025 to	
Concomitant Medication(s): AZD0901 (S) | | CAPECITABINE (S) | Tiotropium bromide (C) | Tamsulosine (C) | Acetylsalicylic acid (C) | Atorvastatin (C) | Omeprazole (C) | Ferrogradumet (C) | Olanzapine (C)									

SOC:Nervous system disorders

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A177592	UNITED KINGDOM 56 Years Male	**Cerebrovascular accident (Stroke)***	Fatal	04-Aug-2024 12 days	AZD0901	Infusion	750 milligram q3w Intravenous use	24-JUL-2024 to 07-AUG-2024 15 days	Periodic Report Comment. Patient experienced stroke, Inv, related to Azd0901, Inv, not related to Azd2936, Inv, not related to Capecitabine, CCA : not related to Azd2936, CCA : not related to Azd0901, CCA: not related to Capecitabine

Concomitant Medication(s): | AZD 2936 (S) | CAPECITABINE (S) | Amytal (C) | Atorvastatin (C) | Ramipril (C) | Oramorph (C) | Codeine (C) | Ferrous furmarate and sodium docusate (C) | Lansoprazole (C) | Amitriptyline (C)

SOC:Renal and urinary disorders

202504GLO015653JP	JAPAN 75 Years Male	**Renal failure (Renal failure)***	Not Recovered	10-Apr-2025 29 days	CAPECITABINE	Tablet	1000 milligram/sq. meter Oral use	13-MAR-2025 to 30-APR-2025 1 month 18 days	

Concomitant Medication(s): AZD2936 (S) | AZD0901 (S) | | Silodosin (C) | Telmisartan (C) | Vonoprazan fumarate (C) | Levothyroxine sodium (C) | Mitiglinide calcium hydrate (C)

SOC:Respiratory, thoracic and mediastinal disorders

2024A198878	UNITED KINGDOM Male	**Pulmonary embolism (Pulmonary embolism)***	Recovered	30-Aug-2024 nk	AZD0901	Infusion Infusion	2.2 milligram/kilogram q3w Intravenous use 2.2 milligram/kilogram q3w	08-APR-2025 to 20-MAY-2025 1 month 13 days 09-JUL-2024 to 25-FEB-2025	Periodic Report Comment. Male patient with event: PULMONARY EMBOLISM-Pulmonary embolism, reporter causality: related to 5-FLUOROURACIL and AZD0901 not related to AZD2936, CCA: not related.

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
							Intravenous use	7 months 17 days	
					5-FLUOROURACIL	Infusion	3000 milligram/sq. meter q2w Intravenous use	03-DEC-2024 to 03-DEC-2024 1 day	
						Infusion	3000 milligram/sq. meter q2w Intravenous use	08-APR-2025 to 25-MAY-2025 1 month 18 days	
						Infusion	3000 milligram/sq. meter q2w Intravenous use	25-FEB-2025 to 02-MAR-2025 6 days	
						Infusion	600 milligram/sq. meter q2w Intravenous use	14-JAN-2025 to 09-FEB-2025 27 days	
						Infusion	800 milligram/sq. meter q2w Intravenous use	09-JUL-2024 to 14-JUL-2024 6 days	
						Infusion	800 milligram/sq. meter q2w Intravenous use	20-AUG-2024 to 15-SEP-2024 27 days	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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	800 milligram/sq. meter q2w Intravenous use	30-JUL-2024 to 04-AUG-2024 6 days	
Concomitant Medication(s): | 5-FLUOROURACIL (S) | AZD2936 (S) | Ach amlodipine (C) | Domperidone (C) | Lansoprazole (C) | Ondansetron (C) | Docusate (C) | Bisoprolol (C) | Ramipril (C) | Enoxaparin (C)									
202509GLO002662KR	KOREA, REPUBLIC OF 73 Years Male	**Pneumonitis (Pneumonitis)***	Fatal	01-Sep-2025 21 days	AZD0901	Infusion	2.2 milligram/kilogram q3w Intravenous use	12-AUG-2025 to 12-AUG-2025 1 day	Periodic Report Comments. Patient has event Pneumonitis. Action taken with AZD0901, AZD2936 was No change and with 5-fluorouracil was Dose increased. Investigator Causality: Related, CC: Not Related for study therapy.
					AZD2936	Solution	750 milligram q3w Intravenous use	12-AUG-2025 to 1 day	
Concomitant Medication(s): | AZD2936 (S) | 5-fluorouracil (S) | Encover (C) | Nystatin (C) | Tropherine (C) | Ultracet er (C) | Aloxi (C) | Dexamethasone (C) | Peniramin (C) | Tagamet (C)									

SOC:Skin and subcutaneous tissue disorders

2023A075799	KOREA, REPUBLIC OF 56 Years Female	**Rash (Skin rash)** Thrombocytopenia (Thrombocytopenia)*	Recovered	24-Mar-2023 1 month 15 days	MEDI5752	Infusion	750 milligram q3w Intravenous use	10-FEB-2023 to 14-JUN-2023 4 months 5 days	Periodic Report Comment. Pt experienced Skin Rash, Inv-Related with MEDI575 and Thrombopenia related with MEDI575 and Oxaliplatin.

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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): | OXALIPLATIN (S) | CAPECITABINE (S) | Norepinephrine (C) | Morphine (C) | Tazoperan (C) | Levofloxacin (C) | Lantus (C) | Apidra (C) | Paracet (C) | Legalon (C) | Ursa (C) | Aloxi (C) | Albumin (C) | Lasix (C) | Dulackhan (C) | Loperamide (C) | Macperan (C) | Mago (C) | Lyrica (C) | Adipam (C) | Itomed (C) | Cortisolu (C) | Rbc (C) | Chlorpheniramine maleate (C) | Pantoline (C) | Tridol (C) | Xerova (C) | Potassium chloride (C) | Disolin (C) | Ocodone (C) | Phosten (C) | Platelets (C) | Lidostar (C) | Cetizal (C) | Solondo (C) | Celebrex (C) | Diabex (C) | Acetaminophen (C) | Chlorpheniramin (C) | Gaster (C) | Albumin 20 trcs (C) | Furix (C) | Triaxone (C) | Meckool (C) | Bearoban (C) | Trajenta (C) | Twolion (C) | Fotagel (C) | Vancozin (C) | Lacticare (C) | Montezal (C) | Rupafin (C) | Ativan (C) | Epinephrine (C) | Pethidine (C) | Pospenem (C) | Trolac (C) | Almagel (C) | Humulin r (C) | Magnesium (C) | Esroban (C)									
202511GLO008938TW	TAIWAN 71 Years Female	**Rash (Skin rash)*** Stevens-Johnson syndrome (Stevens Johnson syndrome)*	Not Recovered	02-Nov-2025 nk	AZD0901	Infusion Intravenous use		07-APR-2025 to	
						Infusion Intravenous use		08-SEP-2025 to	
						Infusion Intravenous use		09-JUN-2025 to	
						Infusion Intravenous use		17-MAR-2025 to	
						Infusion Intravenous use		19-MAY-2025 to	
						Infusion Intravenous use		20-OCT-2025 to	
						Infusion Intravenous use		21-JUL-2025 to	
						Infusion Intravenous use		24-FEB-2025 to	

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

Project ID: D7986

Study ID: D7986C00001

EudraCT No: 2024-510977-27-00

Study Design: Not Blinded

Study Description: D7986C00001 Phase II GC Platform Study (China Led) - An Open-Label, Multi-Drug, Multi-Centre, Phase II Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Novel Combinations in Participants with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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-APR-2025 to	
						Infusion	Intravenous use	29-SEP-2025 to	
						Infusion	Intravenous use	30-JUN-2025 to	

Concomitant Medication(s): | RILVEGOSTOMIG (S) | CAPECITABINE (S) | Bisoprolol (C) | Olmesartan (C) | Oxcarbazepine (C) | Sennosides (C) | Medicon a (C) | Glycyrrhiza (C) | Sevikar (C) | Metoclopramide (C) | Lorazepam (C) | Megetol (C) | Takepron (C) | Codeine Phosphate (C)

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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									
202411GLO004960ES	SPAIN 71 Years Female	**Neutropenia (Neutropenia)***	Fatal	07-Nov-2024 3 months	MEDI5752	Infusion	500 milligram q3w Intravenous use	08-AUG-2024 to 08-AUG-2024 1 day	Periodic Report Comments. Patient has event: BILE DUCT OBSTRUCTION, NEUTROPENIA. Action Taken with study therapy was MEDI5752, LENVATINIB Not Applicable. Investigator Causality: Related CC: Not related. MEDI5752. Investigator Causality: Not related CC: Not related. LENVATINIB;Periodic Report Comments. Patient has event: BILE DUCT OBSTRUCTION, NEUTROPENIA. Action Taken with study therapy was MEDI5752, LENVATINIB Not Applicable. Investigator Causality: Not Related CC: Not related. MEDI5752. Investigator Causality: Not related CC: Not related. LENVATINIB
						Infusion	500 milligram q3w Intravenous use	16-OCT-2024 to 16-OCT-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	29-AUG-2024 to 29-AUG-2024 1 day	
Concomitant Medication(s): | LENVATINIB (S) | Tiamazol (C) | Acetylsalicylic acid (C) | Atorvastatin (C) | Calcifediol monohydrate (C) | Bromazepam (C) | Trazodone HCL (C) | Pantoprazole (C) | Plantaben (C) | Megestrol acetate (C) | Retinol palmitate (C) | Dl-alpha tocopheryl acetate (C) | Clebopride (C) | Simethicone (C) | Propanolol (C) | Ursodeoxycholic acid (C) | Carvedilol (C) | Spironolactone (C) | Loperamide (C) | Thiamazole (C) | Furosemide (C) | Albumin (C) | Piperacillin (C) | Tazobactam (C) | Lorazepam (C) | Filgrastim (C) | Methylprednisolone (C) | Phytomenadione (C) | Sodium bicarbonate (C) | Butylscopolamine (C) | Midazolam (C) | Morphine (C) | Pethidine (C)									
202412GLO009395CN	CHINA 51.9 Years Male	**Anaemia (Anaemia aggravated)***	Recovered	11-Dec-2024 3 months 13 days	AZD2936	Solution	750 milligram q3w Intravenous use	01-NOV-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
						Solution	750 milligram q3w Intravenous use	11-OCT-2024 to	
						Solution	750 milligram q3w Intravenous use	19-SEP-2024 to	
						Solution	750 milligram q3w Intravenous use	21-NOV-2024 to	
						Solution	750 milligram q3w Intravenous use	29-AUG-2024 to 2 months 24 days	
Concomitant Medication(s): | BEVACIZUMAB (S) | Tenofovir disoproxil fumarate (C) | Irbesartan (C) | Acetaminophen (C) | Esomeprazole sodium (C) | Flurbiprofen axetil (C) | Carbazochrome sodium sulfonate and sodium chloride (C) | Pronase (C) | Lysine acetylsalicylate (C) | Compound dyclonine hydrochloride and monthal (C) | Proactiv solution advanced daily oil control (C) | Carvedilol (C)									
2024A052928	SPAIN 63 Years Male	**Febrile neutropenia (Febrile neutropenia)***	Recovered	28-Feb-2024 3 weeks	GEMCITAB INE	Infusion	1000 milligram/sq. meter qw Intravenous use	07-FEB-2024 to	Periodic Report Comment. Patient experienced febrile neutropenia ,Inves: related to Gemcitabine. CCA: related to Gemcitabine
						Infusion	1000 milligram/sq. meter qw Intravenous use	13-FEB-2024 to	
						Infusion	500 milligram/sq. meter qw	02-JUL-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
							Intravenous use		
						Infusion	500 milligram/sq. meter qw	02-MAY-2024 to	
							Intravenous use		
						Infusion	500 milligram/sq. meter qw	05-JUN-2024 to	
							Intravenous use		
						Infusion	500 milligram/sq. meter qw	09-APR-2024 to	
							Intravenous use		
						Infusion	500 milligram/sq. meter qw	19-MAR-2024 to	
							Intravenous use		
						Infusion	500 milligram/sq. meter qw	24-JUL-2024 to	
							Intravenous use		
						Infusion	500 milligram/sq. meter qw	26-JUN-2024 to	
							Intravenous use		

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

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EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	500 milligram/sq. meter qw Intravenous use	26-MAR-2024 to	
						Infusion	500 milligram/sq. meter qw Intravenous use	29-MAY-2024 to	
						Infusion	500 milligram/sq. meter qw Intravenous use	30-JUL-2024 to	
						Infusion	500 milligram/sq. meter qw Intravenous use	28-AUG-2024 to 04-SEP-2024 8 days	
						Infusion	750 milligram/sq. meter qw Intravenous use	08-MAY-2024 to	
						Infusion	750 milligram/sq. meter qw Intravenous use	17-APR-2024 to	

Concomitant Medication(s): CISPLATIN (S) | | MEDI5752 (S) | STUDY PROCEDURE (S) | AXHIDROX (C) | ACETYLSALICYLIC ACID (C) | ALLANTOIN (C) | EBASTINE (C) | PARACETAMOL (C) | MEROPENEM (C) | TEICOPLANIN (C) | INDOMETACINE (C) | FUROSEMIDE (C)

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

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Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
2024A081697	TAIWAN 65.2 Years Male	**Autoimmune haemolytic anaemia (Anemia hemolytic autoimmune)***	Not Recovered	06-Mar-2024 30 weeks 6 days	MEDI5752	Infusion	250 milligram q3w Intravenous use	09-APR-2025 to	Periodic Report Comment. Patient experienced grade two anemia. Inv, related to Medi5752. CCA: not related.; PRC. The patient experienced Anaemia. Investigator: related to MEDI5752~Company physician: Not related to study therapy.;PRC. The patient experienced Anaemia. Investigator: related to MEDI5752 Company physician: Not related to study therapy.; Patient experienced ANEMIA. Inv, related to Medi5752. CCA: not related.;Periodic report comment. Patient has event : ANEMIA. For study therapy Action Taken: Dose reduced, Investigator Causality: Related, CC: Not Related. Outcome: Recovered
						Infusion	250 milligram q3w Intravenous use	16-MAR-2025 to 16-MAR-2025 1 day	
						Infusion	250 milligram q3w Intravenous use	30-APR-2025 to	
						Infusion	500 milligram q3w Intravenous use	18-DEC-2024 to 18-DEC-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	24-APR-2024 to 16-OCT-2024 5 months 23 days	
						Infusion	750 milligram q3w Intravenous use	03-AUG-2023 to 03-AUG-2023 1 day	
						Infusion	750 milligram q3w Intravenous use	04-OCT-2023 to 04-OCT-2023 1 day	
						Infusion	750 milligram q3w Intravenous use	10-JAN-2024 to 10-JAN-2024 1 day	

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Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	750 milligram q3w	13-SEP-2023 to 13-SEP-2023	
							Intravenous use	1 day	
						Infusion	750 milligram q3w	21-DEC-2023 to 21-DEC-2023	
							Intravenous use	1 day	
						Infusion	750 milligram q3w	21-FEB-2024 to 13-MAR-2024	
							Intravenous use	22 days	
						Infusion	750 milligram q3w	23-AUG-2023 to 23-AUG-2023	
							Intravenous use	1 day	
						Infusion	750 milligram q3w	25-OCT-2023 to 25-OCT-2023	
							Intravenous use	1 day	
						Infusion	750 milligram q3w	29-NOV-2023 to 29-NOV-2023	
							Intravenous use	1 day	
						Infusion	750 milligram q3w	31-JAN-2024 to 31-JAN-2024	
							Intravenous use	1 day	

Concomitant Medication(s): | Xanax (C) | Ulstop (C) | Mosad (C) | Zcough (C) | Veterin (C) | Buscopan (C) | Famotidine (C) | Takepron (C) | Pantoprazole (C) | Chlorpheniramine (C) | Celebrex (C) | Ferrous gluconate (C) | Folic acid (C) | Uroso (C) | Tramtor (C) | Neomycin (C) | Pantoloc (C) | Gaslan (C) | Ulstop (C) | Rhin (C) | Tramal (C)

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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									
202501GLO018976GB	UNITED KINGDOM 76.1 Years Male	**Myocarditis (Myocarditis)*** Myasthenia gravis (Myasthenia gravis)*	Recovered	21-Jan-2025 14 days	AZD2936	Solution	750 milligram q3w Intravenous use	08-JAN-2025 to 1 day	Patient experienced troponin increase: event related to Azd2936, MEDI5752 and not related to Bevacizumab. CCA: related to Azd2936, MEDI5752 and not related to Bevacizumab.
Concomitant Medication(s): MEDI5752 (S) | | BEVACIZUMAB (S) | Amlodipine (C) | Atorvastatin (C) | Finasteride (C) | Tamsulosin (C) | Chlorphenamine (C) | Cetirizine (C) | Mycophenolate mofetil (C) | Ramipril (C) | Clindamycin (C)									
202503GLO026195ES	SPAIN 43.2 Years Female	**Myocarditis (Myocarditis)***	Recovered	28-Mar-2025 4 days	BEVACIZUMAB	Infusion	820.5 milligram q3w Intravenous use	25-MAR-2025 to 15-APR-2025 22 days	
Concomitant Medication(s): MEDI5752 (S) | | AZD2936 (S) | Progesteron (C) | Minoxidil (C) | Alendronic acid (C) | Ceftriaxone (C) | Ferric Carboxymaltose (C) | Furosemide (C) | Ursobilane (C)									
202504GLO015807US	UNITED STATES 72 Years Male	**Cardiac arrest (Cardiac arrest)*** Myasthenia gravis (Myasthenia gravis)*	Fatal	22-Apr-2025 nk	BEVACIZUMAB MEDI5752	Infusion Infusion	Intravenous use Intravenous use	to 10-MAR-2025 to 10-MAR-2025 1 day	Periodic Report Comments. Patient experienced the event "Cardiac arrest" and Myocarditis . INV related to MEDI5752 Company causality not related to MEDI5752 & AZD2936 & BEVACIZUMAB.;Periodic Report Comments. The patient experienced Respiratory distress. Investigator causality related for suspect MEDI5752 and not related for AZD2936 and bevacizumab. CCA not related.

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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): MEDI5752 (S) | AZD2936 (S) | | Montelukast (C) | Pantoprazole (C) | Propranolol (C) | Levocetirizine (C) | Motrin (C) | Turmeric (C) | Tylenol (C) | Valsartan (C) | Mupirocin (C) | Lactulose (C) | Bactrim ds (C) | Ondansetron (C) | Trazodone (C) | Furosemide (C) | Insulin aspart (C) | Polyethylene glycol (C) | Prednisone (C) | Magnesium sulfate (C) | Oxycodone (C)									
SOC:Endocrine disorders									
2024A079488	SPAIN 83 Years Female	**Hypothyroidism (Hypothyroidism)***	Not Recovered	30-Mar-2024 12 weeks 2 days	MEDI5752	Infusion	750 milligram q3w Intravenous use	04-JAN-2024 to 27-JUN-2024 28 weeks 2 days	Periodic Report Comment. Patient experienced hypothyroidism. INV; related to one Study therapy Not Related to other two study therapy CCC: not related to Study therapy.
Concomitant Medication(s): | CISPLATIN (S) | GEMCITABINE (S) | ATORVASTATIN (C) | BISOPROLOL (C) | RIFAXIMINE (C) | Rivaroxaban (C) | DEXAMETHAZONE (C) | Aj ondansetron (C) | POLARAMINE (C) | Sodium Chloride 0.9% & Dextrose 5% (C) | CASENGLICOL (C) | CETIRIZINA (C) | PRIMERAN (C) | TRANKIMAZIN (C) | Apo propranolol (C) | SUMIAL (C) | APO FLUCONAZOL (C) | MYCOSTATIN (C) | Xerostom saliva substitute (C) | LORAZEPAM (C) | ZDROVIT MAGNESIUM (C) | SUBOLIGO MANGANESE (C) | AMOXICILIN/CLAVULANIC ACID KRKA (C) | PUNTUALSENNA (C) | AMPLOCILIN (C) | LEVOTIROXIN (C) | MONUROL (C) | AJU OMEPRAZOLE (C) | PARACETAMOL (C) | Aft Cetirizine (C) | Whole blood acd (C) | Wamp folic acid (C) | Septrin forte (C) | LEVOTIROXIN (C) | Ag pantoprazole (C) | ERTAPENEM (C) | Whole blood cpd (C) | Apt Cefuroxime (C) | BRENTAN (C)									
2024A100712	HONG KONG 62.3 Years Male	**Hyperthyroidism (Hyperthyroidism)***	Recovered	22-Apr-2024 20 days	BEVACIZUMAB	Infusion	15 milligram/kilogram q3w Intravenous use	03-APR-2024 to 04-SEP-2024 5 months 2 days	Periodic Report Comment. The patient experienced hyperthyrodism. INV: related to study therapy Com: not related.
Concomitant Medication(s): MEDI5752 (S) | | Ag amlodipine (C) | SIMVASTATIN (C) | ENTECAVIR (C) | Aciclovir (C) | Amlodipine (C) | Hydrocortisone (C) | Thyroxine sodium (C) | Paxlovid (C)									
2024A147849	HONG KONG 71.5	**Thyroiditis (Thyroiditis)***	Recovered	12-Jun-2024 2 months 3 days	LENVATINIB	Capsule	12 milligram qd	10-APR-2024 to 11-JUN-2024	Periodic Report Comment. Patient experienced Thyroiditis, related to LENVATINIB,

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

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Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	
	Years Male						Oral use	3 weeks 1 day		ME DI57 52. Com pany caus ality not relat ed.
						Capsule	8 milligram qd	09-JUL-2024 to 25-SEP-2024		
							Oral use	3 weeks 1 day		
					MEDI5752	Infusion	500 milligram q3w	10-APR-2024 to 09-JUL-2024		
							Intravenous use	3 months		
						Infusion	500 milligram q3w	31-JUL-2024 to 31-JUL-2024		
							Intravenous use	1 day		
Concomitant Medication(s): MEDI5752 (S) | | ENTECAVIR (C) | AMOXYCILLIN (C)										
202510GLO028973CN	CHINA 62.8 Years Male	**Adrenal insufficiency (Hypoadrenocorticism)** Hypothyroidism (Hypothyroidism)*	Not Recovered	10-Oct-2025 8 months 18 days 9 hrs 28 min	MEDI5752	Infusion	1500 milligram q3w	21-JAN-2025 14:32 to 21-JAN-2025 15:24	Periodic Report Comments. Patient experienced hypothyroidism, investigator assessed causality with Azd2936, Medi5752 and Bevacizumab as related.	
							Intravenous use	52 min		
						Infusion	750 milligram q3w	10-JUL-2025 09:41 to 10-JUL-2025 10:41		
							Intravenous use	1 hr		
						Infusion	750 milligram q3w	16-APR-2025 10:05 to 16-APR-2025 11:07		
							Intravenous use	1 hr 2 min		

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

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Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	750 milligram q3w Intravenous use	31-OCT-2025 11:19 to 31-OCT-2025 12:17 58 min	
					BEVACIZUMAB	Infusion	1155 milligram q3w Intravenous use	05-MAR-2025 12:51 to 05-MAR-2025 13:53 1 hr 2 min	
						Infusion	1155 milligram q3w Intravenous use	08-MAY-2025 12:34 to 08-MAY-2025 13:06 32 min	
						Infusion	1155 milligram q3w Intravenous use	10-OCT-2025 13:06 to 10-OCT-2025 13:40 34 min	
						Infusion	1155 milligram q3w Intravenous use	11-SEP-2025 16:31 to 11-SEP-2025 17:04 33 min	
						Infusion	1155 milligram q3w Intravenous use	13-FEB-2025 12:54 to 13-FEB-2025 14:38 1 hr 44 min	
						Infusion	1155 milligram q3w Intravenous use	19-JUN-2025 11:51 to 19-JUN-2025 12:27	

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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
								36 min	
						Infusion	1155 milligram q3w Intravenous use	21-NOV-2025 to	
						Infusion	1155 milligram q3w Intravenous use	26-MAR-2025 11:42 to 26-MAR-2025 12:13 31 min	
						Infusion	1155 milligram q3w Intravenous use	29-MAY-2025 12:55 to 29-MAY-2025 13:57 1 hr 2 min	
						Infusion	1155 milligram q3w Intravenous use	31-JUL-2025 13:20 to 31-JUL-2025 14:00 40 min	
					AZD2936	Solution	750 milligram q3w Intravenous use	05-MAR-2025 10:46 to 05-MAR-2025 11:47 1 hr 1 min	
						Solution	750 milligram q3w Intravenous use	08-MAY-2025 10:29 to 08-MAY-2025 11:31 1 hr 2 min	

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

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EudraCT No: 2022-502317-29-00

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Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary Cancer

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						Solution	750 milligram q3w Intravenous use	10-OCT-2025 10:52 to 10-OCT-2025 11:56 1 hr 4 min	
						Solution	750 milligram q3w Intravenous use	11-SEP-2025 14:28 to 11-SEP-2025 15:29 1 hr 1 min	
						Solution	750 milligram q3w Intravenous use	13-FEB-2025 10:45 to 13-FEB-2025 11:49 1 hr 4 min	
						Solution	750 milligram q3w Intravenous use	19-JUN-2025 09:42 to 19-JUN-2025 10:47 1 hr 5 min	
						Solution	750 milligram q3w Intravenous use	21-NOV-2025 to	
						Solution	750 milligram q3w Intravenous use	26-MAR-2025 09:39 to 26-MAR-2025 10:40 1 hr 1 min	
						Solution	750 milligram q3w Intravenous use	29-MAY-2025 10:42 to 29-MAY-2025 11:54 1 hr 12 min	

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						Solution	750 milligram q3w Intravenous use	31-JUL-2025 11:19 to 31-JUL-2025 12:19 1 hr	

Concomitant Medication(s): | AZD2936 (S) | BEVACIZUMAB (S) | Entecavir (C) | Levamlodipine besylate (C) | Tenofovir disoproxil fumarate (C) | Zoledronic acid (C) | Nifedipine (C) | Levothyroxine (C) | Vitamin b6 (C) | Bicyclol (C) | Omeprazole (C) | Sodium chloride (C)

SOC:Gastrointestinal disorders

202410GLO000271KR	KOREA, REPUBLIC OF 66 Years Male	**Enterocolitis (Enterocolitis)***	Recovered	30-Sep-2024 6 months 27 days	LENVATINIB	Capsule	8 milligram qd Oral use	04-MAR-2024 to 26-AUG-2024 5 months 23 days	
202411GLO009131US	UNITED STATES 67 Years Male	**Upper gastrointestinal haemorrhage (Upper gastrointestinal hemorrhage)***	Fatal	12-Nov-2024 3 months 13 days	BEVACIZUMAB	Infusion	1000 milligram q3w Intravenous use	20-AUG-2024 to 20-AUG-2024 1 day	
						Infusion	1000 milligram q3w Intravenous use	22-OCT-2024 to 22-OCT-2024 1 day	
						Infusion	1000 milligram q3w Intravenous use	28-OCT-2024 to 28-OCT-2024 1 day	

Concomitant Medication(s): MEDI5752 (S) | | | Gliatamin (C) | Folsan (C) | Vemlidy (C) | Tantum forte (C) | Adalat oros (C) | Midazolam (C) | Tridol (C)

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						Infusion	1000 milligram q3w Intravenous use	31-JUL-2024 to 31-JUL-2024 1 day	
Concomitant Medication(s): MEDI5752 (S) | | Folic acid (C) | Vitamin b12 (C) | Senna glycosides (C) | Lactulose (C) | Magnesium oxide (C) | Rifaximin (C) | Furosemide (C) | Magnesium sulfate (C) | Trazodone (C) | Methylprednisolone (C) | Sennoside a+b calcium (C) | Sodium chloride (C) | Spironolactone (C)									
202412GLO018406HK	HONG KONG 61 Years Male	**Varices oesophageal (Varices oesophageal)***	Recovering	19-Dec-2024 8 months 17 days	BEVACIZUMAB	Infusion	960 milligram q3w Intravenous use	03-APR-2024 to 18-DEC-2024 8 months 16 days	
					MEDI5752	Infusion	500 milligram q3w Intravenous use	03-APR-2024 to 28-MAY-2025 1 year 1 month 26 days	
Concomitant Medication(s): MEDI5752 (S) | | Hydrocortisone acetate (C) | Entecavir (C) | Amlodipine (C) | Simvastatin (C) | Thyroxine sodium (C) | Paracetamol (C) | Paxlovid (C) | Propranolol (C) | Carbimazole (C) | Betahistine (C) | Piriton (C) | Dequadin (C) | Bromhexine HCL (C) | Potassium chloride (C)									
202412GLO021490CN	CHINA 61.9 Years Male	**Ascites (Ascites)***	Not Recovered	04-Dec-2024 2 months 22 days	BEVACIZUMAB	Infusion	15 milligram/kilogram q3w Intravenous use	03-JAN-2025 to 22-JAN-2025 20 days	The patient experienced ASCITES. Investigator: related to BEVACIZUMAB and not related to AZD2936. Company: not related
						Infusion	15 milligram/kilogram q3w Intravenous use	12-FEB-2025 to 17-JUN-2025 4 months 6 days	

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						Infusion	15 milligram/kilogram q3w Intravenous use	13-SEP-2024 to 19-NOV-2024 2 months 7 days	
Concomitant Medication(s): AZD2936 (S) | | Entecavir (C) | Silymarin (C) | Avatrombopag maleate (C) | Compound glycyrrhizin (C) | Omeprazole (C) | Methylprednisolone (C) | Methylprednisolone sodium succinate (C) | Esomeprazole magnesium (C) | Tenofovir amibufenamide (C) | Potassium chloride (C) | Allisartan isoproxil (C) | Magnesium Isoglycyrrhizinate (C) | Bicyclol (C)									
202412GLO024805CN	CHINA 43 Years Male	**Upper gastrointestinal haemorrhage (Upper gastrointestinal hemorrhage)***	Recovered	28-Dec-2024 2 months 19 days 10 hrs 30 min	BEVACIZUMAB	Infusion	15 milligram/kilogram q3w Intravenous use	08-OCT-2024 13:30 to 03-JAN-2025 2 months 25 days 10 hrs 30 min	Periodic Report Comments. Patient experienced UPPER GASTROINTESTINAL HEMORRHAGE. Investigator: not related to Rilvegostomig and related to Bevacizumab. Company: not related to Rilvegostomig and not related to Bevacizumab. Not related to study procedure.
Concomitant Medication(s): AZD2936 (S) | | Entecavir (C)									
2024A063172	CHINA 64 Years Male	**Enteritis (Enteritis)***	Recovered	07-Mar-2024 5 months 10 days	LENVATINIB	Capsule	8 milligram qd Oral use	27-SEP-2023 to 11-MAR-2024 5 months 14 days	Periodic Report Comment. Patient experienced DRUG ENTERITIS ,Inves: related to study therapy
					MEDI5752	Infusion	500 milligram q3w Intravenous use	27-SEP-2023 to 17-OCT-2023 21 days	

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Concomitant Medication(s): | MEDI5752 (S) | Entecavir (C) | Ag tenofovir (C) | Levothyroxine sodium (C) | Prednisone acetate (C) | Bi tofacitinib (C) | Pregabalin (C) | Calcium carbonate and vitamin d3 tablets (ii) (C) | Pc phosphatidylcholine (C) | Actifed Compound (C) | (2-(Diphenylmethoxy)ethyl)diethylmethylammoniumiodide (C) | Quetiapine (C) | Sodium chloride (C) | Ranitidine (C) | Glycyrrhizin (C) | Glutathione (C) | Tenofovir (C) | Bicyclol (C) | Sodium chloride (C) | Potassium (C) | Tramadol (C) | Vitamine (C) | Dexamethasone (C) | Ertapenem sodium (C) | Chloride (C) | Ranitidine hydrochloride (C) | Glycyrrhizin (C) | Glycerin (C) | Ketorolac (C) | Glutathion (C) | Omeprazole sodium (C) | Paraffin oil (C) | Albumin (C) | Albuterol sulfate (C) | Methylcobalamin (C) | Simethicone (C) | Vancomycin (C) | Alanyl glutamine (C) | Alcloxa | Cinchocaine hydrochloride | Neomycin sulfate | Prednisolone acetate | Tocopheryl acetate (C) | Rivaroxaban (C) | Famotidine (C)									
202503GLO020869JP	JAPAN 67.2 Years Male	**Stomatitis (Mucositis oral)***	Recovering	06-Mar-2025 nk	AZD2936	Solution Intravenous use	750 milligram q3w 1 day	05-DEC-2024 to 05-DEC-2024	Periodic Report Comments. The patient experienced oral mucositis.: related to AZD2936 and not related to MEDI5752 and BEVACIZUMAB to company causality not related to study therapy.
						Solution Intravenous use	750 milligram q3w 1 day	06-FEB-2025 to 06-FEB-2025	
						Solution Intravenous use	750 milligram q3w 1 day	16-JAN-2025 to 16-JAN-2025	
						Solution Intravenous use	750 milligram q3w 1 day	26-DEC-2024 to 26-DEC-2024	
						Solution Intravenous use	750 milligram q3w 1 day	27-FEB-2025 to 27-FEB-2025	
Concomitant Medication(s): MEDI5752 (S) | | BEVACIZUMAB (S) | Feburic (C) | Metgluco (C) | Trazenta (C) | Amlodipine (C) | Bayaspirin (C) | Lansoprazole (C) | Maintate (C) | Nazal (C) | Mecobalamin (C) | Shakuyakukanzoto (C) | Torasemide (C) | Restamin kowa (C) | Rinderon (C) | Pitavastatin calcium (C)									

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202504GLO011927HK	HONG KONG 64 Years Male	**Diarrhoea (Diarrhea)***	Recovered	14-Apr-2025 3 months 28 days	AZD2936	Solution	750 milligram q3w Intravenous use	18-DEC-2024 to 28-AUG-2025 8 months 11 days	Patient experienced grade 3 DIARRHEA, Investigator Causality: related to AZD2936, BEVACIZUMAB and MEDI5752. Company causality considered as not related to AZD2936 & related with BEVACIZUMAB and MEDI5752.
Concomitant Medication(s): | BEVACIZUMAB (S) | MEDI5752 (S) | Propanolol (C) | Entecavir (C) | Thyroxine (C)									
202507GLO009243CN	CHINA 62.5 Years Male	**Upper gastrointestinal haemorrhage (Upper gastrointestinal bleeding)***	Fatal	11-Jul-2025 9 months 29 days	BEVACIZUMAB	Infusion	825 milligram q3w Intravenous use	17-JUN-2025 to	
						Infusion	840 milligram q3w Intravenous use	22-JAN-2025 to	
						Infusion	847.5 milligram q3w Intravenous use	05-MAR-2025 to	
						Infusion	855 milligram q3w Intravenous use	03-APR-2025 to	
						Infusion	855 milligram q3w Intravenous use	12-FEB-2025 to	

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						Infusion	855 milligram q3w Intravenous use	12-FEB-2025 to 17-JUN-2025 4 months 6 days	
						Infusion	877.5 milligram q3w Intravenous use	03-JAN-2025 to	
						Infusion	907.5 milligram q3w Intravenous use	27-MAY-2025 to	
						Infusion	922.5 milligram q3w Intravenous use	13-SEP-2024 to	
						Infusion	952.5 milligram q3w Intravenous use	14-OCT-2024 to	
						Infusion	960 milligram q3w Intravenous use	19-NOV-2024 to	
Concomitant Medication(s): AZD2936 (S) | | Entecavir (C) | Avatrombopag maleate (C) | Silymarin (C) | Methylprednisolone (C) | Esomeprazole magnesium (C) | Bicyclol (C) | Potassium chloride (C) | Tenofovir amibufenamide (C) | Sacubitril valsartan sodium (C) | Furosemide (C) | Spironolactone (C) | Carvedilol (C) | Compound glycyrrhizin (C) | Levothyroxine sodium (C) | Losartan potassium (C) | Lusutrombopag (C) | Levofloxacin (C)									
202511GLO009329CN	CHINA 50 Years Male	**Gastrointestinal haemorrhage (Gastrointestinal bleeding)***	Not Recovered	11-Nov-2025 1 year 2 months 5 days 6 hrs 4 min	AZD2936	Solution	750 milligram q3w Intravenous use	05-SEP-2024 17:56 to 18-APR-2025 11:03 7 months 12 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
								17 hrs 7 min	

Concomitant Medication(s): | BEVACIZUMAB (S) | Entecavir (C) | Metoprolol succinate (C) | Ademetionine 1,4-butanedisulfonate (C) | Losartan potassium and hydrochlorothiazide (C) | Leucogen (C) | Ursodeoxycholic acid (C)

SOC:General disorders and administration site conditions

2023A253789	KOREA, REPUBLIC OF 73.8 Years Male	**Fatigue (Fatigue)***	Recovering	26-Oct-2023 18 weeks	MEDI5752	Infusion	750 milligram q3w	03-AUG-2023 to 03-AUG-2023	Periodic Report Comment. Patient experienced fatigue, Inves: related to study therapy, CCA-Not related.
							Intravenous use	1 day	
						Infusion	750 milligram q3w	05-OCT-2023 to 05-OCT-2023	
							Intravenous use	1 day	
						Infusion	750 milligram q3w	11-SEP-2023 to 11-SEP-2023	
							Intravenous use	1 day	
						Infusion	750 milligram q3w	13-JUL-2023 to 13-JUL-2023	
							Intravenous use	1 day	
						Infusion	750 milligram q3w	22-JUN-2023 to 22-JUN-2023	
							Intravenous use	1 day	
						Infusion	750 milligram q3w	24-AUG-2023 to 24-AUG-2023	
							Intravenous use	1 day	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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): LENVATINIB (S) | | Carvedilol (C) | Dapagliflozin (C) | Vogli m (C) | Gl pitavastatin calcium (C) | Loperamide hydrochloride (C) | Ursodeoxycholic acid (C) | Lacticare hc (C) | Levocetirizine hydrochloride (C) | Camostat mesilate (C) | Mypol (C) | Synthyroxine (C) | Sama Tantum gargle (C) | Lanopepden mesilate (C)									
202410GLO019433KR	KOREA, REPUBLIC OF 58 Years Male	**Sudden cardiac death (Sudden cardiac death)*** Adrenal insufficiency (Adrenal insufficiency)	Fatal	25-Sep-2025 1 year 6 months 21 days	LENVATINIB	Capsule	Oral use	08-OCT-2024 to	
						Capsule	Oral use	09-NOV-2024 to	
						Capsule	Oral use	15-OCT-2024 to	
						Capsule	Oral use	21-SEP-2024 to	
						Capsule	Oral use	26-AUG-2025 to	
						Capsule	Oral use	28-JAN-2025 to	
						Capsule	Oral use	29-MAY-2024 to	
						Capsule	12 milligram q3w Oral use	05-MAR-2024 to 2 months 24 days	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
						Capsule	12 milligram q3w Oral use	08-MAY-2024 to	
						Capsule	12 milligram q3w Oral use	17-APR-2024 to	
						Capsule	12 milligram q3w Oral use	28-MAR-2024 to	
						Capsule	4 milligram q3w Oral use	01-JUL-2025 to	
						Capsule	4 milligram q3w Oral use	02-SEP-2025 to	
						Capsule	4 milligram q3w Oral use	03-DEC-2024 to	
						Capsule	4 milligram q3w Oral use	07-FEB-2025 to	
						Capsule	4 milligram q3w Oral use	08-APR-2025 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
						Capsule	4 milligram q3w Oral use	10-JUN-2025 to	
						Capsule	4 milligram q3w Oral use	12-AUG-2025 to	
						Capsule	4 milligram q3w Oral use	12-NOV-2024 to	
						Capsule	4 milligram q3w Oral use	14-JAN-2025 to	
						Capsule	4 milligram q3w Oral use	20-MAY-2025 to	
						Capsule	4 milligram q3w Oral use	21-MAR-2025 to	
						Capsule	4 milligram q3w Oral use	22-JUL-2025 to	
						Capsule	4 milligram q3w Oral use	24-DEC-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
						Capsule	4 milligram q3w Oral use	27-AUG-2025 to	
						Capsule	4 milligram q3w Oral use	28-FEB-2025 to	
						Capsule	4 milligram q3w Oral use	29-APR-2025 to	
						Capsule	4 milligram q3w Oral use	29-JAN-2025 to	
						Capsule	8 milligram q3w Oral use	04-JUN-2024 to 2 months 24 days	
						Capsule	8 milligram q3w Oral use	06-NOV-2024 to	
						Capsule	8 milligram q3w Oral use	07-AUG-2024 to	
						Capsule	8 milligram q3w Oral use	17-JUL-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
						Capsule	8 milligram q3w Oral use	26-JUN-2024 to	
						Capsule	8 milligram q3w Oral use	26-SEP-2024 to 12 days	
						Capsule	8 milligram q3w Oral use	28-AUG-2024 to 24 days	
		Sudden cardiac death (Sudden cardiac death)* Adrenal insufficiency (Adrenal insufficiency)*	Fatal	25-Sep-2025 1 year 6 months 19 days 9 hrs 10 min	MEDI5752	Infusion	500 milligram q3w Intravenous use	04-JUN-2024 16:00 to 23-SEP-2025 15:55 1 year 3 months 18 days 23 hrs 55 min	
						Infusion	500 milligram q3w Intravenous use	05-MAR-2024 14:50 to 05-MAR-2024 15:50 1 hr	
						Infusion	500 milligram q3w Intravenous use	07-MAY-2024 15:40 to 08-APR-2025 17:40 11 months 1 day 2 hrs	
						Infusion	500 milligram q3w Intravenous use	16-APR-2024 16:40 to 16-APR-2024 18:40 2 hrs	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	500 milligram q3w Intravenous use	27-MAR-2024 16:37 to 27-MAR-2024 19:00 2 hrs 23 min	
Concomitant Medication(s): MEDI5752 (S) | | Tenofovir alafenamide (C) | Methylprednisolone (C) | Chlorpheniramine maleate (C) | Ebastine (C) | Levocetirizine HCL (C) | Methylprednisolone aceponate (C) | Ultracet er (C) | Baclan (C) | Dages (C) | Motilitone (C) | Clobetasol propionate (C) | Desowen (C) | Mupirocin (C) | Urea (C) | Ultracet (C) | Furuson (C) | Levotin (C) | Macperan (C) | Magnesium sulfate (C) | Neurontin (C) | Fexuclue (C)									
2024A101801	CHINA 77 Years Male	**Malaise (Malaise)***	Recovered	12-Apr-2024 nk	BEVACIZUMAB	Infusion		to	Periodic Report Comment. Patient experienced malaise. INV; related to study therapy Bevacizumab and Medi5752, comp: not related to study therapy Bevacizumab and Medi5752.
						Infusion	Intravenous use	20-JAN-2024 to 20-JAN-2024 1 day	
						Infusion	741 milligram qw Intravenous use	04-JUL-2024 to 04-JUL-2024 1 day	
						Infusion	741 milligram qw Intravenous use	13-JUN-2024 to 13-JUN-2024 1 day	
						Infusion	741 milligram qw Intravenous use	23-MAY-2024 to 23-MAY-2024 1 day	
						Infusion	741 milligram qw Intravenous use	25-JUL-2024 to 25-JUL-2024 1 day	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	844.5 milligram qw	08-FEB-2024 to 08-FEB-2024	
							Intravenous use	1 day	
						Infusion	844.5 milligram qw	11-APR-2024 to 11-APR-2024	
							Intravenous use	1 day	
						Infusion	844.5 milligram qw	21-MAR-2024 to 21-MAR-2024	
							Intravenous use	1 day	
						Infusion	844.5 milligram qw	29-FEB-2024 to 29-FEB-2024	
							Intravenous use	1 day	
					MEDI5752	Infusion		to	
						Infusion		20-JAN-2024 to 20-JAN-2024	
							Intravenous use	1 day	
						Infusion	500 milligram qw	04-JUL-2024 to 04-JUL-2024	
							Intravenous use	1 day	
						Infusion	500 milligram qw	08-FEB-2024 to 08-FEB-2024	
							Intravenous use	1 day	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	500 milligram qw Intravenous use	11-APR-2024 to 11-APR-2024 1 day	
						Infusion	500 milligram qw Intravenous use	13-JUN-2024 to 13-JUN-2024 1 day	
						Infusion	500 milligram qw Intravenous use	21-MAR-2024 to 21-MAR-2024 1 day	
						Infusion	500 milligram qw Intravenous use	23-MAY-2024 to 23-MAY-2024 1 day	
						Infusion	500 milligram qw Intravenous use	25-JUL-2024 to 25-JUL-2024 1 day	
						Infusion	500 milligram qw Intravenous use	29-FEB-2024 to 29-FEB-2024 1 day	
Concomitant Medication(s): MEDI5752 (S) | | Calcium dobesilate (C) | Bisoprolol fumarate (C) | Rosuvastatin calcium kaken (C) | Valsartan hydrochlorothiazide krka (C) | Acarbose (C) | Dapagliflozin (C) | Finasteride (C) | Insulin glargine (C) | Metformin hydrochloride (C) | REPAGLINIDA EDIGEN (C) | ENTECAVIR (C) | Compound glycyrrhizin (C) | Diammonium glycyrrhizinate (C) | Anestezol (C)									
2024A105109	HONG KONG 71 Years Male	**Pyrexia (Fever)***	Recovered	01-May-2024 22 days	LENVATINIB	Capsule	12 milligram qd Oral use	10-APR-2024 to 12-JUN-2024 2 months 3 days	Periodic Report Comment. male patient experienced fever-serious related to study therapy CCA not related to study therapy.

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
						Capsule	8 milligram qd Oral use	09-JUL-2024 to 19-SEP-2024	
					MEDI5752	Infusion	500 milligram q3w Intravenous use	09-JUL-2024 to 09-JUL-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	09-MAY-2024 to 09-MAY-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	10-APR-2024 to 10-APR-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	16-SEP-2024 to 16-SEP-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	29-MAY-2024 to 29-MAY-2024 1 day	
						Infusion	750 milligram q3w Intravenous use	31-JUL-2024 to 31-JUL-2024 1 day	

Concomitant Medication(s): MEDI5752 (S) | | AMOXYCILLIN (C) | Augmentin (C) | Entecavir (C) | Dopamine HCL (C) | Clavulanic acid (C) | Cotrimoxazole (C) | Cotrimoxazole (C) | Phosphate sandoz (C) | Meropenem (C) | Urea (C) | Gabapentin (C) | Calamine (C) | Propranolol HCL (C) | Tioconazole (C) | Thyroxine sodium (C) | Tamsulosin HCL (C) | Simvastatin (C) | Paraffin soft (C) | Paracetamol (C) | Mometasone furoate (C) | Liquid paraffin (C) | Lactulose (C) | Aspirin (C) | Crotamiton (C) | Fucicort (C) | Pantoprazole (C) | Bisacodyl (C)

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
2024A188906	HONG KONG 71 Years Male	**Pyrexia (Fever)***	Recovered	16-Aug-2024 4 months 7 days	LENVATINIB	Capsule	12 milligram qd Oral use	10-APR-2024 to 11-JUN-2024 2 months 2 days	Periodic Report Comment. Patient experienced fever and hypotention.Investigator: related to study therapy. CCA:not related to study therapy.
						Capsule	8 milligram qd Oral use	09-JUL-2024 to 25-SEP-2024 2 months 17 days	
		Pyrexia (Fever)* Wound infection (Wound infection)*	Recovered	16-Aug-2024 4 months 7 days	MEDI5752	Infusion	500 milligram qw Intravenous use	10-APR-2024 to 09-JUL-2024 3 months	
						Infusion	500 milligram qw Intravenous use	31-JUL-2024 to 31-JUL-2024 1 day	
						Infusion	750 milligram qw Intravenous use	31-JUL-2024 to 31-JUL-2024 1 day	

Concomitant Medication(s): MEDI5752 (S) | | Entecavir (C) | Propranolol HCL (C) | Simvastatin (C) | Crotamitonum (C) | Gabapentin (C) | Paracetamol (C) | Aspirin (C) | Vaselina liquida (C) | Ckd mometasone furoate (C) | Ag pantoprazole sodium (C) | Paraffin (C) | Cotrimoxazole (C) | Abbott dopamine hcl (C) | Meropenem (C) | Levothyroxine sodium (C) | Hydrocortisone (C) | Urea (C) | Apo tamsulosin sr (C) | Zinc phosphate (C) | Bisacodyl (C) | Apo-lactulose (C) | Fucicort (C) | Calamine (C) | Augmentin (C) | Crotamiton (C) | Mometasone furoate (C) | Liquid paraffin (C) | Pantoprazole (C) | Dopamine HCL (C) | Thyroxine sodium (C) | Tioconazole (C) | Tamsulosin HCL (C) | Phosphate sandoz (C)

SOC:Hepatobiliary disorders

202409GLO007812CN	CHINA 50 Years Male	**Hepatic function abnormal (Function liver abnormal)***	Recovered	11-Sep-2024 8 months 4	AZD2936	Solution	750 milligram q3w	08-JAN-2024 to 08-JAN-2024	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
				days				1 day	
						Solution	750 milligram q3w	18-DEC-2024 to 18-DEC-2024	
								1 day	
						Solution	750 milligram q3w	20-FEB-2025 to 20-FEB-2025	
								1 day	
						Solution	750 milligram q3w	27-JAN-2025 to 27-JAN-2025	
								1 day	
						Solution	750 milligram q3w	02-OCT-2024 to 02-OCT-2024	
							Intravenous use	1 day	
						Solution	750 milligram q3w	05-SEP-2024 to 05-SEP-2024	
							Intravenous use	1 day	
						Solution	750 milligram q3w	07-NOV-2024 to 07-NOV-2024	
							Intravenous use	1 day	
						Solution	750 milligram q3w	21-OCT-2024 to 21-OCT-2024	
							Intravenous use	1 day	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
						Solution	750 milligram q3w Intravenous use	28-NOV-2024 to 28-NOV-2024 1 day	
Concomitant Medication(s): | BEVACIZUMAB (S) | Nifedipine (C) | Haemocoagulase (C) | Metoprolol (C) | Codeine (C) | Esomeprazole (C) | Tuberculin (C) | Glycyrrhizin (C) | Indapamide (C) | Methylprednisolone (C) | Entecavir (C) | Pu ji zhi chuang (C) | San qi hua zhi (C)									
202412GLO016157JP	JAPAN 55 Years Female	**Hepatic function abnormal (Hepatic dysfunction NOS)***	Recovered	18-Dec-2024 11 months 2 days	AZD2936	Solution	750 milligram q3w Intravenous use	17-JAN-2024 to 27-NOV-2024 10 months 11 days	Patient experienced liver dysfunction: event related to Azd2936, not related to Cisplatin and Gemcitabine. CCA: event related to Azd2936, not related to Cisplatin and Gemcitabine.
Concomitant Medication(s): | CISPLATIN (S) | GEMCITABINE (S) | Betamethasone dipropionate (C) | Fexofenadine hydrochloride (C) | Heparinoid (C) | Montelukast sodium (C) | Relvar ellipta (C) | Clotiazepam (C) | Metoclopramide (C) | Toledomin (C) | Triazolam (C) | Cortril (C) | Sodium ferrous citrate (C) | Lendormin (C) | Dexamethasone sodium phosphate (C) | Magnesium sulfate (C) | Palonosetron hydrochloride (C) | Soldem 3a (C) | Calonal (C) | Ciprofloxacin (C) | Amlodipine besilate (C) | Predonine (C) | Lansoprazole (C) | Trazodone hydrochloride (C) | Prednisolone (C)									
2024A104575	CHINA 53 Years Male	**Liver injury (Liver injury)***	Recovered	29-Apr-2024 18 days 20 hrs 26 min	MEDI5752	Infusion	500 milligram q3w Intravenous use	10-APR-2024 11: 10 to 10-APR-2024 12:09 59 min	Periodic Report Comment. Patient experienced liver injury. INV; related to study therapy Medi5752, Bevacizumab, comp: not related to study therapy Medi5752, Bevacizumab.
					BEVACIZUMAB	Infusion	943.5 milligram q3w Intravenous use	10-APR-2024 to 10-APR-2024 1 day	
						Infusion	943.5 milligram q3w Intravenous use	30-APR-2024 to 30-APR-2024 1 day	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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): | BEVACIZUMAB (S) | ENTECAVIR (C) | Tenofovir amibufenamide (C) | Magnesium Isoglycyrrhizinate (C) | PROPACETAMOL (C) | Ranitidine hydrochloride (C) | Reduced glutathione sodium (C) | Compound glycyrrhizin (C) | SILYMARIN (C) | CEFIXIME (C) | LEVOFLOXACIN (C) | BICYCLOL (C) | Magnesium Isoglycyrrhizinate (C) | Methylprednisolone sodium succinate (C) | METHYLPREDNISOLONE (C) | OMEPRAZOLE (C) | Entecavir (C) | Tenofovir amibufenamide (C) | Magnesium Isoglycyrrhizinate (C) | Propacetamol (C) | Ranitidine hydrochloride (C) | Reduced Glutathione (C) | Compound glycyrrhizin (C) | Silymarin (C) | Cefixime (C) | Levofloxacin (C)									
2024A139174	CHINA 52 Years Male	**Hepatic function abnormal (Impaired liver function)***	Not Recovered	05-Jun-2024 3 weeks 6 days	MEDI5752	Infusion Infusion	750 milligram q3w Intravenous use 750 milligram q3w Intravenous use	09-MAY-2024 to 30-MAY-2024 to	Periodic Report Comment. The patient experienced CTC grade threeliver function impairment , Invst Related to study therapy, CCC not related.
Concomitant Medication(s): | ENTECAVIR (C) | CARBAZOCHROME (C) | Codeine phosphate and platycodon tablets (C) | Act Esomeprazole (C) | Ambroxol + amoxicilina (C) | AG CELECOXIB (C) | Bai xiao (C) | Amantadine compound (C) | Ambroxol + clembuterol (C) | Allobarbital (C) | AMCAL BUDESONIDE HAYFEVER (C) | Compound allantoin (C) | CEFUFARM (C) | HONGUIL (C) | KECAP (C) | 7 KETO DHEA BB PHARM (C) | MIDECAMYCIN (C) | Aceclofenac (C) | Acide ursodeoxycholique (C) | ADEMETIONIN (C) | 2-aminoethyl dihydrogen phosphate magnesium (C) | POLYENE (C) | Loratadine (C) | Calamine lotion phenolated (C) | Ambroxol acefyllinate (C) | MIZOLASTINE (C) | Tramadol hydrochloride sustained release tablets (ii) (C) | ESTAZOLAM (C) | ARROW BUDESONIDE (C) | Acetylcysteine (C) | APO-CEFUROXIME (C) | Amplio Concentrated EPA / DHA (C) | 2-ETHYLHEXYL HYDROGEN SULFATE (C) | HEMOCOAGULASE (C) | HYDROPREDNISONE (C) | ALTI-IPRATROPIUM (C) | Da bu yao jiu (C) | Amlong h (C) | 3rd age senior multi (C) | Accomin multivitamin (C) | Acesulfame potassium (C) | Abbott rabeprazole (C) | Abatacept Recombinant (C) | Aconitum napellus extract (C) | Actraphan human (C) | Zinplex calcium (C) | PLANJIN (C) | Abtei vitamin c (C) | Dongkoo piperacillin (C) | Amylocaine (C) | ((dimethylarsino)oxy)sodium as-oxide (C) | Aceglutamide (C) | APO-KETOTIFEN (C) | 3,3'-Diindolylmethane (C) | Acetylsalicylic acid (C) | Human immunoglobulin against tick-borne encephalitis (C) | 4-amino-3-hydroxybutyric acid (C) | Alemtuzumab (C) | Ornithine (C) | Arginine (C) | 5fu + heparin (C) | Hypurin protamine zinc (C) | Paracetamol, pseudoephedrine hydrochloride and chlorphenamine maleate tablets(I) (C) | ACT FLUCONAZOLE (C) | ETAMSYLAT (C) | Compound alpha ketoacid (C) | Chloroprednisone acetate (C) | Bai 101 (C) | Chininsulfat KSA (C) | Methotrexate (C) | Zhi bai di huang (C) | Aminophylline (C) | Levofloxacin (C) | Lidocaine hydrochloride (C) | Propofol (C) | Glycyrrhizin (C)									
2024A184620	SPAIN 66.6 Years Male	**Immune-mediated hepatitis (Immune-mediated hepatitis)***	Recovered	12-Aug-2024 3 months 15 days	BEVACIZUMAB	Infusion	1167 milligram q3w Intravenous use	29-APR-2024 to 12-AUG-2024 3 months 15 days	Periodic Report Comment. The patient experienced ctc grade three immune-mediated hepatitis , investigator causality

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	15 milligram q3w Intravenous use	12-AUG-2024 to	related with study therapy medi5752 and bevacizumab and cca not related to study therapy.
Concomitant Medication(s): MEDI5752 (S) | | Aliskiren Fumarate (C) | 5-oxyanthranilic acid (C) | 21st century folic acid (C) | Aig esomeprazole (C) | Ag olmesartan (C) | Alila multivitamin (C) | Ethinylestradiol (C) | Alendronate/cholecalciferol accord (C) | Ascorbic acid (C) | Sulfamethoxazole (C) | Cyanocobalamin (C) | Mycophenolate mofetil (C) | Macrogol 3350 (C) | Apo ondansetron (C) | Aldioxa (C) | Acetylsalicylic acid (C) | Tazobactam (C) | ANIDULAFUNGIN (C) | (6S)-5-methyltetrahydrofolate glucosamine (C) | Artemisia dracunculus (C) | 5-Methyltetrahydrofolate (C)									
2024A201771	HONG KONG 55.7 Years Male	**Autoimmune hepatitis (Autoimmune hepatitis)***	Recovered with Sequelae	04-Sep-2024 11 months	MEDI5752	Infusion	500 milligram q3w Intravenous use	05-OCT-2023 to JUL-2024	Periodic Report Comment. Patient experienced autoimmune hepatitis ,Inves: related to Medi5752
Concomitant Medication(s): | BEVACIZUMAB (S) | Amlodipine besylate (C) | Entecavir (C) | Calcium carbonate (C) | Tenofovir (C) | Lisinopril (C) | Methylprednisolone (C) | Prednisolone (C) | Potassium chloride (C)									
202501GLO009488CN	CHINA 60 Years Male	**Drug-induced liver injury (Drug-induced liver injury)***	Recovered	09-Jan-2025 nk	AZD2936	Solution	750 milligram q3w Intravenous use	06-MAY-2025 to	Periodic Report Comments. The patient experienced Liver damage. Investigator causality related to Medi5752, not related to AZD2936 and Bevacizumab. CCA not related to Medi5752, AZD2936 and Bevacizumab.; Periodic Report Comments. The patient experienced Liver damage. Investigator Causality: Related CC: Related.
						Solution	750 milligram q3w Intravenous use	14-MAR-2025 to	
						Solution	750 milligram q3w Intravenous use	21-FEB-2025 to	
						Solution	750 milligram q3w Intravenous use	24-JAN-2025 to 3 months 13 days	

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

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EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
					BEVACIZUMAB	Infusion	15 milligram q3w	24-JAN-2025 to 07-AUG-2025	
							Intravenous use	6 months 15 days	
						Infusion	915 milligram q3w	06-MAY-2025 to	
							Intravenous use		
						Infusion	915 milligram q3w	07-AUG-2025 to	
							Intravenous use		
						Infusion	915 milligram q3w	12-SEP-2025 to	
							Intravenous use		
						Infusion	915 milligram q3w	14-MAR-2025 to	
							Intravenous use		
						Infusion	915 milligram q3w	18-JUL-2025 to	
							Intravenous use		
						Infusion	915 milligram q3w	21-FEB-2025 to	
							Intravenous use		
						Infusion	915 milligram q3w	24-JAN-2025 to	
							Intravenous use		

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

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Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

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						Infusion	915 milligram q3w Intravenous use	26-JUN-2025 to	
Concomitant Medication(s): MEDI5752 (S) | | BEVACIZUMAB (S) | Amlodipine besylate (C) | Entecavir (C) | Tenofovir disoproxil fumarate (C) | Dexamethasone sodium phosphate (C) | Promethazine hydrochloride (C) | Vitamin b6 (C) | Vitamin C (C) | Compound glycyrrhizin (C) | Methylprednisolone (C)									
202501GLO019204KR	KOREA, REPUBLIC OF 53 Years Male	**Hepatitis toxic (Hepatitis toxic)***	Recovered	21-Jan-2025 9 months 14 days	MEDI5752	Infusion	750 milligram q3w Intravenous use	08-APR-2024 to 24-DEC-2024 8 months 17 days	Periodic Report Comments. Patient had TOXIC HEPATITIS . MEDI5752 was Discontinued. Investigator: event related MEDI5752.
Concomitant Medication(s): | Cisplatin (C) | Gemcitabine (C) | Macperan (C) | Solondo (C) | Foipan (C) | Dexamethasone (C) | Nucomyt (C) | Ebastel (C) | Tylenol (C)									
202503GLO006983CN	CHINA Male	**Liver injury (Liver injury)***	Recovered	10-Mar-2025 22 days	MEDI5752	Infusion	1500 milligram Intravenous use	17-FEB-2025 to	Periodic Report Comments. Patient experienced Liver injury, Inv, related to MEDI5752, AZD2936 and BEVACIZUMAB, the sponsor did not find the evidence to suggest a reasonable possibility of a causal relationship between the event and MEDI5752, AZD2936 and BEVACIZUMAB.
Concomitant Medication(s): | AZD2936 (S) | BEVACIZUMAB (S) | Ademetionine (C) | Tenofovir (C) | Atorvastatin (C) | Esomeprazole (C) | Lactulose (C) | Polyene phosphatidylcholine (C) | Silymarin (C) | Rosuvastatin (C)									

SOC:Infections and infestations

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

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EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
202411GLO007981TW	TAIWAN 55.9 Years Male	**Pneumonia (Pneumonia)***	Not Recovered	12-Nov-2024 6 months 14 days	MEDI5752	Infusion	750 milligram q3w Intravenous use	05-JUL-2024 to 05-JUL-2024 1 day	
						Infusion	750 milligram q3w Intravenous use	08-OCT-2024 to 08-OCT-2024 1 day	
						Infusion	750 milligram q3w Intravenous use	11-JUN-2024 to 11-JUN-2024 1 day	
						Infusion	750 milligram q3w Intravenous use	19-SEP-2024 to 19-SEP-2024 1 day	
						Infusion	750 milligram q3w Intravenous use	21-MAY-2024 to 21-MAY-2024 1 day	
						Infusion	750 milligram q3w Intravenous use	30-APR-2024 to 30-APR-2024 1 day	
						Infusion	750 milligram q3w Intravenous use	30-AUG-2024 to 30-AUG-2024 1 day	
						Infusion	750 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

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Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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): | Cisplatin (S) | Gemcitabine (S) | Glimepiride (C) | 17-amino acid (C) | Valsartan (C) | Empagliflozin (C) | Tenofovir alafenamide (C) | Acetaminophen (C) | Suwell (C) | Heparin (C) | Betamethasone (C) | Diphenhydramine (C) | Metoclopramide (C) | Palonosetron (C) | Netupitant (C) | Prochlorperazine (C) | Betamethasone valerate (C) | Cetirizine (C) | Methimazole (C) | Nebivolol (C) | Pitavastatin (C) | Mebhydrolin (C) | Platelets (C) | Filgrastim (C) | Megestrol (C) | Insulin Actrapid (C) | Acetylcysteine (C) | Lactated ringer (C) | Cefepime (C) | Piperacillin (C) | Ciprofloxacin (C) | Rinderon (C) | Levothyroxine (C) | Dimethicone (C) | Mosapride (C)									
202411GLO009091TW	TAIWAN 54 Years Male	**Pneumonia (Pneumonia)***	Not Recovered	12-Nov-2024 5 months 23 days	MEDI5752	Infusion		08-OCT-2024 to 08-OCT-2024 1 day	Periodic Report Comment. The patient experienced PNEUMONIA.: not related to Volrustomig (MEDI5752), GEMCITABINE and CISPLATIN.
						Infusion		19-SEP-2024 to 19-SEP-2024 1 day	
						Infusion		30-OCT-2024 to 30-OCT-2024 1 day	
						Infusion	q3w Intravenous use	30-APR-2024 to 30-APR-2024 1 day	
						Infusion	750 milligram q3w Intravenous use	to	
						Infusion	750 milligram q3w Intravenous use	05-JUL-2024 to 05-JUL-2024 1 day	
						Infusion	750 milligram q3w	11-JUN-2024 to 11-JUN-2024	

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

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							Intravenous use	1 day	
						Infusion	750 milligram q3w	30-AUG-2024 to 30-AUG-2024	
							Intravenous use	1 day	
Concomitant Medication(s): | GEMCITABINE (S) | CISPLATIN (S)									
202412GLO017237TW	TAIWAN 69 Years Male	**Encephalitis (Encephalitis)***	Recovered	17-Dec-2024 3 months 29 days	MEDI5752	Infusion	500 milligram q3w	19-AUG-2024 to 05-DEC-2024	initial. Male patient with event: SUSPECT ISCHEMIC STROKE, Inv causality: related to Bevacizumab, CCA: not related.
							Intravenous use	3 months 17 days	
Concomitant Medication(s): | BEVACIZUMAB (S) | Esomeprazole magnesium (C) | Tenofovir alafenamide (C) | Tamsulosin HCL (C) | Dextromethorphan (C) | Cortisone acetate (C) | Aspirin (C) | Dextrose (C) | Pregabalin (C) | Rabeprazole (C) | Tramadol HCL (C) | Cinnarizine (C) | Insulin (C) | Vitamin b (C) | Labetalol (C) | Methylprednisolone (C) | Amlodipine (C) | Co-trimoxazole (C) | Nystatin (C) | Prednisolone (C)									
2024A093726	CHINA 66 Years Male	**Pneumonia (Pneumonia)***	Not Recovered	01-Apr-2024 9 months 26 days	LENVATINIB	Capsule	8 milligram qd	07-JUN-2023 to 05-JUN-2024	Periodic Report Comment. Patient experienced pneumonia. Inv: Related. Company: Not related. Seriousness: Yes.
							Oral use	11 months 30 days	
					MEDI5752	Infusion	750 milligram q3w	07-JUN-2023 to 26-JUN-2024	
							Intravenous use	1 year 20 days	
Concomitant Medication(s): MEDI5752 (S) | | Compound glycyrrhizin (C) | Reduced glutathione sodium (C) | Bicyclol (C) | Promethazine hydrochloride (C) | Promethazine hydrochloride (C) | Dexamethasone sodium (C) | Olanzapin (C) | Aciclovir (C) | Aciclovir (C) | Glycyrrhizin (C) | Glutathione (C) | Entecavir (C) | Leucogen (C) | Tenofovir alafenamide fumarate (C) | Torasemide (C) | Polymyxin b (C) | Mecobalamin (C) | Pregabalin (C) | Dexamethasone sodium phosphate (C) | Dexamethasone sodium phosphate (C) | Palonosetron hydrochloride (C) | Avatrombopag maleate (C) | Olanzapine (C) | Olanzapine (C) | Ceftazidime (C) | Diammonium glycyrrhizinate (C) | Methylprednisolone sodium succinate (C) | Amlodipine besylate (C) | Cefaclor (C) | Ceftriaxone sodium (C)									

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

Project ID: D7987

Study ID: D7987C00001

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Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary Cancer

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2024A141529	SPAIN 61 Years Male	**Escherichia bacteraemia (Escherichia coli bacteremia)***	Recovered	14-Jun-2024 nk	CISPLATIN	Infusion		to	Periodic Report Comment. Patient experience e. coli bacteremia serious and Inv. related to Cisplatin, Gemcitabine CCA: Not related to study therapy.
						Infusion	25 milligram/sq. meter qw Intravenous use	09-JAN-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	06-FEB-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	07-MAY-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	09-APR-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	11-JUN-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	12-MAR-2024 to	

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						Infusion	25 milligram/sq. meter qw Intravenous use	14-MAY-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	16-JAN-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	20-FEB-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	23-APR-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	26-MAR-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	27-FEB-2024 to	
						Infusion	25 milligram/sq. meter qw	28-MAY-2024 to	

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							Intravenous use		
						Infusion	25 milligram/sq. meter qw	30-JAN-2024 to	
							Intravenous use		
						Infusion	25 milligram/sq. meter qw	30-JUL-2024 to	
							Intravenous use		
					GEMCITABINE	Infusion		to	
						Infusion	1000 milligram/sq. meter qw	09-JAN-2024 to	
							Intravenous use		
						Infusion	1000 milligram/sq. meter qw	06-FEB-2024 to	
							Intravenous use		
						Infusion	1000 milligram/sq. meter qw	07-MAY-2024 to	
							Intravenous use		
						Infusion	1000 milligram/sq.	09-APR-2024 to	

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							meter qw Intravenous use		
						Infusion	1000 milligram/sq. meter qw Intravenous use	11-JUN-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	12-MAR-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	14-MAY-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	16-JAN-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	20-FEB-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	23-APR-2024 to	

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						Infusion	1000 milligram/sq. meter qw Intravenous use	26-MAR-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	27-FEB-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	28-MAY-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	30-JAN-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	30-JUL-2024 to	
Concomitant Medication(s): | GEMCITABINE (S) | MEDI5752 (S) | ALLOPURINOL (C) | Acetylsalicylic acid (C) | Ag bisoprolol (C) | Act metformin (C) | PANCREATINE MYLAN (C) | ADCO VALSARTAN (C) | PARACETAMOL (C) | Aig esomeprazole (C) | Ag azithromycin (C) | BEMIPARIN (C) | BUDESONIDE (C) | CEFTRIAXONE (C) | DEXAMETHASONE (C) | Ipratropium bromide and salbutamol sulfate (C) | LEVOFLOXACINO (C) | AMIODARONE (C) | Actraphan human (C) | Potassium Hydrogen Carbonate (C) | MAGNESIUM (C) | APO-CEFUROXIME (C) | Hanooxygen E (C)									
2024A167118	TAIWAN 55.6	**Pneumonia (Pneumonia)***	Recovered	21-Jul-2024 2 months 22 days	MEDI5752	Infusion	75 milligram qw	30-APR-2024 to 30-AUG-2024	Periodic Report Comment. Patient expereinced Pneumonitis-Inv: related to

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
	Years Male						Intravenous use	4 months 1 day	Medi5752 and study procedure, not related to Gemcitabine, Cisplatin. CCA not related.
Concomitant Medication(s): | Cisplatin (C) | Gemcitabine (C) | Glimepiride (C) | Empagliflozin (C) | Acetaminophen (C) | Heparin (C) | Betamethasone (C) | Diphenhydramine (C) | Metoclopramide (C) | Palonosetron (C) | Mebhydrolin (C) | Cetirizine (C) | Methimazole (C) | Apo nebivolol (C) | Acetaminophen and dextromethorphan hydrobromide (C) | Rinderon (C) | Abamox (C) | Methylprednisolone (C) | Actrapid insulin novo (C) | Acetylcysteine (C) | Cefepime (C) | Piperacillin (C) | Cefoperazon (C) | Ciprofloxacin (C) | Prednisolone (C)									
202507GLO014205GB	UNITED KINGDOM 74 Years Male	**Sepsis (Sepsis)***	Recovered	02-Jul-2025 nk	LENVATINIB	Capsule	Oral use	to	Periodic Report Comments. The investigator did not consider that there was a reasonable possibility of a causal relationship between the study therapy Azd2936, Bevacizumab and the following event(s): sepsis. The investigator considered that there was a reasonable possibility of a causal relationship between the study therapy Lenvatinib 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). sepsis
Concomitant Medication(s): AZD2936 (S) | BEVACIZUMAB (S) | | Amlodipine (C) | Metformin (C) | Aspirin (C) | Atorvastatin (C) | Irbesartan (C) | Alogliptin (C) | Oramorph (C) | Paracetamol (C) | Entecavir (C) | Scandishake mix (C) | Magnesium aspartate (C) | Doxazosin (C)									
202511GLO004429TW	TAIWAN 68.8 Years Male	**Cellulitis (Cellulitis)***	Not Recovered	03-Nov-2025 nk	BEVACIZUMAB	Infusion	1027.5 milligram q3w Intravenous use	31-OCT-2025 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	916.5 milligram q3w Intravenous use	08-AUG-2025 to	
						Infusion	918 milligram q3w Intravenous use	27-JUN-2025 to	
						Infusion	928.5 milligram q3w Intravenous use	06-JUN-2025 to	
						Infusion	939 milligram q3w Intravenous use	16-MAY-2025 to	
						Infusion	945 milligram q3w Intravenous use	29-AUG-2025 to	
						Infusion	975 milligram q3w Intravenous use	19-SEP-2025 to	
					MEDI5752	Infusion	1500 milligram q3w Intravenous use	23-APR-2025 to	
						Infusion	750 milligram q3w Intravenous use	09-OCT-2025 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	750 milligram q3w Intravenous use	18-JUL-2025 to	
					RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	06-JUN-2025 to	
						Solution	750 milligram q3w Intravenous use	08-AUG-2025 to	
						Solution	750 milligram q3w Intravenous use	16-MAY-2025 to	
						Solution	750 milligram q3w Intravenous use	19-SEP-2025 to	
						Solution	750 milligram q3w Intravenous use	27-JUN-2025 to	
						Solution	750 milligram q3w Intravenous use	29-AUG-2025 to	
						Solution	750 milligram q3w Intravenous use	31-OCT-2025 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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): MEDI5752 (S) | RILVEGOSTOMIG (S) | | Metformin (C) | Fenofibrate (C) | Sennoside (C) | Tamsulosin (C) | Tenofovir alafenamide (C) | Esomeprazole magnesium (C) | Amlodipine besylate (C) | Levothyroxine sodium (C) | Lorazepam (C) | Acetaminophen (C) | Chlorzoxazone (C) | Influenza vaccine inactivated (C) | Furosemide (C) | Silver sulfadiazine (C) | Tetracycline HCL (C) | Dapagliflozin | Saxagliptin (C) | Ampicillin (C)									
SOC:Injury, poisoning and procedural complications									
202410GLO028532CN	CHINA 57 Years Male	**Infusion related reaction (Infusion related reaction)***	Recovered	30-Oct-2024 1 month 27 days	AZD2936	Solution	750 milligram q3w Intravenous use	04-SEP-2024 to 04-SEP-2024 1 day	periodic report comments. patient experiencing infusion related reaction, investigator causality related, sponsor not related
						Solution	750 milligram q3w Intravenous use	25-SEP-2024 to 25-SEP-2024 1 day	
						Solution	750 milligram q3w Intravenous use	30-OCT-2024 to 30-OCT-2024 1 day	
Concomitant Medication(s): | BEVACIZUMAB (S) | Tenofovir disoproxil fumarate (C) | Amlodipine besylate (C) | Bicyclol (C) | Bacillus lichenformis (C)									
202510GLO018243ES	SPAIN 79.6 Years Male	**Wrist fracture (Wrist fracture)***	Recovered	17-Aug-2025 nk	LENVATINIB	Capsule Oral use		05-FEB-2024 to	
						Capsule Oral use		05-MAR-2025 to	
						Capsule Oral use		11-DEC-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
						Capsule Oral use		11-FEB-2025 to	
						Capsule Oral use		20-NOV-2024 to	
						Capsule Oral use		22-JAN-2025 to	
						Capsule Oral use		22-MAR-2024 to	
						Capsule Oral use		23-SEP-2024 to	
						Capsule Oral use		24-NOV-2023 to	
						Capsule Oral use		29-OCT-2024 to	
						Capsule Oral use		31-DEC-2024 to	
						Capsule Oral use	12 milligram q3w	12-DEC-2023 to	
						Capsule	12 milligram q3w	14-NOV-2023 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
							Oral use		
						Capsule	4 milligram q3w	04-APR-2024 to	
							Oral use		
						Capsule	4 milligram q3w	04-OCT-2024 to	
							Oral use		
						Capsule	4 milligram q3w	05-JUN-2024 to	
							Oral use		
						Capsule	4 milligram q3w	07-AUG-2024 to	
							Oral use		
						Capsule	4 milligram q3w	15-MAY-2024 to	
							Oral use		
						Capsule	4 milligram q3w	18-SEP-2024 to	
							Oral use		
						Capsule	4 milligram q3w	24-APR-2024 to	
							Oral use		

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

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EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
						Capsule	4 milligram q3w Oral use	25-JUN-2024 to	
						Capsule	4 milligram q3w Oral use	27-AUG-2024 to	
						Capsule	8 milligram q3w Oral use	04-JAN-2024 to	
						Capsule	8 milligram q3w Oral use	06-MAR-2024 to	
						Capsule	8 milligram q3w Oral use	13-FEB-2024 to	
						Capsule	8 milligram q3w Oral use	24-JAN-2024 to	
						Capsule	8 milligram q3w Oral use	27-DEC-2023 to	
					MEDI 5752	Infusion	 Intravenous use	to	

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

Project ID: D7987

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Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	500 milligram q3w Intravenous use	04-APR-2024 to	
						Infusion	500 milligram q3w Intravenous use	04-JAN-2024 to	
						Infusion	500 milligram q3w Intravenous use	05-JUN-2024 to	
						Infusion	500 milligram q3w Intravenous use	05-MAR-2025 to	
						Infusion	500 milligram q3w Intravenous use	06-MAR-2024 to	
						Infusion	500 milligram q3w Intravenous use	06-MAY-2025 to	
						Infusion	500 milligram q3w Intravenous use	07-AUG-2024 to	
						Infusion	500 milligram q3w Intravenous use	09-OCT-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

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Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	500 milligram q3w Intravenous use	11-DEC-2024 to	
						Infusion	500 milligram q3w Intravenous use	11-FEB-2025 to	
						Infusion	500 milligram q3w Intravenous use	12-DEC-2023 to	
						Infusion	500 milligram q3w Intravenous use	13-FEB-2024 to	
						Infusion	500 milligram q3w Intravenous use	14-NOV-2023 to	
						Infusion	500 milligram q3w Intravenous use	15-JUL-2025 to	
						Infusion	500 milligram q3w Intravenous use	15-MAY-2024 to	
						Infusion	500 milligram q3w Intravenous use	16-APR-2025 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	500 milligram q3w Intravenous use	18-JUL-2024 to	
						Infusion	500 milligram q3w Intravenous use	18-JUN-2025 to	
						Infusion	500 milligram q3w Intravenous use	19-SEP-2024 to	
						Infusion	500 milligram q3w Intravenous use	20-NOV-2024 to	
						Infusion	500 milligram q3w Intravenous use	22-JAN-2025 to	
						Infusion	500 milligram q3w Intravenous use	24-APR-2024 to	
						Infusion	500 milligram q3w Intravenous use	24-JAN-2024 to	
						Infusion	500 milligram q3w Intravenous use	26-JUN-2024 to	

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

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Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	500 milligram q3w Intravenous use	26-MAR-2025 to	
						Infusion	500 milligram q3w Intravenous use	28-AUG-2024 to	
						Infusion	500 milligram q3w Intravenous use	28-MAY-2025 to	
						Infusion	500 milligram q3w Intravenous use	31-DEC-2024 to	

Concomitant Medication(s): MEDI 5752 (S) | | Diazepam (C) | Timolol (C) | Rabeprazole (C) | Calcifediol (C) | Natecal (C) | Paracetamol (C) | Finasterida (C) | Silodosina (C) | Carvedilol (C) | Lactitol (C) | Atarax (C) | Umeclidinium (C) | Betmiga (C) | Sinemet (C) | Tramadol (C)

SOC:Investigations

2023A201290	CHINA 58 Years Male	**Troponin increased (Cardiac troponin increased)***	Recovered	28-Aug-2023 7 weeks 6 days	BEVACIZUMAB	Infusion	15 milligram/kilogram q3w Intravenous use	04-JUL-2023 to 14-DEC-2023 5 months 11 days	Periodic Report Comment. 58 y. o. male patient with hepatobiliary cancer. Pt exp. increased cardiac troponin. Inv: event related to MEDI5752, Bevacizumab unrelated to Study procedure.
					MEDI5752	Infusion	750 milligram q3w Intravenous use	04-JUL-2023 to 04-JUL-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	750 milligram q3w Intravenous use	04-SEP-2023 to 04-SEP-2023 1 day	
						Infusion	750 milligram q3w Intravenous use	25-JUL-2023 to 25-JUL-2023 1 day	
						Infusion	750 milligram q3w Intravenous use	26-SEP-2023 to 26-SEP-2023 1 day	
Concomitant Medication(s): MEDI5752 (S) | | Entecavir (C) | Tenofovir alafenamide fumarate (C) | Valsartan (C) | Silybin meglumine (C)									
2024A033176	HONG KONG 60.9 Years Male	**Troponin T increased (Troponin T increased)***	Recovered	08-Nov-2023 2 weeks 6 days	MEDI5752	Infusion	500 milligram qw Intravenous use	07-DEC-2023 to	Periodic Report Comment. Patient experienced Troponin T increased, Investigator : related with MEDI5752, not related with Bevacizumab, CCA : not related.
						Infusion	500 milligram qw Intravenous use	07-MAR-2024 to	
						Infusion	500 milligram qw Intravenous use	09-MAY-2024 to	
						Infusion	500 milligram qw Intravenous use	16-FEB-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	500 milligram qw Intravenous use	18-APR-2024 to	
						Infusion	500 milligram qw Intravenous use	19-JAN-2024 to	
						Infusion	500 milligram qw Intravenous use	19-OCT-2023 to	
						Infusion	500 milligram qw Intravenous use	29-DEC-2023 to	
Concomitant Medication(s): BEVACIZUMAB (S) | | Tenofovir (C) | Amlodipine besylate (C) | Potassium chloride (C)									
2024A085744	CHINA 59 Years Male	**Blood bilirubin increased (Bilirubin elevated)*** Hepatic function abnormal (Impaired liver function)*	Not Recovered	25-Mar-2024 6 days 7 hrs 8 min	MEDI5752	Infusion	750 milligram q3w Intravenous use	18-MAR-2024 16:52 to 18-MAR-2024 17:58 1 hr 6 min	Periodic Report Comment. The patient experienced HISTORY OF LIVER DYSFUNCTION WORSENS and ELEVATED BILIRUBIN. Inv: related to study therapy. CCA: not related to study therapy.;Periodic Report Comments. The patient experienced HISTORY OF LIVER DYSFUNCTION WORSENS and ELEVATED BILIRUBIN. Inv: not reported to study therapy. CCA: not related to study therapy.; Periodic Report Comments. Patient experienced events - elevated bilirubin and history of

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

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Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
									liver dysfunction worsens Investigator states event related to Medi5752. Company physician considers event not related to Medi5752.
Concomitant Medication(s): | Compound amino acid injection (18aa) (C) | Etamsylate (C) | Haemocoagulase Agkistrodon (C) | Lidocaine hydrochloride (C) | Tenofovir alafenamide fumarate (C) | Diammonium glycyrrhizinate (C) | Magnesium Isoglycyrrhizinate (C) | Polyene phosphatidylcholine (C) | Tramadol hydrochloride sustained release tablets (ii) (C) | Compound glycyrrhizin (C) | Esomeprazole magnesium (C)									
2024A200396	SPAIN 67 Years Male	**Troponin I increased (Troponin I increased)***	Recovered	30-Aug-2024 2 months 7 days	MEDI5752	Infusion Intravenous use Infusion Intravenous use	500 milligram q3w 500 milligram q3w	10-FEB-2025 to 10-FEB-2025 1 day 24-JUN-2024 to 20-JAN-2025 6 months 28 days	Periodic Report Comment. The patient experienced troponin elevation. Inv: related to Medi5752(medi 5752) and not related with Bevacizumab (bevacizumab), com: related to study therapy.
Concomitant Medication(s): BEVACIZUMAB (S) | | Dapagliflozin (C) | Ag metformin (C) | Acetylsalicylic acid (C) | Ag simvastatin (C) | Insulin glargine (C) | Apo tenofovir (C) | Ag bisoprolol (C) | Act ramipril (C) | Aig esomeprazole (C) | Amorolfine hydrochloride (C) | Calcifediol (C) | Ferroglycine sulfate (C) | Clopidogrel (C) | Atorvastatin (C)									
202501GLO000866CN	CHINA 42 Years Male	**Alanine aminotransferase increased (Alanine aminotransferase increased)***	Recovered	07-Oct-2023 17 days	MEDI5752	Infusion Intravenous use Infusion Intravenous use	500 milligram q3w 500 milligram q3w	21-SEP-2023 to 07-NOV-2024 1 year 1 month 18 days 22-NOV-2024 to 12-FEB-2025 2 months 22 days	Periodic Report Comments. Patient experienced alanine aminotransferase increased Inv causality: Related to MEDI5752, Lenvatinib. CCA: related to Lenvatinib. not related: MEDI5752. Study therapy: not related
Concomitant Medication(s): | LENVATINIB (S) | Entecavir (C) | Omeprazole (C) | Irbesartan (C) | Urea (C) | Calcium carbonate (C) | Methylprednisolone (C)									

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
202501GLO012231CN	CHINA 64 Years Male	**Platelet count decreased (Platelet count decreased)***	Not Recovered	15-Jan-2025 6 days 9 hrs 28 min	AZD2936	Solution	750 milligram q3w Intravenous use	09-JAN-2025 to 1 day	PRC. Patient experienced DECREASED PLATELET COUNT. Inv: event Not related to MEDI5752, BEVACIZUMAB RELATED to AZD2936 CCA: not related.
Concomitant Medication(s): MEDI5752 (S) | | BEVACIZUMAB (S) | Tenofovir amibufenamide (C) | Silymarin (C) | Paracetamol (C) | Tramadol hydrochloride (C) | Zopiclone (C) | Copper chloride (C) | Hui fu dong (C) | Levocetirizine dihydrochloride (C) | Zolpidem tartrate (C) | Entecavir (C) | Bicyclol (C)									
202502GLO024881CN	CHINA 58 Years Male	**Aspartate aminotransferase increased (Aspartate aminotransferase increased)***	Recovered	17-Feb-2025 nk	AZD2936	Solution	750 milligram q3w Intravenous use	18-FEB-2025 to 30-MAY-2025 3 months 13 days	Periodic Report Comments. The patient experienced Male even: Aspartate aminotransferase increased. serious related to MEDI5752, AZD2936,CCA: Not related.;Periodic Report Comments. Pateint experienced event ASPARTATE AMINOTRANSFERASE INCREASED. Investigator causality: Related to MEDI5752 and AZD2936 , Not related to Bevacizumab .CCA: Not related
Concomitant Medication(s): MEDI5752 (S) | | BEVACIZUMAB (S) | Tenofovir alafenamide fumarate (C) | Nifedipine (C) | Bicyclol (C) | Silymarin (C)									
202503GLO026321CN	CHINA 74.2 Years Male	**Platelet count decreased (Platelet count decreased)***	Recovered	24-Mar-2025 nk	MEDI5752	Infusion Infusion	500 milligram q3w Intravenous use 500 milligram q3w Intravenous use	04-JUL-2024 to 04-JUL-2024 1 day 05-SEP-2024 to 05-SEP-2024 1 day	Periodic Report Comments. Patient experienced the event "Platelet count decreased" . INV related for MEDI5752 & not related for BEVACIZUMAB. Company causality not related to MEDI5752 & BEVACIZUMAB.

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	500 milligram q3w	08-NOV-2024 to 08-NOV-2024	
							Intravenous use	1 day	
						Infusion	500 milligram q3w	09-JAN-2025 to 09-JAN-2025	
							Intravenous use	1 day	
						Infusion	500 milligram q3w	11-APR-2024 to 11-APR-2024	
							Intravenous use	1 day	
						Infusion	500 milligram q3w	12-MAR-2025 to 12-MAR-2025	
							Intravenous use	1 day	
						Infusion	500 milligram q3w	12-OCT-2024 to 12-OCT-2024	
							Intravenous use	1 day	
						Infusion	500 milligram q3w	13-JUN-2024 to 13-JUN-2024	
							Intravenous use	1 day	
						Infusion	500 milligram q3w	16-AUG-2024 to 16-AUG-2024	
							Intravenous use	1 day	
						Infusion	500 milligram q3w	20-DEC-2024 to 20-DEC-2024	
							Intravenous use	1 day	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	500 milligram q3w Intravenous use	21-MAR-2024 to 21-MAR-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	23-MAY-2024 to 23-MAY-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	27-JAN-2025 to 27-JAN-2025 1 day	
						Infusion	500 milligram q3w Intravenous use	30-APR-2024 to 30-APR-2024 1 day	
Concomitant Medication(s): | BEVACIZUMAB (S) | Telmisartan (C) | Sofosbuvir and velpatasvir (C) | Montmorillonite (C) | Human Albumin (C) | Huang kui (C) | Levothyroxine (C) | Potassium citrate (C) | Erythropoietin (C)									
202506GLO007156US	UNITED STATES 74.4 Years Female	**Troponin I increased (Cardiac troponin I increased)***	Not Recovered	03-Jun-2025 1 year 4 months 5 days	AZD2936	Solution	750 milligram q3w Intravenous use	01-APR-2025 to	
						Solution	750 milligram q3w Intravenous use	03-JUN-2024 to	
						Solution	750 milligram q3w Intravenous use	03-SEP-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
						Solution	750 milligram q3w Intravenous use	05-NOV-2024 to	
						Solution	750 milligram q3w Intravenous use	06-AUG-2024 to	
						Solution	750 milligram q3w Intravenous use	07-JAN-2025 to	
						Solution	750 milligram q3w Intravenous use	11-MAR-2025 to	
						Solution	750 milligram q3w Intravenous use	12-MAR-2024 to	
						Solution	750 milligram q3w Intravenous use	13-MAY-2024 to	
						Solution	750 milligram q3w Intravenous use	13-MAY-2025 to	
						Solution	750 milligram q3w Intravenous use	15-JUL-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
						Solution	750 milligram q3w Intravenous use	15-OCT-2024 to	
						Solution	750 milligram q3w Intravenous use	17-DEC-2024 to	
						Solution	750 milligram q3w Intravenous use	18-FEB-2025 to	
						Solution	750 milligram q3w Intravenous use	20-FEB-2024 to	
						Solution	750 milligram q3w Intravenous use	22-APR-2024 to	
						Solution	750 milligram q3w Intravenous use	22-APR-2025 to	
						Solution	750 milligram q3w Intravenous use	23-SEP-2024 to	
						Solution	750 milligram q3w Intravenous use	24-JUN-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

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Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
						Solution	750 milligram q3w Intravenous use	26-NOV-2024 to	
						Solution	750 milligram q3w Intravenous use	28-JAN-2025 to 3 months 16 days	
						Solution	750 milligram q3w Intravenous use	30-JAN-2024 to 11 months 30 days	
					CISPLATIN	Infusion	25 milligram/sq. meter q3w Intravenous use	01-JUL-2024 to	
						Infusion	25 milligram/sq. meter q3w Intravenous use	03-JUN-2024 to	
						Infusion	25 milligram/sq. meter q3w Intravenous use	06-FEB-2024 to	
						Infusion	25 milligram/sq. meter q3w Intravenous use	11-JUN-2024 to	

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	25 milligram/sq. meter q3w Intravenous use	12-MAR-2024 to	
						Infusion	25 milligram/sq. meter q3w Intravenous use	13-MAY-2024 to	
						Infusion	25 milligram/sq. meter q3w Intravenous use	15-JUL-2024 to	
						Infusion	25 milligram/sq. meter q3w Intravenous use	19-MAR-2024 to	
						Infusion	25 milligram/sq. meter q3w Intravenous use	20-FEB-2024 to	
						Infusion	25 milligram/sq. meter q3w Intravenous use	20-MAY-2024 to	
						Infusion	25 milligram/sq. meter q3w	22-APR-2024 to	

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
							Intravenous use		
						Infusion	25 milligram/sq. meter q3w	22-JUL-2024 to	
							Intravenous use		
						Infusion	25 milligram/sq. meter q3w	24-JUN-2024 to	
							Intravenous use		
						Infusion	25 milligram/sq. meter q3w	26-FEB-2024 to	
							Intravenous use		
						Infusion	25 milligram/sq. meter q3w	29-APR-2024 to	
							Intravenous use		
						Infusion	25 milligram/sq. meter q3w	30-JAN-2024 to 5 months 23 days	
							Intravenous use		
					GEMCITABINE	Infusion	1000 milligram/sq. meter q3w	01-JUL-2024 to	
							Intravenous use		

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

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Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	1000 milligram/sq. meter q3w Intravenous use	03-JUN-2024 to	
						Infusion	1000 milligram/sq. meter q3w Intravenous use	06-FEB-2024 to	
						Infusion	1000 milligram/sq. meter q3w Intravenous use	11-JUN-2024 to	
						Infusion	1000 milligram/sq. meter q3w Intravenous use	12-MAR-2024 to	
						Infusion	1000 milligram/sq. meter q3w Intravenous use	13-MAY-2024 to	
						Infusion	1000 milligram/sq. meter q3w Intravenous use	15-JUL-2024 to	
						Infusion	1000 milligram/sq. meter q3w	19-MAR-2024 to	

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
							Intravenous use		
						Infusion	1000 milligram/sq. meter q3w	20-FEB-2024 to	
							Intravenous use		
						Infusion	1000 milligram/sq. meter q3w	20-MAY-2024 to	
							Intravenous use		
						Infusion	1000 milligram/sq. meter q3w	22-APR-2024 to	
							Intravenous use		
						Infusion	1000 milligram/sq. meter q3w	22-JUL-2024 to	
							Intravenous use		
						Infusion	1000 milligram/sq. meter q3w	24-JUN-2024 to	
							Intravenous use		
						Infusion	1000 milligram/sq. meter q3w	26-FEB-2024 to	
							Intravenous use		

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

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EudraCT No: 2022-502317-29-00

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	1000 milligram/sq. meter q3w Intravenous use	29-APR-2024 to	
						Infusion	1000 milligram/sq. meter q3w Intravenous use	30-JAN-2024 to 5 months 23 days	
Concomitant Medication(s): | GEMCITABINE (S) | CISPLATIN (S) | Xanax (C) | Buspirone (C) | Megestrol (C) | Ondansetron (C) | Famotidine (C) | Guaifenesin (C) | Benzonatate (C) | Pantoprazole (C) | Eliquis (C) | Lidocaine (C) | Fluticasone propionate (C) | Fluticasone (C) | Xarelto (C) | Enoxaparin (C) | Sennosides (C) | Cetirizine (C) | Sucralfate (C)									
202507GLO013806GB	UNITED KINGDOM 60.5 Years Male	**Alanine aminotransferase increased (ALT increased)***	Not Recovered	03-Jun-2025 21 days	BEVACIZUMAB	Infusion	1225 milligram q3w Intravenous use	11-JUN-2025 to	Periodic Report Comments. Patient experienced alt increase. Investigator states event alt increase related toRilvegostomig ,Bevacizumab
						Infusion	1225 milligram q3w Intravenous use	14-MAY-2025 to	
					RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	11-JUN-2025 to	
						Solution	750 milligram q3w Intravenous use	14-MAY-2025 to	
Concomitant Medication(s): RILVEGOSTOMIG (S) | | Amlodipine (C) | Omeprazole (C) | Codamol (C) | Cyclizine (C) | Loperamide (C) | AMOXICILLIN (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
202512GLO003390GB	UNITED KINGDOM 75 Years Male	**Blood bilirubin increased (Blood bilirubin increased)***	Not Recovered	02-Dec-2025 6 months 12 days	AZD2936	Solution	750 milligram q3w Intravenous use	21-MAY-2025 to 03-SEP-2025 3 months 14 days	
					BEVACIZUMAB	Infusion	1067.5 milligram q3w Intravenous use	21-MAY-2025 to 22-OCT-2025 5 months 2 days	
Concomitant Medication(s): | BEVACIZUMAB (S) | Metformin (C) | Lansoprazole (C) | Atorvastatin (C) | Vitamin d (C) | Trust diclofenac gel (C) | Difflam (C) | Prednisolone (C) | Zeroveen (C)									
202512GLO003529GB	UNITED KINGDOM 75.9 Years Male	**Blood bilirubin increased (Bilirubin increased)***	Not Recovered	02-Dec-2025 6 months 12 days	AZD2936	Solution	750 milligram q3w Intravenous use	02-JUL-2025 to	
						Solution	750 milligram q3w Intravenous use	03-SEP-2025 to	
						Solution	750 milligram q3w Intravenous use	11-JUN-2025 to	
						Solution	750 milligram q3w Intravenous use	21-MAY-2025 to	
						Solution	750 milligram q3w Intravenous use	23-JUL-2025 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

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
					BEVACIZUMAB	Infusion	1067.5 milligram q3w Intravenous use	02-JUL-2025 to	
						Infusion	1067.5 milligram q3w Intravenous use	03-SEP-2025 to	
						Infusion	1067.5 milligram q3w Intravenous use	11-JUN-2025 to	
						Infusion	1067.5 milligram q3w Intravenous use	21-MAY-2025 to	
						Infusion	1067.5 milligram q3w Intravenous use	22-OCT-2025 to	
						Infusion	1067.5 milligram q3w Intravenous use	23-JUL-2025 to	
Concomitant Medication(s): | BEVACIZUMAB (S) | Lansoprazole (C) | Metformin (C) | Atorvastatin (C) | Diclofenac (C) | Vitamin d (C) | Co careldopa (C) | Zeroveen (C)									
202512GLO016333US	UNITED STATES 72 Years Female	**Amylase increased (Serum amylase increased)***	Not Recovered	16-Dec-2025 nk	MEDI5752	Infusion	750 milligram q3w Intravenous use	01-JUL-2024 to	

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Study Design: Not Blinded

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						Infusion	750 milligram q3w Intravenous use	02-APR-2025 to	
						Infusion	750 milligram q3w Intravenous use	03-SEP-2024 to	
						Infusion	750 milligram q3w Intravenous use	04-JUN-2025 to	
						Infusion	750 milligram q3w Intravenous use	04-NOV-2024 to	
						Infusion	750 milligram q3w Intravenous use	05-AUG-2025 to	
						Infusion	750 milligram q3w Intravenous use	05-FEB-2024 to	
						Infusion	750 milligram q3w Intravenous use	07-JAN-2025 to	
						Infusion	750 milligram q3w Intravenous use	07-OCT-2025 to	

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

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Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	750 milligram q3w Intravenous use	08-APR-2024 to	
						Infusion	750 milligram q3w Intravenous use	11-JUN-2024 to	
						Infusion	750 milligram q3w Intravenous use	11-MAR-2025 to	
						Infusion	750 milligram q3w Intravenous use	12-AUG-2024 to	
						Infusion	750 milligram q3w Intravenous use	13-MAY-2025 to	
						Infusion	750 milligram q3w Intravenous use	14-JUL-2025 to	
						Infusion	750 milligram q3w Intravenous use	15-OCT-2024 to	
						Infusion	750 milligram q3w Intravenous use	15-SEP-2025 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	750 milligram q3w Intravenous use	17-DEC-2024 to	
						Infusion	750 milligram q3w Intravenous use	18-FEB-2025 to	
						Infusion	750 milligram q3w Intravenous use	18-MAR-2024 to	
						Infusion	750 milligram q3w Intravenous use	20-MAY-2024 to	
						Infusion	750 milligram q3w Intravenous use	22-APR-2025 to	
						Infusion	750 milligram q3w Intravenous use	23-JUL-2024 to	
						Infusion	750 milligram q3w Intravenous use	23-JUN-2025 to	
						Infusion	750 milligram q3w Intravenous use	23-SEP-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	750 milligram q3w Intravenous use	26-AUG-2025 to	
						Infusion	750 milligram q3w Intravenous use	26-FEB-2024 to	
						Infusion	750 milligram q3w Intravenous use	26-NOV-2024 to	
						Infusion	750 milligram q3w Intravenous use	28-JAN-2025 to	
						Infusion	750 milligram q3w Intravenous use	28-OCT-2025 to	
						Infusion	750 milligram q3w Intravenous use	29-APR-2024 to	
Concomitant Medication(s): GEMCITABINE (S) | CISPLATIN (S) | | Levothyroxine (C) | Nexium (C) | Multiple vitamins (C) | Crestor (C) | Diovan (C) | Oxycodone (C) | Pepcid (C) | Ondansetron (C) | Magnesium oxide (C) | Enoxaparin (C) | Tramadol (C) | Atovaquone (C)									
202512GLO016374US	UNITED STATES 72 Years Female	**Lipase increased (Lipase increased)*** Suspected drug-induced liver injury (Suspected Hy's law case)	Not Recovered	16-Dec-2025 nk	MEDI5752	Infusion	750 milligram q3w Intravenous use	01-JUL-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	750 milligram q3w	02-APR-2025 to	
		Amylase increased (Serum amylase increased)*					Intravenous use		
						Infusion	750 milligram q3w	03-SEP-2024 to	
							Intravenous use		
						Infusion	750 milligram q3w	04-JUN-2025 to	
							Intravenous use		
						Infusion	750 milligram q3w	04-NOV-2024 to	
							Intravenous use		
						Infusion	750 milligram q3w	05-AUG-2025 to	
							Intravenous use		
						Infusion	750 milligram q3w	05-FEB-2024 to	
							Intravenous use		
						Infusion	750 milligram q3w	07-JAN-2025 to	
							Intravenous use		
						Infusion	750 milligram q3w	07-OCT-2025 to	
							Intravenous use		

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	750 milligram q3w Intravenous use	08-APR-2024 to	
						Infusion	750 milligram q3w Intravenous use	11-JUN-2024 to	
						Infusion	750 milligram q3w Intravenous use	11-MAR-2025 to	
						Infusion	750 milligram q3w Intravenous use	12-AUG-2024 to	
						Infusion	750 milligram q3w Intravenous use	13-MAY-2025 to	
						Infusion	750 milligram q3w Intravenous use	14-JUL-2025 to	
						Infusion	750 milligram q3w Intravenous use	15-OCT-2024 to	
						Infusion	750 milligram q3w Intravenous use	15-SEP-2025 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	750 milligram q3w Intravenous use	17-DEC-2024 to	
						Infusion	750 milligram q3w Intravenous use	18-FEB-2025 to	
						Infusion	750 milligram q3w Intravenous use	18-MAR-2024 to	
						Infusion	750 milligram q3w Intravenous use	20-MAY-2024 to	
						Infusion	750 milligram q3w Intravenous use	22-APR-2025 to	
						Infusion	750 milligram q3w Intravenous use	23-JUL-2024 to	
						Infusion	750 milligram q3w Intravenous use	23-JUN-2025 to	
						Infusion	750 milligram q3w Intravenous use	23-SEP-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	750 milligram q3w Intravenous use	26-AUG-2025 to	
						Infusion	750 milligram q3w Intravenous use	26-FEB-2024 to	
						Infusion	750 milligram q3w Intravenous use	26-NOV-2024 to	
						Infusion	750 milligram q3w Intravenous use	28-JAN-2025 to	
						Infusion	750 milligram q3w Intravenous use	28-OCT-2025 to	
						Infusion	750 milligram q3w Intravenous use	29-APR-2024 to	

Concomitant Medication(s): GEMCITABINE (S) | CISPLATIN (S) | | Levothyroxine (C) | Nexium (C) | Multiple vitamins (C) | Crestor (C) | Pepcid (C) | Ondansetron (C) | Magnesium oxide (C) | Enoxaparin (C) | Diovan (C) | Oxycodone (C) | Eliquis (C) | Lidocaine (C) | Flonase (C) | Tramadol (C) | Atovaquone (C) | Prednisone (C) | Lantus Solostar (C) | Novolog flexpen (C)

SOC:Metabolism and nutrition disorders

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
2023A288303	CHINA 45 Years Male	**Hypoglycaemia (Hypoglycemia)***	Recovered	13-Dec-2023 1 month 6 days	BEVACIZUMAB	Infusion	795 milligram qw Intravenous use	08-NOV-2023 to	Periodic Report Comment. Patient experienced Hypoglycemia, Invcausality: related to all suspects. CCC: Not related
						Infusion	795 milligram qw Intravenous use	16-DEC-2023 to	
					MEDI5752	Infusion	500 milligram qw Intravenous use	08-NOV-2023 to	
						Infusion	500 milligram qw Intravenous use	24-DEC-2023 to	
						Infusion	500 milligram qw Intravenous use	30-NOV-2023 to	
Concomitant Medication(s): MEDI5752 (S) | | Bicyclol (C) | Diammonium glycyrrhizinate (C) | Entecavir (C) | 6S yinyu (C) | Ursodeoxycholic acid (C) | Ademetionine (C) | Magnesium Isoglycyrrhizinate (C) | Methylprednisolone sodium succinate (C) | Esomeprazole sodium (C) | Tropisetron hydrochloride (C) | Fat emulsion, amino acids (17) and glucose (11%) (C) | Esomeprazole (C) | Insulin injection (C) | Hemocoagulase (C) | Glucose (C)									
2023A292085	CHINA 63.9 Years Male	**Type 1 diabetes mellitus (Type 1 diabetes mellitus)***	Not Recovered	27-Nov-2023 2 months 13 hrs 51 min	MEDI5752	Infusion	750 milligram q3w Intravenous use	27-SEP-2023 10:09 to 01-JUL-2024 16:00 9 months 4 days 5 hrs 51 min	Periodic Report Comment. Patient experienced type 2 diabetes mellitus, Inves: related to study therapy

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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): | Potassium chloride 15% (C) | Aig esomeprazole (C) | Calcium carbonate and vitamin d3 tablets (ii) (C) | Methylprednisolone (C) | Irbesartan (C) | Entecavir (C) | Omeprazole (C) | Irbesartan (C) | Nifedipine (C) | Lidocaine hydrochloride (C) | Paracetamol (C) | Esomeprazole (C) | Calcium carbonate (C) | Methylprednisolone (C) | Linagliptin (C) | Metformin hydrochloride (C) | Loratadine (C) | Bisoprolol fumarate (C) | Disodium cantharidinate (C) | Omeprazole sodium (C) | Oxacillin sodium (C) | Vitamin C (C) | Dapagliflozin (C) | Acarbose (C)									
202412GLO000964TW	TAIWAN Male	**Hyponatraemia (Hyponatremia)***	Not Recovered	15-Nov-2024 2 months 28 days	MEDI5752	Infusion	500 milligram q3w Unknown	09-SEP-2024 to	Periodic Report Comments. The patient experienced event: Hyponatremia. serious .Inv-related .CCA:Not related.
						Infusion	500 milligram q3w Unknown	15-NOV-2024 to	
						Infusion	500 milligram q3w Unknown	19-AUG-2024 to	
						Infusion	500 milligram q3w Unknown	25-OCT-2024 to	
						Infusion	500 milligram q3w Unknown	27-SEP-2024 to	
Concomitant Medication(s): BEVACIZUMAB (S) | | Vemlidy (C) | Harnalidge (C) | Allegra (C) | Promeran (C) | Strocain (C) | Eurodin (C)									
202412GLO001926US	UNITED STATES 77 Years Male	**Hyperglycaemia (Hyperglycemia)***	Recovered	02-Dec-2024 29 days	MEDI5752	Infusion	1500 milligram Intravenous use	04-NOV-2024 to 04-NOV-2024 1 day	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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): | AZD2936 (S) | BEVACIZUMAB (S) | Trelegy ellipta (C) | Gabapentin (C) | Hydrochlorothiazide (C) | Morphine (C) | Nifedipine (C) | Omeprazole (C) | Oxycodone (C) | Alogliptin and pioglitazone (C) | Prolia (C) | Hydrocortisone (C)									
202412GLO017215TW	TAIWAN 69 Years Male	**Hyperglycaemia (Hyperglycemia)***	Recovered	13-Dec-2024 11 months 4 days	CISPLATIN	Infusion	25 milligram/sq. meter q3w Intravenous use	10-JAN-2024 to 04-JUL-2024 5 months 25 days	
					GEMCITABINE	Infusion	1000 milligram/sq. meter q3w Intravenous use	10-JAN-2024 to 04-JUL-2024 5 months 25 days	
					MEDI5752	Infusion	750 microgram q3w Intravenous use	10-JAN-2024 to 29-AUG-2024 7 months 20 days	
Concomitant Medication(s): MEDI5752 (S) | GEMCITABINE (S) | | Atorvastatin (C) | Empagliflozin (C) | Insulin degludec (C) | Metformin HCL (C) | Pioglitazone (C) | Dimethicone (C) | Tramadol (C) | Acetaminophen (C) | Neomycin (C) | Aprepitant (C) | Diphenhydramine (C) | Metoclopramide (C) | Netupitant (C) | Camphor (C) | Fexofenadine (C) | Hydro (C) | Megestrol (C) | Amlodipine (C) | Lorazepam (C) | Lenograstim (C) | Hydroxyzine (C) | Magnesium oxide (C) | Mecobalamin (C) | Pyridoxine (C) | Sennoside a+b (C) | Thiamine (C) | Cefepime (C) | Tramadol/acetaminophen (C) | Cefixime (C) | Lactulose (C) | Dexamethasone (C) | Furosemide (C) | Denosumab (C) | Cortisone (C)									
2024A165750	CHINA 64 Years Male	**Diabetic ketoacidosis (Diabetic ketoacidosis)***	Recovered	19-Jul-2024 9 months 23 days	MEDI5752	Infusion	750 milligram q3w Intravenous use	27-SEP-2023 to 01-JUL-2024 9 months 5 days	Periodic Report Comment. Patient experienced diabetes ketoacidosis. Inves: related to study therapy; CCA: Not related.
Concomitant Medication(s): | ENTECAVIR (C) | IRBESARTAN (C) | Nifedipine (C) | Compound glycyrrhizin (C) | Aig esomeprazole (C) | Insulin aspart (C) | Insulin glargine (C)									

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
202508GLO020478CN	CHINA 60 Years Male	**Hyponatraemia (Hyponatremia)*** Diarrhoea (Diarrhea)	Recovered	12-Aug-2025 nk	MEDI5752	Infusion	1500 milligram q3w Intravenous use	18-DEC-2024 to	Periodic Report Comments. Investigator assessed causality for MEDI5752 with Hyponatremia with as not reported and Diarrhea as related, AZD2936 with Hyponatremia with as not reported and Diarrhea as related, BEVACIZUMAB with Hyponatremia with as not reported and Diarrhea as related. CCA: not related with study therapy, MEDI5752, AZD2936 and BEVACIZUMAB.
						Infusion	750 milligram q3w Intravenous use	10-APR-2025 to	
		Hyponatraemia (Hyponatremia)* Diarrhoea (Diarrhea)*	Recovered	12-Aug-2025 nk	AZD2936	Solution	750 milligram q3w Intravenous use	06-MAY-2025 to 06-MAY-2025 1 day	
						Solution	750 milligram q3w Intravenous use	14-MAR-2025 to	
						Solution	750 milligram q3w Intravenous use	21-FEB-2025 to	
						Solution	750 milligram q3w Intravenous use	24-JAN-2025 to	

Concomitant Medication(s): | AZD2936 (S) | BEVACIZUMAB (S) | Entecavir (C) | Tenofovir disoproxil fumarate (C) | Compound glycyrrhizin (C) | Bicyclol (C) | Reduced Glutathione (C) | Methylprednisolone (C) | Levamlodipine besylate (C) | Sacubitril valsartan sodium (C) | Concentrated sodium chloride (C) | Famotidine (C) | Glucose (C) | Potassium chloride (C) | Bisoprolol fumarate (C) | Amlodipine besylate (C) | Dexamethasone sodium phosphate (C) | Promethazine hydrochloride (C) | Vitamin b6 (C) | Vitamin C (C) | Glutathione (C) | Magnesium Isoglycyrrhizinate (C) | Ranitidine hydrochloride (C) | Nifedipine (C) | Silymarin (C) | Valsartan (C) | Methylprednisolone sodium succinate (C) | Omeprazole sodium (C) | Human insulin (C) | Etamsylate (C) | Hemocoagulase (C) | Montmorillonite (C) | Domperidone (C) | Sodium chloride (C) | Trimebutine maleate (C) | Glucose and sodium chloride (C) | Prednisone acetate (C)

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
202510GLO026176CN	CHINA 60 Years Male	**Diabetes mellitus (Diabetes mellitus aggravated)***	Recovered	28-Oct-2025 10 months 12 hrs 34 min	MEDI5752	Infusion	1500 milligram q3w Intravenous use	27-DEC-2024 11: 26 to 27-DEC-2024 12:29 1 hr 3 min	
						Infusion	750 milligram q3w Intravenous use	09-OCT-2025 15: 40 to 09-OCT-2025 16:40 1 hr	
						Infusion	750 milligram q3w Intravenous use	12-JUN-2025 11: 02 to 12-JUN-2025 11:59 57 min	
						Infusion	750 milligram q3w Intravenous use	20-MAR-2025 15: 47 to 20-MAR-2025 16:50 1 hr 3 min	
					AZD2936	Solution	750 milligram q3w Intravenous use	15-JAN-2025 11: 13 to	

Concomitant Medication(s): | AZD2936 (S) | BEVACIZUMAB (S) | Tenofovir alafenamide fumarate (C) | Ademetionine (C) | Insulin aspart (C) | Insulin glargine (C) | Silymarin (C) | Ursodeoxycholic acid (C) | Allisartan isoproxil (C) | Nifedipine (C) | Bicyclol (C) | Medroxyprogesterone acetate (C)

SOC:Musculoskeletal and connective tissue disorders

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
2024A136725	ITALY 83 Years Female	**Myositis (Myositis)***	Recovered	03-Jun-2024 4 months 25 days	AZD 2936	Solution	750 milligram qw Intravenous use	03-APR-2024 to 03-APR-2024 1 day	Periodic Report Comment. Patient experienced myositis. Inv: related to Rilvegostomig, not related to Gemcitabine and Cisplatin. CCA: not related.
						Solution	750 milligram qw Intravenous use	10-JAN-2024 to 10-JAN-2024 1 day	
						Solution	750 milligram qw Intravenous use	12-MAR-2024 to 12-MAR-2024 1 day	
						Solution	750 milligram qw Intravenous use	14-MAY-2024 to 14-MAY-2024 1 day	
						Solution	750 milligram qw Intravenous use	20-FEB-2024 to 20-FEB-2024 1 day	
						Solution	750 milligram qw Intravenous use	23-APR-2024 to 23-APR-2024 1 day	
						Solution	750 milligram qw Intravenous use	30-JAN-2024 to 30-JAN-2024 1 day	
					CISPLATIN	Infusion	20 milligram/sq. meter qw 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: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	20 milligram/sq. meter qw Intravenous use	30-APR-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	03-APR-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	06-FEB-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	10-APR-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	10-JAN-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	12-MAR-2024 to	
						Infusion	25 milligram/sq. meter qw	17-JAN-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
							Intravenous use		
						Infusion	25 milligram/sq. meter qw Intravenous use	19-MAR-2024 to 19-MAR-2024 1 day	
						Infusion	25 milligram/sq. meter qw Intravenous use	20-FEB-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	23-APR-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	27-FEB-2024 to	
						Infusion	25 milligram/sq. meter qw Intravenous use	30-JAN-2024 to 30-JAN-2024 1 day	
					GEMCITABINE	Infusion	1000 milligram/sq. meter qw Intravenous use	03-APR-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	1000 milligram/sq. meter qw Intravenous use	06-FEB-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	10-APR-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	10-JAN-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	12-MAR-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	17-JAN-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	19-MAR-2024 to	
						Infusion	1000 milligram/sq. meter qw Intravenous use	20-FEB-2024 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

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Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
							Intravenous use		
						Infusion	1000 milligram/sq. meter qw	23-APR-2024 to	
							Intravenous use		
						Infusion	1000 milligram/sq. meter qw	27-FEB-2024 to	
							Intravenous use		
						Infusion	1000 milligram/sq. meter qw	30-JAN-2024 to	
							Intravenous use		
						Infusion	850 milligram/sq. meter qw	14-MAY-2024 to	
							Intravenous use		
						Infusion	850 milligram/sq. meter qw	30-APR-2024 to	
							Intravenous use		

Concomitant Medication(s): | CISPLATIN (S) | GEMCITABINE (S) | Coaprovel (C) | Insulin (C) | Dexamethasone (C) | Pantoprazole (C) | Furosemide (C) | Granisetron (C)

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

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Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

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
SOC:Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
202505GLO021227TW	TAIWAN 64.4 Years Male	**Liver carcinoma ruptured (Liver carcinoma ruptured)***	Recovered	26-May-2025 3 months 9 days	AZD2936	Solution	750 milligram q3w Intravenous use	18-FEB-2025 to	Periodic Report Comments. The investigator considered that there was a reasonable possibility of a causal relationship between the study therapy and the event(s). hcc rupture. The company physician did not consider that there was a reasonable possibility of a causal relationship between the study therapy and the event(s). hcc rupture.
					BEVACIZUMAB	Infusion	928.5 milligram q3w Intravenous use	16-MAY-2025 to	
						Infusion	936 milligram q3w Intravenous use	14-MAR-2025 to	
						Infusion	939 milligram q3w Intravenous use	22-APR-2025 to	
						Infusion	940.5 milligram q3w Intravenous use	01-APR-2025 to	
						Infusion	960 milligram q3w Intravenous use	18-FEB-2025 to	
Concomitant Medication(s): | BEVACIZUMAB (S) | Entecavir (C) | Sennoside a+b calcium (C) | Fentanyl (C) | Amlodipine (C) | Diphenhydramine (C) | Lorazepam (C) | Fexofenadine (C)									
SOC:Nervous system disorders									

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
2023A248722	CHINA 64.8 Years Male	**Immune-mediated neuropathy (Immune-mediated neuropathy)***	Recovering	24-Oct-2023 28 days	LENVATINIB	Capsule	8 milligram qd Oral use	07-FEB-2024 to 11-MAR-2024 1 month 5 days	Periodic Report Comment. Patient experienced IMMUNE-MEDIATED PERIPHERAL NEUROPATHY. Investigator event related to study therapy. CCA: not related to study therapy.
						Capsule	8 milligram qd Oral use	27-SEP-2023 to 07-FEB-2024 4 months 12 days	
					MEDI5752	Infusion	500 milligram q3w Intravenous use	27-SEP-2023 to 17-OCT-2023 21 days	

Concomitant Medication(s): MEDI5752 (S) | | Entecavir (C) | Omeprazole (C) | Tofacitinib citrate (C) | Dani-lactulose (C) | Pregabalin (C) | SULPIRIDE (C) | 1,3,5-TRIMETHOXYBENZENE (C) | Urea (C) | Calcium carbonate and vitamin d3 tablets (ii) (C) | Famotidine (C) | Mixed protamine human insulin injection (30r) (C) | Zolpidem tartrate (C) | Alprazolam (C) | Polyene phosphatidylcholine (C) | Clonazepam (C) | Ascorbic acid (C) | Methylcobalamin (C) | Boryung loxoprofen sodium (C) | Dbl meropenem (C) | DBL Pethidine Hydrochloride (C) | Compound amino acid and vitamin (C) | Nicardipine hydrochloride sodium chloride (C) | Ascorbic acid (C) | Sodium chloride (C) | Captopril (C) | Ceftriaxone sodium (C) | Estradiol (C) | Flurbiprofen (C) | Acetic acid (C) | Methylcobalamin (C) | Rifaximin (C) | Vitamin K (C) | Pinaverium bromide (C) | Concentrated sodium chloride (C) | Calcium chloride (C) | 2-dimethylamino-1,1-diphenyl-aethan (C) | Compound potassium hydrogen phosphate (C) | Medium and long chain fat emulsion injection (C6-24) (C) | Methylcobalamin (C) | Simethicone (C) | Torsemide (C) | Acetylglutamine (C) | Compound amino acid injection (14aa) (C) | Etomidate (C) | Methylprednisolone (C) | Nadroparin calcium (C) | Acidum ursodeoxycholicum (C) | Live combined bifidobacterium and lactobacillus (C) | Rivaroxaban (C) | Famotidine (C) | Quetiapine fumarate (C) | Carbazochrome sodium sulfonate and sodium chloride (C) | Ranitidine hydrochloride (C) | Compound glycyrrhizin (C) | Entecavir (C) | Glutathione (C) | Tenofovir alafenamide fumarate (C) | Bicyclol (C)

SOC:Renal and urinary disorders

202505GLO005009GB	UNITED KINGDOM 68.3 Years Male	**Acute kidney injury (Acute kidney injury)***	Not Recovered	28-Apr-2025 1 year 5 days	MEDI5752	Infusion	500 milligram q3w Intravenous use	24-APR-2024 to 09-APR-2025 11 months 17 days	periodic report comment. Patient has event : Acute kidney injury with Hyperkalemia. For study therapy Action Taken: No change, Investigator Causality: Related, CC: Not Related.

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
									Outcome: not Recovered.

Concomitant Medication(s): | LENVATINIB (S) | Omeprazole (C) | Metformin (C) | Amlodipine (C) | Empagliflozin (C) | Ipratropium (C) | Benzydamine hydrochloride (C) | Co codamol (C) | Cyclizine (C) | Tamsulosin (C) | Sertraline (C) | Haloperidol (C) | Candesartan (C) | Levothyroxine (C)

SOC:Reproductive system and breast disorders

202501GLO019170HK	HONG KONG 62.1 Years Male	**Scrotal ulcer (Scrotal ulcer)***	Recovered	20-Jan-2025 1 year 3 months 2 days	BEVACIZUMAB	Infusion	1018 milligram q3w Intravenous use	30-OCT-2024 to
						Infusion	1027 milligram q3w Intravenous use	21-NOV-2024 to
						Infusion	1029 milligram q3w Intravenous use	10-OCT-2024 to
						Infusion	1033 milligram q3w Intravenous use	30-AUG-2024 to
						Infusion	1051 milligram q3w Intravenous use	20-SEP-2024 to

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

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Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

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	1071 milligram q3w Intravenous use	07-DEC-2023 to	
						Infusion	1071 milligram q3w Intravenous use	29-DEC-2023 to	
						Infusion	1074 milligram q3w Intravenous use	20-JUN-2024 to	
						Infusion	1075 milligram q3w Intravenous use	11-JUL-2024 to	
						Infusion	1078 milligram q3w Intravenous use	31-DEC-2024 to	
						Infusion	1087.5 milligram q3w Intravenous use	19-JAN-2024 to	
						Infusion	1087.5 milligram q3w Intravenous use	30-MAY-2024 to	
						Infusion	1093.5 milligram q3w Intravenous use	19-OCT-2023 to	

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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	1102.5 milligram q3w Intravenous use	09-MAY-2024 to	
						Infusion	1108.5 milligram q3w Intravenous use	16-FEB-2024 to	
						Infusion	1123.5 milligram q3w Intravenous use	18-APR-2024 to	
						Infusion	1162.5 milligram q3w Intravenous use	07-MAR-2024 to	
						Infusion	15 milligram/kilogram q3w Intravenous use	19-OCT-2023 to 21-NOV-2024 1 year 1 month 3 days	
					MEDI5752	Infusion	500 milligram q3w Intravenous use	19-OCT-2023 to 31-DEC-2024 1 year 2 months 13 days	

Concomitant Medication(s): MEDI5752 (S) | | Tenofovir (C) | Loratadine (C) | Beclomethasone (C) | Losartan (C) | Thyroxine (C) | Atenolol (C)

SOC:Respiratory, thoracic and mediastinal disorders

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
202409GLO002869JP	JAPAN 68 Years Male	**Interstitial lung disease (Pneumonia interstitial diffuse)***	Recovered	15-Sep-2024 20 days	MEDI5752	Infusion	500 milligram q3w Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	Periodic Report Comments. A 68 years old male patient experienced pneumonia interstitial, Investigator causality related to volrustomig (MEDI5752) and not related with Bevacizumab, Company causality Not related.
Concomitant Medication(s): | BEVACIZUMAB (S) | Spironolactone (C) | Ursodeoxycholic acid (C) | Lansoprazole (C) | Brotizolam (C) | Shakuyakukanzoto (C) | Tokishigyakukagoshuyushokyoto (C) | Amlodipine (C) | Azelnidipine (C) | Brotizolam (C) | Epalrestat (C) | Irbesartan (C) | Mecobalamin (C) | Metformin hydrochloride (C) | Mitiglinide (C) | Sennoside (C) | Onglyza (C) | Lansoprazole (C) | Loxoprofen sodium (C) | Spironolactone (C) | Loxonin (C) | Predonine (C) | Prednisolone (C) | Humulin r (C)									
202503GLO008218US	UNITED STATES 84.2 Years Female	**Hypoxia (Hypoxia)***	Fatal	05-Mar-2025 nk	MEDI5752	Infusion	1500 milligram Intravenous use	07-NOV-2024 to 07-NOV-2024 1 day	
					AZD2936	Solution	750 milligram q3w Intravenous use	04-DEC-2024 to 1 day	
						Solution	750 milligram q3w Intravenous use	23-DEC-2024 to 1 day	
					BEVACIZUMAB	Infusion	750 milligram q3w Intravenous use	04-DEC-2024 to 1 day	
Concomitant Medication(s): | AZD2936 (S) | BEVACIZUMAB (S) | Calcium (C) | Metoprolol (C) | Diphenhydramine (C) | Prednisone (C) | Levothyroxine (C) | Furosemide (C) | Spironolactone (C) | Multivitamin (C) | Alendronate (C) | Calmoseptine (C) | Pancrelipase (C) | Enoxaparin (C) | Infliximab (C) | Pantoprazole (C) | Prednisolone (C) | Trimethoprim (C) | Mirtazapine (C)									

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EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

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202503GLO016544CN	CHINA 42 Years Male	**Immune-mediated lung disease (Immune-mediated pneumonitis)***	Recovered	10-Mar-2025 1 year 5 months 18 days	MEDI5752	Infusion	500 milligram q3w Intravenous use	21-SEP-2023 to 06-MAR-2025 1 year 5 months 14 days	Periodic Report Comments. Patient experiencing Immune pneumonitis Inv causality: RELATED to MEDI5752 NOT RELATED to Lenvatinib CCC: NOT RELATED;PRC. The patient experienced immune-mediated pneumonitis. Investigator: related to medi5752 and not related to lenvatinib company physician: not related to study therapy.
Concomitant Medication(s): | LENVATINIB (S) | Atropine sulfate (C) | Butorphanol tartrate (C) | Midazolam (C) | Phloroglucinol (C) | Propofol (C) | Irbesartan (C) | Omeprazole (C) | Irbesartan and hydrochlorothiazide (C) | Potassium chloride (C) | Urea and vitamin e (C) | Entecavir (C)									
202510GLO018592US	UNITED STATES 78 Years Female	**Hypoxia (Hypoxia)***	Recovered	20-Mar-2024 nk	MEDI5752	Infusion	750 milligram q3w Intravenous use	12-FEB-2024 to	Periodic Report Comments. Investigator assessed causality for MEDI5752 with HYPOXIA with as not reported and BEVACIZUMAB with HYPOXIA with as not reported. CCA: not related with study therapy, MEDI5752, AZD2936 and BEVACIZUMAB.
Concomitant Medication(s): BEVACIZUMAB (S) | | Amlodipine (C) | Atorvastatin (C) | Carvedilol (C) | Levemir (C) | Meclizine (C) | Omeprazole (C) | Ozempic (C) | Lumigan (C) | Vascepa (C) | Torsemide (C) | Spironolactone (C) | Colace (C) | Humalog kwikpen (C) | Benzonatate (C) | Guaifenesin (C) | Insulin glargine (C) | Latanoprost (C) | Loperamide (C) | Loratadine (C) | Ondansetron (C) | Bisacodyl (C) | Ammonium lactate (C) | Polyethylene glycol 3350 (C) | Nystatin (C) | Simethicone (C) | Triamcinolone (C) | Hydromorphone (C) | Acetaminophen (C) | Senna (C) | Pantoprazole (C) | Albuterol (C)									
202511GLO014918JP	JAPAN 74.9 Years Male	**Pleurisy (Pleuritis)***	Not Recovered	14-Nov-2025 1 year 5 months 24 days	MEDI5752	Infusion	1500 milligram 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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EudraCT No: 2022-502317-29-00

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	750 milligram q3w Intravenous use	06-AUG-2025 to	
						Infusion	750 milligram q3w Intravenous use	14-AUG-2024 to	
						Infusion	750 milligram q3w Intravenous use	14-MAY-2025 to	
						Infusion	750 milligram q3w Intravenous use	19-FEB-2025 to	
						Infusion	750 milligram q3w Intravenous use	27-NOV-2024 to	
					AZD2936	Solution	750 milligram q3w Intravenous use	08-OCT-2025 to	
						Solution	750 milligram q3w Intravenous use	12-JUN-2024 to 1 year 3 months 6 days	

Concomitant Medication(s): | AZD2936 (S) | BEVACIZUMAB (S) | Labetalol hydrochloride (C) | Olmesartan medoxomil (C) | Vildagliptin (C) | Famotidine (C) | Ketoprofen (C) | Latanoprost (C) | Brinzolamide (C) | Indometacin (C) | Lactec (C) | Sitagliptin Phosphate (C) | Prednisolone (C) | Codeine phosphate hydrate (C) | L-carbocisteine (C) | Hydrocortisone (C) | Sitagliptin (C) | Epinastine hydrochloride (C) | Ursodeoxycholic acid (C) | Fexofenadine hydrochloride (C)

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202511GLO016336CN	CHINA 61.9 Years Male	**Interstitial lung disease (Interstitial pneumonia)***	Not Recovered	17-Nov-2025 10 months 3 days	AZD2936	Solution	750 milligram q3w Intravenous use	06-NOV-2025 to	
						Solution	750 milligram q3w Intravenous use	07-FEB-2025 to	
						Solution	750 milligram q3w Intravenous use	07-JUL-2025 to	
						Solution	750 milligram q3w Intravenous use	10-APR-2025 to	
						Solution	750 milligram q3w Intravenous use	12-SEP-2025 to	
						Solution	750 milligram q3w Intravenous use	15-JAN-2025 to 9 months 23 days	
						Solution	750 milligram q3w Intravenous use	22-MAY-2025 to	
						Solution	750 milligram q3w Intravenous use	25-AUG-2025 to	

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

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Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
						Solution	750 milligram q3w Intravenous use	27-FEB-2025 to	
						Solution	750 milligram q3w Intravenous use	29-APR-2025 to	

Concomitant Medication(s): MEDI5752 (S) | | BEVACIZUMAB (S) | Tenofovir alafenamide fumarate (C) | Ademetionine 1,4-butanedisulfonate (C) | Gliclazide (C) | Linagliptin (C) | Haemocoagulase Agkistrodon (C) | Nifedipine (C) | Allisartan (C) | Ursodeoxycholic acid (C)

SOC:Skin and subcutaneous 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
2024A181173	HONG KONG 71 Years Male	**Immune-mediated dermatitis (Immune-mediated dermatitis)** *	Recovering	12-Jun-2024 2 months 2 days 16 hrs 43 min	MEDI5752	Infusion	500 milligram q3w Intravenous use	10-APR-2024 to 09-JUL-2024 3 months	Periodic Report Comment. Patient experienced immune related skin reaction,Inv, related to Medi5752,Inv, not related to Lenvatinib, CCA : not related to Medi5752, CCA: not related to Lenvatinib
						Infusion	500 milligram q3w Intravenous use	31-JUL-2024 to 31-JUL-2024 1 day	

Concomitant Medication(s): | LENVATINIB (S) | Entecavir (C) | Amoxycillin (C) | Augmentin 12h (C) | Amoxicillin/clavulanic acid (C) | Augmentin 12 h (C) | Gabapentin (C) | Calamine (C) | Augmentin (C) | Propranolol HCL (C) | Simvastatin (C) | Crotamiton (C) | Fucicort (C) | Mometasone furoate (C) | Liquid paraffin (C) | Paraffin (C) | Paracetamol (C) | Aspirin (C) | Pantoprazole (C) | Cotrimoxazole (C) | Dopamine HCL (C) | Meropenem (C) | Thyroxine sodium (C) | Tioconazole (C) | Urea (C) | Tamsulosin HCL (C) | Phosphate sandoz (C) | Bisacodyl (C) | Lactulose (C)

SOC:Vascular disorders

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

Project ID: D7987

Study ID: D7987C00001

EudraCT No: 2022-502317-29-00

Study Design: Not Blinded

Study Description: D7987C00001 MEDI5752 Ph2 liver cancer study - A Phase II, Open-Label, Multi-Drug, Multi-Centre, Master Protocol to Evaluate the Efficacy and Safety of Novel Immunomodulators as Monotherapy and in Combination with Anticancer Agents in Participants with Advanced Hepatobiliary 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
202412GLO004045TW	TAIWAN 62 Years Male	**Aortic dissection (Type A aortic dissection)***	Recovered	04-Dec-2024 16 days	BEVACIZUMAB	Infusion	15 milligram/kilogram q3w Intravenous use	19-NOV-2024 to 19-NOV-2024 1 day	

Concomitant Medication(s): MEDI 5752 (S) | AZD2936 (S) | | Tamsulosin HCL (C) | Amlodipine besylate (C) | Esomeprazole magnesium (C) | Elomet (C) | Mometasone furoate (C) | Rabeprazole sodium (C) | Zopiclone (C) | Furosemide (C) | Entecavir (C) | Hyoscine butylbromide (C) | Hydroxocobalamin acetate (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
SOC:Blood and lymphatic system disorders									
2023A078787	FRANCE 76 Years Male	**Anaemia (Anemia)***	Recovered	28-Feb-2023 6 weeks 1 day	CARBOPLATIN	Infusion	Intravenous use	02-MAR-2023 to	
						Infusion	Intravenous use	06-FEB-2023 to	
						Infusion	Intravenous use	16-JAN-2023 to	
					PEMETREXED	Infusion	Intravenous use	02-MAR-2023 to	
						Infusion	Intravenous use	06-FEB-2023 to	
						Infusion	Intravenous use	16-JAN-2023 to	
Concomitant Medication(s): DURVALUMAB (S) | MONALIZUMAB (S) | PEMETREXED (S) |									
202411GLO014519US	UNITED STATES 81 Years Female	**Thrombocytopenia (Thrombocytopenia)***	Recovered	07-Nov-2024 3 months 8 days	MEDI5752	Infusion	250 milligram Intravenous use	21-AUG-2024 to	Periodic Report Comments. Patient experience THROMBOCYTOPENIA. Investigator causality: Related to MEDI5752, and Not Related to PEMETREXED and CARBOPLATIN. CCA: Not related to Study therapy.
						Infusion	750 milligram	31-JUL-2024 to	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

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
							Intravenous use		
Concomitant Medication(s): | PEMETREXED (S) | CARBOPLATIN (S) | Amlodipine-valsartan (C) | Apixaban (C) | Atorvastatin (C) | Dexamethasone (C) | Escitalopram (C) | Metoprolol succinate (C) | Ondansetron (C) | Prochlorperazine (C) | Trelegy ellipta (C) | Milk of magnesia (C) | Prednisone (C) | Trimethoprim sulfamethoxazole (C) | Hydroxyzine (C) | Amiodarone (C) | Blood (C) | Benadryl (C)									
202411GLO014527US	UNITED STATES 81 Years Female	**Thrombocytopenia (Thrombocytopenia)***	Recovered with Sequelae	07-Nov-2024 3 months 8 days	MEDI5752	Infusion	250 milligram single Intravenous use	21-AUG-2024 to 21-AUG-2024 1 day	Periodic Report Comments. Patient experience event thrombocytopenia. Investigator-related to MEDI5257, not related to Pemetrexed and Carboplatin. CCC- not related
						Infusion	750 milligram single Intravenous use	31-JUL-2024 to 31-JUL-2024 1 day	
Concomitant Medication(s): | PEMETREXED (S) | CARBOPLATIN (S) | Amlodipine-valsartan (C) | Apixaban (C) | Atorvastatin (C) | Dexamethasone (C) | Escitalopram (C) | Metoprolol succinate (C) | Ondansetron (C) | Prochlorperazine (C) | Trelegy ellipta (C) | Milk of magnesia (C) | Prednisone (C) | Trimethoprim sulfamethoxazole (C) | Hydroxyzine (C) | Amiodarone (C) | Blood (C) | Benadryl (C) | Acetaminophen (C) | Rosuvastin (C)									
2024A077631	ITALY 71 Years Male	**Thrombocytopenia (Thrombocytopenia)*** Anaemia (Anemia)*	Recovered	20-Mar-2024 10 weeks	CARBOPLATIN	Infusion		05-APR-2024 to 05-APR-2024 1 day	Periodic Report Comment. Patient experience anaemia and thrombocytopenia serious and Inv. related to study therapy.
						Infusion		05-MAR-2024 to 05-MAR-2024 1 day	
						Infusion		07-FEB-2024 to 07-FEB-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
						Infusion		10-JAN-2024 to 10-JAN-2024 1 day	
					DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	05-APR-2024 to 05-APR-2024 1 day	
						Injection	Intravenous use	05-MAR-2024 to 05-MAR-2024 1 day	
						Injection	Intravenous use	07-FEB-2024 to 07-FEB-2024 1 day	
						Injection	Intravenous use	10-JAN-2024 to 10-JAN-2024 1 day	
					DURVALUMAB	Infusion	Intravenous use	05-APR-2024 to 26-JUN-2024 11 weeks 6 days	
						Infusion	Intravenous use	05-MAR-2024 to 05-MAR-2024 1 day	
						Infusion	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: 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	Intravenous use	10-JAN-2024 to 10-JAN-2024 1 day	
Concomitant Medication(s): DURVALUMAB (S) | DATOPOTAMAB DERUXTECAN (S) | | Ondansetron (C) | Desametasone (C) | Trimeton (C) | Salbutamol (C) | Pantoprazolo (C) | Irbesartan (C) | Hydrochlorothiazide (C) | Aclidinium Bromide (C) | Aprepitant (C)									
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)									
2024A191163	FRANCE 57 Years Male	**Neutropenia (Neutropenia)***	Recovered	16-Jul-2024 4 weeks 4 days	CARBOPLATIN	Infusion		05-JUL-2024 to	
						Infusion		14-JUN-2024 to	
						Infusion		19-AUG-2024 to	
						Infusion		29-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
Concomitant Medication(s): MEDI 5752 (S) | | PEMETREXED (S)									
202505GLO014166ES	SPAIN 54 Years Female	**Febrile neutropenia (Febrile neutropenia)***	Recovered	08-May-2025 7 days 14 hrs 10 min	AZD2936	Solution	750 milligram 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)									
SOC:Cardiac disorders									
202409GLO011097US	UNITED STATES 81 Years Female	**Supraventricular tachycardia (Supraventricular tachycardia)***	Recovered	17-Sep-2024 1 month 18 days	MEDI5752	Infusion	250 milligram Intravenous use	21-AUG-2024 to	
						Infusion	750 milligram Intravenous use	31-JUL-2024 to	
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | Ondansetron (C) | Atorvastatin (C) | Dexamethasone (C) | Escitalopram (C) | Metoprolol succinate (C) | Prednisone (C) | Sulfamethoxazole (C) | Palonosetron (C) | Hydroxyzine (C) | Amiodarone (C) | Benadryl (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
2024A041468	SPAIN 63 Years Male	**Immune-mediated myocarditis (Immune-mediated myocarditis)***	Recovered	13-Feb-2024 6 weeks 5 days	DATOPOTAMAB DERUXTECAN DURVALUMAB	Injection Infusion	Intravenous use 1500 milligram Intravenous use	28-DEC-2023 to 15-MAR-2024 2 months 17 days 28-DEC-2023 to 15-MAR-2024 2 months 17 days	Periodic Report Comment. Patient experienced immune-mediated myocarditis. Investigator related to Durvalumab and Datopotamab Deruxtecan. CCA: not related.
Concomitant Medication(s): DURVALUMAB (S) | | CARBOPLATIN (S) | SIMVASTATIN (C) | TELMISARTAN (C) | METFORMIN (C)									
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	Patient has event: Event: Respiratory failure, Action taken with study drug: Not Applicable, Investigator causality: related, Company Causality: Not related
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | Simvastatin (C) | Lisinopril (C) | Morphine sulfate (C) | Pregabalin (C) | Sevredol (C)									
202509GLO021585IE	IRELAND 67 Years Female	**Myocardial infarction (Myocardial infarction)***	Not Recovered	19-Sep-2025 2 months 2 days	AZD2936	Solution	750 milligram q3w Intravenous use	18-JUL-2025 to 09-SEP-2025 1 month 23 days	
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | Aspirin (C) | Telmisartan (C) | Amlodipine (C) | Pantoprazole (C) | Atorvastin (C) | Serc (C) | Folic acid (C) | Vit b12 (C) | Mycostatin (C) | Lidocaine (C) | Chlorhexidine (C) | Rcc (C) | Combivent (C) | Furosemide (C) | Methylprednisolone (C) | Tamiflu (C) | Amoxicillin (C) | Hartmanns (C) | Paracetamol (C) | Ondansetron (C) | Amikacin (C) | Teicoplanin (C) | Flucloxacillin (C) | Meropenem (C) | Hydrocortisone (C) | Ipratropium (C) | Sodium chloride (C) | Magnesium sulphate (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
SOC:Endocrine disorders									
2024A002981	ITALY 71 Years Male	**Hypopituitarism (Hypopituitarism)***	Not Recovered	27-Dec-2023 34 weeks 6 days	MEDI 5752	Infusion	Intravenous use	05-DEC-2023 to 05-DEC-2023 1 day	Periodic Report Comment. Patient experience hypopituitarism serious and Investigator related to study therapy.CCA: Not related to study therapy.
						Infusion	Intravenous use	07-NOV-2023 to 07-NOV-2023 1 day	
						Infusion	Intravenous use	09-JUN-2023 to 09-JUN-2023 1 day	
						Infusion	Intravenous use	17-OCT-2023 to 17-OCT-2023 1 day	
						Infusion	Intravenous use	18-MAY-2023 to 18-MAY-2023 1 day	
						Infusion	Intravenous use	26-SEP-2023 to 26-SEP-2023 1 day	
						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: 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 Intravenous use		30-JUN-2023 to 30-JUN-2023 1 day	
Concomitant Medication(s): | Hyaluronic Acid (C) | Fluprednidene (C) | Sodium alginate (C) | Phytonadione (C) | Silodosine (C)									
2024A131902	FRANCE 68 Years Female	**Adrenal insufficiency (Adrenal insufficiency)***	Recovering	28-May-2024 42 weeks 4 days	MONALIZUMAB	Infusion Intravenous use Infusion Intravenous use	1500 milligram q3w 1500 milligram q3w	04-AUG-2023 to 07-MAY-2024 39 weeks 5 days 07-JUN-2024 to 22-NOV-2024 39 weeks 5 days	Periodic Report Comment. Patient experienced acute adrenal insufficiency. Inv: Related to study therapy. CCA: Not related to study therapy.
Concomitant Medication(s): DURVALUMAB (S) | | PEMETREXED (C) | CARBOPLATIN (C) | METEOXANE (C) | PARACETAMOL (C) | SEROPLEX (C) | ELIQUIS (C) | Ultibro breezhaler (C) | Ventoline (C) | Candesartan (C) | Dexeryl (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 Intravenous use Infusion Intravenous use	380 milligram 380 milligram	06-OCT-2023 to 06-OCT-2023 1 day 12-SEP-2023 to 12-SEP-2023 1 day	Periodic Report Comment. patient experience serious intestinal ischemia. Inv related to Study Procedure. CCA: not related to IP.

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)									
202412GLO006978HU	HUNGARY 60 Years Female	**Diarrhoea (Diarrhea)***	Recovered	04-Dec-2024 1 year 3 months 5 days	DATOPOTAMAB DERUXTECAN	Injection	396 milligram q3w	30-AUG-2023 to 17-OCT-2023 1 month 18 days	
Concomitant Medication(s): DURVALUMAB (S) | | Carboplatin (C) | Tezeo (C) | Paracetamol (C) | Ondansetron (C) | Loperamide (C) | NaCl (C) | Valsartan (C)									
202412GLO018848CA	CANADA 66 Years Male	**Oesophagitis (Oesophagitis)***	Not Recovered	02-Dec-2024 4 months 9 days	MEDI5752	Infusion	750 milligram Intravenous use	24-JUL-2024 to 25-SEP-2024 2 months 2 days	
Concomitant Medication(s): | Bupropion (C) | Perindopril (C) | Indapamide (C) | Pemetrexed (C) | Cisplatin (C) | Salbutamol (C) | Pantoloc (C) | Alendronate (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
2024A046614	ITALY 71 Years Male	**Pancreatic toxicity (Pancreatic toxicity)***	Recovered	20-Feb-2024 9 months 23 days 11 hrs 46 min	MEDI5752	Infusion	Intravenous use	05-DEC-2023 to 05-DEC-2023 1 day	Periodic Report Comment. Patient experience pancreatic toxicity serious and Investigator related to Medi5752. CCA: Not related to Medi5752.;Periodic Report Comments. Patient experience pancreatic toxicity serious and Investigator related to Medi5752. CCA: Not related to Medi5752.;Periodic Report Comments. Patient experience pancreatic toxicity serious, Investigator: Related to Medi5752. CCA: Not related to Medi5752.
						Infusion	Intravenous use	07-NOV-2023 to 07-NOV-2023 1 day	
						Infusion	750 milligram Intravenous use	05-DEC-2023 12:25 to 05-DEC-2023 13:25 1 hr	
						Infusion	750 milligram Intravenous use	07-NOV-2023 12:00 to 07-NOV-2023 13:01 1 hr 1 min	
						Infusion	750 milligram Intravenous use	09-JUN-2023 13:09 to 09-JUN-2023 14:09 1 hr	
						Infusion	750 milligram Intravenous use	17-OCT-2023 12:22 to 17-OCT-2023 13:22 1 hr	
						Infusion	750 milligram Intravenous use	18-MAY-2023 13:18 to 18-MAY-2023 14:19 1 hr 1 min	

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	750 milligram Intravenous use	26-SEP-2023 12:18 to 26-SEP-2023 13:18 1 hr	
						Infusion	750 milligram Intravenous use	27-APR-2023 12:14 to 27-APR-2023 13:20 1 hr 6 min	
						Infusion	750 milligram Intravenous use	30-JUN-2023 12:30 to 30-JUN-2023 13:30 1 hr	
Concomitant Medication(s): | PEMETREXED (S) | CARBOPLATIN (S) | IRON (C) | NYSTATIN (C) | DULOXETINE (C) | Sodium alginate (C) | SILODOSINE (C) | RAMIPRIL (C) | Cortisone acetate (C) | Synjardy (C) | Semaglutide (C) | Vitamin K (C)									
2024A053385	SPAIN 81 Years Male	**Abdominal pain (Abdominal pain)***	Recovered	23-Dec-2023 14 weeks 1 day	DATOPOTAMAB DERUXTECAN	Injection	336 milligram/kilogram q3w Intravenous use	11-OCT-2023 to 11-OCT-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.;Periodic Report Comments. Patient experienced event – Abdominal pain. Investigator states event related to Durvalumab, Datopotamab Deruxtecan and not related to Carboplatin. Company physician considers event not related to Durvalumab, Datopotamab Deruxtecan, Carboplatin.
						Injection	504 milligram/kilogram q3w Intravenous use	15-SEP-2023 to 15-SEP-2023 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
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) | Famotidine (C) | Cholecalciferol (C) | Calcium carbonate (C) | Sulfamethoxazole (C) | Trimetoprim (C) | Fentanyl (C)									
2024A202180	SPAIN 64 Years Female	**Colitis (Colitis)***	Recovered	29-Aug-2024 1 month 29 days	CARBOPLATIN	Infusion	Intravenous use	01-JUL-2024 to 09-AUG-2024 5 weeks 5 days	
Concomitant Medication(s): MEDI 5752 (S) | | PEMETREXED (S) | ENALAPRIL (C) | LEVOTIROXIN (C) | PITAVASTATIN (C)									
202505GLO027160PT	PORTUGAL 62 Years Male	**Immune-mediated enterocolitis (Immune-mediated colitis)***	Recovered	09-May-2025 1 year 3 months 11 days	CARBOPLATIN DATOPOTAMAB DERUXTECAN DURVALUMAB	Infusion Injection Infusion	524 milligram q3w Intravenous use 340 milligram q3w Intravenous use 1500 milligram q3w Intravenous use	29-JAN-2024 to 24-JUN-2024 4 months 27 days 29-JAN-2024 to 03-APR-2024 2 months 6 days 29-JAN-2024 to 30-APR-2025 1 year 3 months 2 days	Periodic Report Comments. Patient has event: immune-mediated colitis. Action Taken with study therapy was DURVALUMAB No Change, CARBOPLATIN, DATOPOTAMAB DERUXTECAN Not applicable. DURVALUMAB Investigator Causality: Related and CC: Not related. CARBOPLATIN, DATOPOTAMAB DERUXTECAN Investigator Causality: Not Reported and CC: Not Applicable.
Concomitant Medication(s): DURVALUMAB (S) | | DATOPOTAMAB DERUXTECAN (S) | Blephaclean (C) | Metoclopramide (C)									
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

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	6 milligram/kilogram q3w Intravenous use	29-JAN-2024 to 03-APR-2024 2 months 6 days	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.
Concomitant Medication(s): DURVALUMAB (S) | | DATOPOTAMAB DERUXTECAN (S) | Artelac (C) | Blephaclean (C) | Metoclopramide (C) | Loperamide (C) | Pantoprazole (C) | Aspirin (C) | Atorvastatin (C)									
202511GLO013966FR	FRANCE 68 Years Female	**Dysphagia (Aphagia)***	Not Recovered	31-Oct-2025 nk	PACLITAXEL	Infusion	Intravenous use	to	Periodic Report Comments. Patient experienced event aphagia. Investigator states event related to DATOPOTAMAB DERUXTECAN and causality not reported for AZD2936, Carboplatin and Paclitaxel. CCC- not related.;Periodic Report Comments. Patient experienced event aphagia. Investigator states event related to DATOPOTAMAB DERUXTECAN, Carboplatin and causality not related to AZD2936 and not reported for Paclitaxel. CCC- not related.
					DATOPOTAMAB DERUXTECAN	Injection	400 milligram Intravenous use	24-OCT-2025 13:30 to 24-OCT-2025 14:59 1 hr 29 min	
					CARBOPLATIN	Infusion	540 milligram q3w Intravenous use	24-OCT-2025 16:50 to 24-OCT-2025 17:50 1 hr	
Concomitant Medication(s): AZD2936 (S) | DATOPOTAMAB DERUXTECAN (S) | CARBOPLATIN (S) | | Diamicron (C) | Metformin (C) | Kardegic (C) | Irbesartan (C) | Hydrochlorothiazide (C) | Ezetimibe (C) | Rosuvastatin (C) | Anoro (C) | Izalgi (C) | Esomeprazole (C) | Dynexan (C) | Fungizone (C) | Tiorfan (C) | Fresubin (C) | Lansoprazole (C) | Xylocaine (C) | Sodium chloride (C) | Folic acid (C) | Sodium bicarbonate (C) | Paracetamol (C) | Augmentin (C) | Celluvisc (C)									

SOC:General disorders and administration site conditions

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
202411GLO009258US	UNITED STATES 69 Years Female	**Fatigue (Fatigue)***	Recovered	07-Nov-2024 1 year 1 month 9 days 7 hrs 55 min	DURVALUMAB	Infusion	1500 milligram q4w Intravenous use	28-SEP-2023 16:05 to 14-NOV-2024 1 year 1 month 16 days 7 hrs 55 min	
					MEDI9447	Infusion	3000 milligram q4w Intravenous use	28-SEP-2023 14:40 to 14-NOV-2024 1 year 1 month 16 days 9 hrs 20 min	
Concomitant Medication(s): | MEDI9447 (S) | CARBOPLATIN (S) | PACLITAXEL (S) | Tylenol (C) | Zocor (C) | Dexamethasone (C) | Prednisone (C) | Prochlorperazine (C) | Ondansetron (C)									
202512GLO021835IE	IRELAND 57 Years Female	**Pyrexia (Fever)***	Recovered	14-Dec-2025 1 month 16 days	AZD2936	Solution	750 milligram Unknown	10-DEC-2025 to	
						Solution	750 milligram Unknown	19-NOV-2025 to	
						Solution	750 milligram Unknown	29-OCT-2025 to	
Concomitant Medication(s): | CARBOPLATIN (S) | PACLITAXEL (S) | Amitriptyline (C) | Singulair (C) | Salbutral (C) | Symbicort (C) | Prolia (C) | Calcichew (C) | Ocuvite lutein (C) | Vitamin b complex (C) | Multivitamin (C)									

SOC:Hepatobiliary disorders

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
2024A193609	FRANCE 57 Years Male	**Hepatic cytolysis (Hepatic cytolysis)***	Recovering	19-Aug-2024 2 months 5 days 8 hrs 59 min	MEDI 5752	Infusion	250 milligram q3w Intravenous use	14-JUN-2024 to 19-AUG-2024 6 weeks 4 days	Periodic Report Comment. the patient experienced liver cytolysis, Related to Medi5752, Com causality not related.
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | Neomercazole (S) | Paracetamol (C) | Izalgi (C) | Esomeprazole eg (C)									
202505GLO027458US	UNITED STATES 64 Years Female	**Cholecystitis (Cholecystitis)***	Recovered	29-May-2025 1 year 3 months 2 days	CISPLATIN	Infusion	75 milligram/sq. meter Intravenous use	28-FEB-2024 to 01-MAY-2024 2 months 4 days	Patient experienced alanine aminotransferase (alt increased), aspartate aminotransferase (ast) increased, blood bilirubin increased and cholelithiasis/cholecystitis Inv causality: NOT RELATED and NOT REPORTED for CISPLATIN CCC: NOT RELATED
Concomitant Medication(s): DURVALUMAB (S) | MONALIZUMAB (S) | PEMETREXED (S) | | Naloxone (C) | Oxycodone (C) | Prochlorperazine (C)									
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	
Concomitant Medication(s): MEDI5752 (S) | PEMETREXED (S) | | Naproxen (C) | Omeprazole (C) | Loperamide (C)									
202510GLO004048BE	BELGIUM 71 Years Male	**Hepatitis acute (Hepatitis acute)***	Not Recovered	01-Oct-2025 1 month 12 days	AZD2936	Solution	750 milligram q3w Intravenous use	10-SEP-2025 to	Periodic Report Comments. Patient had Alanine aminotransferase & aspartate aminotransferase elevation Related to study therapy AZD2936. Did not assess causality for study therapy

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
					CARBOPLATIN	Solution Infusion Infusion	750 milligram q3w Intravenous use Intravenous use 550 milligram Intravenous use	20-AUG-2025 to 10-SEP-2025 22 days 10-SEP-2025 to 10-SEP-2025 to	Carboplatin, Cisplatin, Pemetrexed. Company causality assessment is not related.; Periodic Report Comments. Periodic report comment for all priority 1 , SUSAR Case: Patient has event: Hepatitis acute, Action Taken: Study therapy was temporarily withdraw. Investigator Causality: related, Company Causality: Not Related

Concomitant Medication(s): | PEMETREXED (S) | CARBOPLATIN (S) | CISPLATIN (S) | Coversyl (C) | Spironolactone (C) | L-Thyroxine (C) | Metformine (C) | Nexiam (C) | Toularynx codeini (C) | Paracodine (C) | Fraxiparine (C) | Novorapid (C) | Riopan (C) | Litican (C) | Lactulose (C) | Corsodyl (C) | Lyrica (C) | Alprazolam (C) | Mirtazapine (C) | Magnetop (C) | Providone Iodine (C) | Kamillosan (C)

SOC:Infections and infestations

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event Outcome (If different)	Main AE Date of Onset Time to Onset	Suspect Product	Formulation	Dose/Unit/ Frequency Route	Dates of Treatment Treatment Duration	Comments
2024A120600	IRELAND 66 Years Male	**Pneumonia (Lobar pneumonia)** Pulmonary embolism (Pulmonary embolism)*	Recovered	09-May-2024 6 weeks 3 days	DURVALUMAB	Infusion Infusion Infusion	1500 milligram Intravenous use 1500 milligram Intravenous use 1500 milligram Intravenous use	07-MAY-2024 16:09 to 07-MAY-2024 17:09 1 hr 14-JAN-2025 to 14-JAN-2025 1 day 15-APR-2024 16:50 to 15-APR-2024 17:50 1 hr	Periodic Report Comment. Patient experienced lobar pneumonia and Pulmonary embolism investigator related to study therapy. CCA not related.

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

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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	17-DEC-2024 to 17-DEC-2024 1 day	
						Infusion	1500 milligram Intravenous use	19-NOV-2024 to 19-NOV-2024 1 day	
						Infusion	1500 milligram Intravenous use	22-OCT-2024 to 22-OCT-2024 1 day	
						Infusion	1500 milligram Intravenous use	24-SEP-2024 to 27-SEP-2024 4 days	
						Infusion	1500 milligram Intravenous use	25-MAR-2024 16:42 to 25-MAR-2024 17:42 1 hr	
						Infusion	1500 milligram Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
						Infusion	1500 milligram Intravenous use	28-MAY-2024 14:08 to 28-MAY-2024 15:08 1 hr	
					OLECLUM AB	Infusion	3000 milligram	07-MAY-2024 14:47 to 07-MAY-2024 15:47	

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

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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
							Intravenous use		
									1 hr
						Infusion	3000 milligram		14-JAN-2025 to 14-JAN-2025
									1 day
							Intravenous use		
						Infusion	3000 milligram		15-APR-2024 15:38 to 15-APR-2024 16:38
							Intravenous use		1 hr
						Infusion	3000 milligram		17-DEC-2024 to 17-DEC-2024
							Intravenous use		1 day
						Infusion	3000 milligram		19-NOV-2024 to 19-NOV-2024
							Intravenous use		1 day
						Infusion	3000 milligram		22-OCT-2024 to 22-OCT-2024
							Intravenous use		1 day
						Infusion	3000 milligram		24-SEP-2024 to 24-SEP-2024
									1 day
							Intravenous use		
						Infusion	3000 milligram		25-MAR-2024 15:01 to 25-MAR-2024 16:01
							Intravenous use		1 hr

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	3000 milligram Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
						Infusion	3000 milligram Intravenous use	28-MAY-2024 12:57 to 28-MAY-2024 13:57 1 hr	
					CARBOPLATIN	Infusion	Intravenous use	07-MAY-2024 17:20 to 07-MAY-2024 17:50 30 min	
						Infusion	Intravenous use	28-MAY-2024 16:06 to 28-MAY-2024 16:36 30 min	
					PEMETREXED	Infusion	500 milligram/sq. meter Intravenous use	07-MAY-2024 17:19 to 07-MAY-2024 17:29 10 min	
						Infusion	500 milligram/sq. meter Intravenous use	15-APR-2024 17:46 to 15-APR-2024 17:56 10 min	
						Infusion	500 milligram/sq. meter Intravenous use	25-MAR-2024 18:02 to 25-MAR-2024 18:12 10 min	

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	500 milligram/sq. meter Intravenous use		28-MAY-2024 15:56 to 28-MAY-2024 16:06 10 min
Concomitant Medication(s): | OLECLUMAB (S) | PEMETREXED (S) | CARBOPLATIN (S) | LEVOTHYROXINE (C) | Hydroxyzine EG (C) | Diclofenac hexa (C) | Dexamethasone (C) | METOCLOPRAMIDE (C) | MYCOSTATIN (C) | Cyclizine lactate (C) | OLANZAPINE (C) | ZOFRAN (C) | EMEND (C) | PANTOPRAZOLE (C) | CANDESARTAN (C) | LIPANTIL (C) | HYDROCHLOROTHIAZIDE (C)									
2024A143054	FRANCE 52 Years Male	**Bacteraemia (Bacteremia)***	Recovered	13-Jun-2024 6 weeks	CARBOPLATIN	Infusion Intravenous use		02-MAY-2024 to	Periodic Report Comments. The patient experienced Male event BACTEREMIA serious Inv-related to Paclitaxel and Carboplatin and MEDI5752, CCA:Not related.
						Infusion Intravenous use		23-MAY-2024 to	
					PACLITAXEL	Infusion Intravenous use	700 milligram/sq. meter	02-MAY-2024 to	
						Infusion Intravenous use	700 milligram/sq. meter	23-MAY-2024 to	
Concomitant Medication(s): MEDI 5752 (S) | PACLITAXEL (S) |									
2024A178862	FRANCE 57 Years Female	**Device related infection (Device related infection)***	Recovered	28-Jul-2024 5 days	CARBOPLATIN	Infusion Intravenous use	545 milligram q3w	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.

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

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Study ID: D9077C00001

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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	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	
					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	

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): 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	
					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:Injury, poisoning and procedural complications									
202412GLO023100IT	ITALY 76 Years Female	**Infusion related reaction (Infusion related reaction)***	Recovered	14-Aug-2024 29 days	MEDI5752	Infusion	250 milligram q3w Intravenous use	03-JAN-2025 to	
						Infusion	250 milligram q3w Intravenous use	04-OCT-2024 to	
						Infusion	250 milligram q3w Intravenous use	12-SEP-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
						Infusion	250 milligram q3w Intravenous use	13-DEC-2024 to	
						Infusion	750 milligram q3w Intravenous use	14-AUG-2024 to	
						Infusion	750 milligram q3w Intravenous use	17-JUL-2024 to	
Concomitant Medication(s): | Pemetrexed (S) | Carboplatin (S) | Palonosetron (C) | Soldesam (C) | Deltacortene (C) | Aprepitant (C) | Lansoprazole (C) | Ondansetron hydrochloride (C) | Cetrizine (C) | Metilprednisolone (C)									
2024A028378	PORTUGAL 63 Years Male	**Infusion related reaction (Infusion related reaction)***	Recovered	29-Jan-2024 1 day	CARBOPLATIN	Infusion	524 milligram q3w Unknown	29-JAN-2024 to 02-APR-2024 2 months 5 days	Periodic Report Comment. Patient experience involuntary movements of the legs serious and Investigator related to study procedure.
Concomitant Medication(s): DURVALUMAB (S) | DATOPOTAMAB DERUXTECAN (S) | | ESOMEPRAZOLE (C) | Metoclopramide (C)									
2024A166156	TAIWAN 66 Years Male	**Radiation pneumonitis (Radiation pneumonitis)***	Recovered	05-Jul-2024 27 weeks 3 days	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	26-DEC-2023 to 27-FEB-2024 9 weeks 1 day	
Concomitant Medication(s): DURVALUMAB (S) | | Carboplatin (C) | Nexium (C) | Harnalidge (C) | Optive lubricant (C) | Optive fusion (C) | Amiodarone (C) | Baktar (C)									

SOC:Investigations

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
202410GLO004668TR	TURKEY 70 Years Male	**Weight decreased (Weight loss)***	Not Recovered	23-Sep-2024 12 days	CARBOPLATIN	Infusion	Intravenous use	12-SEP-2024 to 12-SEP-2024 1 day	Periodic Report Comments. patient experienced SECONDARY CEREBELLAR DEGENERATION and WEIGHT LOSS, Investigator causality: related CCA: not related
					PACLITAXEL	Infusion	175 milligram/sq. meter Intravenous use	12-SEP-2024 to 12-SEP-2024 1 day	
Concomitant Medication(s): MEDI5752 (S) | PACLITAXEL (S) | | Diamicron (C) | Ecopirin (C) | Prednol (C) | Acetylcysteine (C) | Novorapid flexpen (C) | Lantus (C) | Cardenor (C)									
202410GLO023631IT	ITALY 58 Years Female	**Aspartate aminotransferase increased (AST increased)***	Recovered	21-Oct-2024 1 year 3 months 7 days 14 hrs 16 min	MONALIZUMAB	Infusion	1500 milligram Intravenous use	13-JUL-2023 09:44 to 16-SEP-2024 12:26 1 year 2 months 3 days 2 hrs 42 min	Periodic Report Comments. Patient experience AST-INCREASE , Study therapy: related, CCA : not related. OUtcome : Not recovered.; Periodic Report Comments. Patient experienced event - AST-increase. Investigator states event related to Durvalumab, Monalizumab. Company physician considers event not related to Durvalumab, Monalizumab.
Concomitant Medication(s): DURVALUMAB (S) | | Cymbalta (C) | Ossicodone (C) | Pantoprazole (C) | Folic acid (C) | Movicol (C) | Aprepitant (C) | Soldesam (C) | Chlorphenamine maleate (C) | Palonosetron (C) | Omeprazolo (C) | Durogesic (C) | Laroxyl (C) | Depalgos (C) | Plasil (C) | Deltacortene (C) | Ondansetron hydrochloride (C) | Vea oris (C) | Pantoprazolo (C) | Methylprednisolone (C) | Dobetin (C)									
2024A158947	ITALY 70 Years Male	**Troponin increased (Troponin increased)***	Not Recovered	04-Jul-2024 29 days	MEDI5752	Infusion	250 milligram Intravenous use	27-JUN-2024 to 22-MAY-2025 10 months 26 days	Periodic Report Comment. Patient experienced Troponin increased, related to MEDI5752, not related to Carboplatin, Paclitaxel. Com causality not related.

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	750 milligram Intravenous use	06-JUN-2024 to	
Concomitant Medication(s): | CARBOPLATIN (S) | PACLITAXEL (S) | Neuraben (C)									
2024A181350	UNITED STATES 73 Years Male	**Troponin T increased (Cardiac troponin T increased)***	Recovered	02-Aug-2024 12 weeks 3 days	MEDI 5752	Infusion	750 milligram Intravenous use	07-MAY-2024 to 12-JUL-2024 9 weeks 4 days	Periodic Report Comment. Patient experienced cardiac troponin t increased. Inv: related to MEDI5752. CCA: not related.
Concomitant Medication(s): | PEMETREXED (C) | CARBOPLATIN (C) | Aspirin (C) | Cyanocobalamin (C) | Theragran (C) | Atorvastatin (C) | Trazodone (C) | Prednisone (C) | Triamcinolone (C) | Pantoprazole (C) | Hydroxyzine HCL (C) | Clobetasol (C)									

SOC:Musculoskeletal and connective tissue disorders

202410GLO023591FR	FRANCE 75 Years Female	**Pain in extremity (Pain of lower extremities)** Paraesthesia (Paresthesia)*	Not Recovered	18-Jul-2024 1 day	PACLITAXEL	Infusion	Unknown	08-AUG-2024 to	
						Infusion	324 milligram Unknown	18-JUL-2024 to	
					MEDI5752	Infusion	750 milligram Unknown	18-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
		Pain in extremity (Pain of lower extremities)*	Not Recovered	18-Jul-2024 1 day	CARBOPLATIN	Infusion	Unknown	08-AUG-2024 to	
		Paraesthesia (Paresthesia)				Infusion	440 milligram Unknown	18-JUL-2024 to	
Concomitant Medication(s): MEDI5752 (S) | CARBOPLATIN (S) | | Acebutolol (C) | Spironolactone (C) | Altizide (C) | Simvastatine (C) | Kardegic (C) | Probiolog (C) | Rabeprazole (C) | Paracetamol (C) | Laroxyl (C) | Vitamin d3 (C) | Macrogol 4000 (C) | Anoro ellipta (C) | Oxycodone (C) | Oxynorm (C) | Prednisone (C) | Prednisone (C) | Bactrim (C) | Cacit d3 (C) | Racecadotril (C) | Amoxicilline (C) | Loperamide (C) | Phosphoneuros (C) | Zometa (C) | Thiamine chlorhydrate (C) | Prednisone (C)									
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	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)									
202505GLO007678IT	ITALY 51 Years Female	**Arthralgia (Arthralgia)***	Recovered	30-Apr-2025 13 days	AZD2936	Solution	750 milligram Intravenous use	18-APR-2025 to	Patient experienced grade 2 arthralgia , Investigator Causality: related to Rilvegostomig ,not relatyed to Pemetrexed and Carboplatin.
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | Folic acid (C) | Iron (C) | Alendronate (C) | Pregabalin (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:Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
202410GLO006136IT	ITALY 71 Years Female	**Invasive breast carcinoma (Invasive breast carcinoma)***	Recovered	09-Sep-2024 6 months 18 days	DATOPOTAMAB DERUXTECAN	Injection	468 milligram Intravenous use	06-MAY-2024 to	
						Injection	468 milligram Intravenous use	15-MAR-2024 to 06-MAY-2024 1 month 22 days	
						Injection	468 milligram Intravenous use	18-MAR-2024 to	
						Injection	468 milligram Intravenous use	23-FEB-2024 to	
Concomitant Medication(s): DURVALUMAB (S) | | Carboplatin (S) | Eutirox (C) | Bonasol (C) | Cipralex (C) | Lansoprazole (C) | Aprepitant (C) | Ondansetron hydrochloride (C)									
SOC:Nervous system disorders									
202410GLO004668TR	TURKEY 70 Years Male	**Secondary cerebellar degeneration (Secondary cerebellar degeneration)***	Not Recovered	02-Oct-2024 21 days	MEDI5752	Infusion	750 milligram Intravenous use	12-SEP-2024 to 12-SEP-2024 1 day	Periodic Report Comments. patient experienced SECONDARY CEREBELLAR DEGENERATION and WEIGHT LOSS, Investigator causality: related CCA: not related

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): | PACLITAXEL (S) | CARBOPLATIN (S) | Diamicron (C) | Ecopirin (C) | Prednol (C) | Acetylcysteine (C) | Novorapid flexpen (C) | Lantus (C) | Cardenor (C)									
2024A002682	UNITED STATES 70 Years Female	**Cerebrovascular accident (Stroke)***	Recovered	26-Dec-2023 5 weeks 1 day	CARBOPLATIN	Infusion	Unknown	20-NOV-2023 to 11-DEC-2023 3 weeks 1 day	
					PEMETREXED	Infusion	500 milligram/sq. meter q3w Unknown	20-NOV-2023 to 11-DEC-2023 3 weeks 1 day	
Concomitant Medication(s): DURVALUMAB (S) | MONALIZUMAB (S) | PEMETREXED (S) | | Folic acid (C) | FLONASE (C) | Bag Balm (C) | MONTELUKAST (C) | Ventolin hfa (C) | VITAMIN D (C) | DEXEDRINE (C) | LORAZEPAM (C) | ESTRADIOL (C) | MIRALAX (C) | CANDESARTAN (C) | PROZAC (C) | GABAPENTIN (C) | ULTRAM (C) | Biotene dry mouth oral rinse (C) | ATORVASTATIN (C) | AMLODIPINE (C)									
202506GLO010302ES	SPAIN 72 Years Male	**Myasthenia gravis (Myasthenia gravis)***	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) | Dexchlorpheniramine (C) | Dexamethasone (C) | Ondansetron (C)									
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.;

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	245 milligram q3w Unknown	02-AUG-2024 to 04-OCT-2024 2 months 3 days	Periodic Report Comments. Patient experienced Bilateral cordal paralysis. Investigator causality not related to MEDI5752 not reported to carboplatin and paclitaxel. CCA, not related.
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)									
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)									
202501GLO026338US	UNITED STATES 75 Years Male	**Immune-mediated nephritis (Immune-mediated nephritis)*** Renal failure (Renal failure)*	Recovered with Sequelae	30-Jan-2025 6 months 8 days	MEDI5752	Infusion	250 milligram q3w Intravenous use	04-SEP-2024 to 04-SEP-2024 1 day	Periodic Report Comments. Male Patient with immune-mediated nephritis , Aspiration pneumonia. Investigator:

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 Infusion Infusion	250 milligram q3w Intravenous use 750 milligram Intravenous use 750 milligram q3w Intravenous use	25-SEP-2024 to 25-SEP-2024 1 day 23-JUL-2024 to 23-JUL-2024 1 day 14-AUG-2024 to 14-AUG-2024 1 day	Related to study therapy for event immune-mediated nephritis and NOT RELATED to Aspiration pneumonia . CCA: Not related to Study therapy. Action taken: Not applicable; Patient has event : IMMUNE-MEDIATED NEPHRITIS, ASPIRATION PNEUMONIA, RENAL FAILURE For study therapy Action Taken: not applicable Investigator Causality: Related, CC: Not Related. Outcome: Recovered, recovering, recovered with sequelae.
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | Dexamethasone (C) | Empagliflozin (C) | Losartan (C) | Metformin (C) | Pravastatin (C) | Benadryl (C) | Ginko (C) | Triamcinolone (C) | Azithromycin (C) | Acetaminophen (C) | Oxycodone (C) | Atorvastatin (C) | Guaifenesin (C)									
202504GLO020796ES	SPAIN 53 Years Female	**Acute kidney injury (Acute kidney failure)***	Recovered	14-Apr-2025 8 months 16 days	MEDI5752	Infusion Infusion Infusion	250 milligram q3w Intravenous use 750 milligram q3w Intravenous use 750 milligram q3w Intravenous use	21-AUG-2024 to 26-MAY-2025 9 months 6 days 30-JUL-2024 to 30-JUL-2024 1 day	Periodic Report Comments. Patient experienced kidney failure. Investigator: related with study therapy MEDI5752. Company physician: Not related.
Concomitant Medication(s): | PEMETREXED (S) | CARBOPLATIN (S) | Folic acid (C) | Vitamin b12 (C) | Dexamethasone (C) | Fosfomicina (C) | Cefixima (C) | Naproxeno (C)									

SOC:Respiratory, thoracic and mediastinal disorders

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
2023A218704	KOREA, REPUBLIC OF 69 Years Male	**Pneumonitis (Pneumonitis)***	Fatal	21-Sep-2023 5 months 19 days	MEDI5752	Infusion	750 milligram q3w Intravenous use	03-APR-2023 to 11-SEP-2023 5 months 9 days	Periodic Report Comment. Patient experienced Pneumonitis and Bacterial Pneumonia. Investigator: related to Pneumonitis; not related to Bacterial Pneumonia. CCA: Not related
Concomitant Medication(s): | Pemetrexed (C) | Carboplatin (C) | CERENADE (C) | DILATREND (C) | NICORAN (C) | ROSUZET (C) | ELIQUIS (C) | Harnal d (C) | Pratam sr (C) | GASTER (C) | Mucosta (C) | Humalog (C) | Tresiba (C) | Ebastel (C)									
2023A251534	ITALY 58 Years Female	**Haemoptysis (Hemoptysis)***	Recovered	25-Aug-2023 nk	DATOPOTAMAB DERUXTECAN DURVALUMAB MEDI5752 MEDI9447 MONALIZUMAB	Injection Infusion Infusion Infusion Infusion	to to to to		
Concomitant Medication(s): DURVALUMAB (S) | MONALIZUMAB (S) | MEDI9447 (S) | | MEDI5752 (S)									
2024A075378	SPAIN 66 Years Male	**Pneumothorax (Pneumothorax)***	Recovered	20-Mar-2024 16 weeks	DATOPOTAMAB DERUXTEC	Injection	Intravenous use	10-JAN-2024 to 10-JAN-2024	Periodic Report Comment. Patient experience left pneumothorax post surgery serious and Inv. 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
					AN			1 day	procedure. CCA: related to Study Procedure and not related to Datopotamab Deruxtecan, Durvalumab.
						Injection	Intravenous use	20-DEC-2023 to 20-DEC-2023 1 day	
						Injection	Intravenous use	29-NOV-2023 to 29-NOV-2023 1 day	
						Injection	milligram/kilogram Intravenous use	06-FEB-2024 to	
Concomitant Medication(s): | DURVALUMAB (S) | CISPLATIN (C) | DEXTROMETORFANO (C) | ALOPURINOL (C) | SULPIRIDE (C) | COLCHICINE (C) | METOCLOPRAMIDE (C) | MAGNESIUM (C) | ROSUVASTATINA (C) | TAMSULOSINE (C)									
202510GLO005356FR	FRANCE 41 Years Male	**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	

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): MEDI5752 (S) | PACLITAXEL (S) |									
202512GLO006136CA	CANADA 67 Years Female	**Pneumonitis (Pneumonitis)***	Not Recovered	29-Nov-2025 5 months 11 days	AZD2936	Solution	Unknown	19-JUN-2025 to 20-NOV-2025 5 months 2 days	Periodic Report Comments. Patient experienced Pneumonitis. Inv: related to AZD2936. Not related to PEMETREXED and carbolplatin. CCA Not related.
Concomitant Medication(s): | CARBOPLATIN (S) | PEMETREXED (S) | Tylenol (C) | Rosuvastatin (C) | Amlodipine (C) | Gabapentin (C) | Codeine (C) | Dexamethasone (C) | Diphenhydramine (C) | Ranitidine (C)									
SOC:Skin and subcutaneous tissue disorders									
2024A188378	FRANCE 77 Years Male	**Toxic skin eruption (Toxicoderma)***	Recovered	09-Aug-2024 1 week 2 days	MEDI 5752	Infusion	750 milligram q3w Intravenous use	31-JUL-2024 to 30-AUG-2024 1 month	Periodic Report Comment. Patient experienced Toxidermia, related to MEDI5752, not related to PACLITAXEL, CARBOPLATIN . Company causality not related.
Concomitant Medication(s): | PACLITAXEL (S) | CARBOPLATIN (S) | COAPROVEL (C) | ROCEPHINE (C)									
2024A201619	FRANCE 77 Years Male	**Dermatitis allergic (Allergic skin reaction)***	Recovered	30-Aug-2024 4 weeks 2 days	MEDI 5752	Infusion	750 milligram q3w Intravenous use	31-JUL-2024 to 30-AUG-2024 4 weeks 3 days	Periodic Report Comment. Patient experienced cutaneous allergic reaction. Inv: related to MEDI5752. Company causality not related.
Concomitant Medication(s): | PACLITAXEL (S) | CARBOPLATIN (S) | COAPROVEL (C) | ROCEPHINE (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									
2023A283157	POLAND 77 Years Male	**Neutropenia (Neutropenia)***	Recovered with Sequelae	06-Dec-2023 1 week	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	31-JAN-2024 to 31-JAN-2024 1 day	Periodic Report Comment. Patient experience neutropenia serious and Investigator related to Datopotamab Deruxtecan, Carboplatin. CCA:Related to carboplatin.
						Injection	6 milligram/kilogram q3w Intravenous use	29-NOV-2023 to 29-NOV-2023 1 day	
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Clemastinum (C) | Dexaven (C) | Paracetamol (C) | Ondasetron (C) | Enoxaparin (C) | Diclofenac (C) | Metoprolol (C) | Kalipoz (C) | Dexamethazon (C) | Allopurinol (C) | Rosuvastatin (C) | Doxazosine (C)									
202412GLO003972US	UNITED STATES 79 Years Female	**Anaemia (Anemia)***	Not Recovered	02-Dec-2024 6 months 10 days	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	23-MAY-2024 to 05-SEP-2024 3 months 14 days	Periodic Report Comments. Patient experienced hyponatremia, creatinine increased (preferred term: Blood creatinine increased) and anemia. Inv: Anemia related to Datopotamab Deruxtecan, not related to Azd2936.
Concomitant Medication(s): | AZD2936 (S) | Acetaminophen (C) | Alendronate (C) | Vitamin d (C) | Esomeprazole (C) | Gabapentine (C) | Levothyroxine (C) | Lidocaine (C) | Robaxin (C) | Zofran (C) | Roxicodone (C) | Compazine (C) | Crestor (C) | Miralax (C) | Dexamethasone (C) | Voltaren (C) | Morphine (C) | Oxycodone (C) | Sodium chloride (C)									
202506GLO002775BE	BELGIUM 68 Years Female	**Neutropenia (Neutropenia)***	Recovered	04-Jun-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	to	PRC comments. Patient has event: neutropenia, Action Taken: Withdrawn. Investigator Causality: Related, Company

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
									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, CARBOPLATIN Investigator Causality: Not related CC: Not related. DURVALUMAB Causality: related CC: related.
						Infusion	1120 milligram q3w Intravenous use	08-MAR-2022 13:50 to 08-MAR-2022 14:50 1 hr	
						Infusion	1120 milligram q3w Intravenous use	10-MAY-2022 12:23 to 10-MAY-2022 13:23 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	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	
						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	

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
								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)									
202412GLO020275US	UNITED STATES 61 Years Female	**Stomatitis (Mucositis oral)*** Candida infection (Thrush)*	Recovered	21-Dec-2024 1 month 28 days	DATOPOTAMAB DERUXTECAN	Injection	360 milligram Unknown	24-OCT-2024 to 12-DEC-2024 1 month 19 days	Periodic Report Comments. Patient experienced serious event oral mucositis and thrush.. Inv: event related to Datopotamab Deruxtecan and not related to Carboplatin, Durvalumab ,. CCA: not related.
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Celecoxib (C) | Lorazepam (C) | Zolpidem (C) | Ibuprofen (C)									
2024A127435	POLAND 73 Years Female	**Oesophagitis (Esophagitis)***	Recovered	29-May-2024 2 weeks	AZD 2936	Solution	750 milligram Intravenous use	15-MAY-2024 to 15-MAY-2024 1 day	Periodic Report Comment. female pt experinced serous event esophagitis related to study drugs CCA: Not related
					DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	15-MAY-2024 to 15-MAY-2024 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | METFORMIN (C) | SPIRONOLACTONE (C) | NITREDIPINO (C) | NEBIWORLD (C) | QUETIAPINE (C) | TORASEMIDE (C) | ATORVASTATIN (C) | ANORO (C) | DEXAMETHASON (C) | CLEMASTIN (C) | PARACETAMOL (C) | ONDASETRON (C) | OPTILIFE MELATONIN (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
2024A197200	POLAND 69 Years Female	**Mucosal toxicity (Mucosal toxicity)***	Recovered	22-Aug-2024 6 months 1 day	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	22-FEB-2024 to 08-AUG-2024 5 months 18 days	Periodic Report Comment. Patient experienced oral mucosal , related to DS1062a, not related to Azd2936. Company causality not related.
Concomitant Medication(s): | AZD2936 (S) | Roxiper (C) | Euthyrox (C)									
202501GLO007961TR	TURKEY 50 Years Male	**Chest pain (Chest pain)*** Infusion related reaction (Infusion related reaction)*	Recovered	10-Jan-2025 24 days	DATOPOTAMAB DERUXTECAN	Injection	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)									
202512GLO009825TW	TAIWAN 65 Years Male	**Pyrexia (Fever)***	Not Recovered	09-Dec-2025 5 months 10 hrs 59 min	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram Unknown	18-NOV-2025 to 18-NOV-2025 1 day	
						Injection	6 milligram/kilogram Unknown	05-AUG-2025 14:11 to 05-AUG-2025 14:41 30 min	
						Injection	6 milligram/kilogram Unknown	09-JUL-2025 13:01 to 09-JUL-2025 14:31 1 hr 30 min	

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
						Injection	6 milligram/kilogram Unknown	16-SEP-2025 to 16-SEP-2025 1 day	
						Injection	6 milligram/kilogram Unknown	26-AUG-2025 to 26-AUG-2025 1 day	
						Injection	6 milligram/kilogram Unknown	28-OCT-2025 to 28-OCT-2025 1 day	

Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S) | Acetylcysteine (C) | Denosumab (C) | Dextromethorphan (C) | Sennoside a+b (C) | Procaterol (C) | Tranexamic acid (C) | Tenofovir alafenamide (C) | Dexamethasone (C) | Hydroxypropyl methyl cellulose (C) | Triamcinolone (C) | Prednisolone (C) | Diphenhydramine (C) | Acetaminophen (C) | Parodontax (C) | Famotidine (C) | Nystatin (C) | Propacetamol (C) | Netupitant (C) | Cough Mixture (C) | Neomycin (C) | Albumin (C) | Terbutaline (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

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
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)									
2024A098729	SPAIN 72 Years Male	**Neutrophil count decreased (Neutrophil count decreased)***	Recovered	15-Apr-2024 3 weeks 6 days	AZD 2936	Solution Solution Solution	750 milligram Intravenous use 750 milligram Intravenous use 750 milligram Intravenous use	05-JUN-2024 to 09-APR-2024 to 09-APR-2024 1 day 19-MAR-2024 to 19-MAR-2024 1 day	Periodic Report Comment. The patient experienced Neutrophil count decreased, serious, Inv: releted to study therapy, company not related

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
					DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	19-MAR-2024 to 19-MAR-2024 1 day	
						Injection	750 milligram Intravenous use	05-JUN-2024 to	
						Injection	750 milligram Intravenous use	09-APR-2024 to 09-APR-2024 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Rosuvastatin (C) | Bisoprolol (C) | Cafinitrina (C) | Tebetane compuesto (C) | Dorzolamida timolol (C) | Colecalciferol (C) | Acetylsalicylic acid (C) | Mirabegron (C)									
202504GLO022176JP	JAPAN 56 Years Male	**Platelet count decreased (Platelet count decreased)***	Recovered	24-Apr-2025 3 months 9 days	CARBOPLATIN	Infusion	750 milligram q3w Intravenous use	03-APR-2025 to 03-APR-2025 1 day	Periodic Report Comments. Patient experienced event - platelet count decreased. Investigator states event related to Carboplatin and not related Datopotamab Deruxtecan and Durvalumab. Company physician considers event not related to Datopotamab Deruxtecan, Durvalumab and Carboplatin.
						Infusion	750 milligram q3w Intravenous use	16-JAN-2025 to 16-JAN-2025 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | Hyaluronate na (C) | Dexart (C) | Dexamethasone (C) | Xylocaine (C)									
202505GLO004812JP	JAPAN 56 Years Male	**Platelet count decreased (Platelet count decreased)***	Recovered	25-Apr-2025 3 months 10 days	CARBOPLATIN	Infusion	q3w Intravenous use	03-APR-2025 to 03-APR-2025 1 day	

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	q3w Intravenous use	16-JAN-2025 to 16-JAN-2025 1 day	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | DURVALUMAB (S) | | Sodium bicarbonate | Sodium gualenate hydrate (C) | Hyaluronate sodium (C) | Olopatadine hydrochloride (C) | Olopatadine hydrochloride (C) | Heparinoid (C) | Hydrocortisone butyrate (C) | Triamcinolone acetonide (C)									
202506GLO017724TW	TAIWAN 70 Years Female	**Lipase increased (Lipase increased)***	Recovered	14-May-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	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
Concomitant Medication(s): | DURVALUMAB (S) | CARBOPLATIN (S)									

SOC:Respiratory, thoracic and mediastinal disorders

2022A236706	UNITED STATES 63 Years Male	**Interstitial lung disease (Interstitial lung disease)***	Fatal	18-Jun-2022 9 weeks 2 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	05-MAY-2022 13:45 to 05-MAY-2022 14:15 30 min	Periodic Report Comment. pt had interstitial lung disease, bronchiolitis obliterans related to IP.

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
						Injection	6 milligram/kilogram q3w Intravenous use	14-APR-2022 13:28 to 14-APR-2022 15:00 1 hr 32 min	
		Obliterative bronchiolitis (Bronchiolitis obliterans)* Interstitial lung disease (Interstitial lung disease)	Fatal	03-Sep-2022 20 weeks 2 days	DURVALUMAB	Infusion	1120 milligram q3w Intravenous use	14-APR-2022 11:46 to 14-APR-2022 12:46 1 hr	
						Infusion	1120 milligram q3w Intravenous use	05-MAY-2022 12:15 to 05-MAY-2022 13:15 1 hr	
Concomitant Medication(s): | DURVALUMAB (S) | Humalog (C) | Lantus (C) | Atorvastatin (C) | Indapamide (C) | Trelegy (C)									
202412GLO014787US	UNITED STATES 78 Years Male	**Pneumonitis (Pneumonitis)** Dyspnoea (Dyspnea exacerbated)*	Not Recovered	12-Dec-2024 6 months 28 days	DATOPOTAMAB DERUXTECAN	Injection	500 milligram Intravenous use	15-MAY-2024 to 09-OCT-2024 4 months 25 days	Periodic Report Comments. Patient has event: pneumonia, pneumonitis and worsening dyspnea. Action Taken with study therapy was No change. Investigator Causality: Not related for DATOPOTAMAB DERUXTECAN for pneumonia. Investigator Causality: related AZD2936 for pneumonitis and worsening dyspnea and AZD2936, DATOPOTAMAB DERUXTECAN, CC: Not related
					AZD2936	Solution	750 milligram Intravenous use	15-MAY-2024 to 09-OCT-2024 4 months 25 days	
Concomitant Medication(s): AZD2936 (S) | | Allopurinol (C) | Aspirin (C) | Carvedilol (C) | Famotidine (C) | Ibuprofen (C) | Montelukast sodium (C) | Multivitamin (C) | Potassium citrate (C) | Rosuvastatin calcium (C) | Refreshoptive (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
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)									
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: D926T

EudraCT No:

Study Design: Not Blinded

Study ID: D926TC00001

Study Description: A Phase III, Randomised, Open-label, Global Study of Adjuvant Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig or Rilvegostomig Monotherapy Versus Standard of Care in Participants With Stage I Adenocarcinoma Non-small Cell Lung Cancer who are ctDNA-positive or Have High-risk Pathological Features, Following Complete Tumour Resection (TROPION Lung12)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
202512GLO009783US	UNITED STATES Female	**Cardiac arrest (Cardiac arrest)***	Fatal	03-Nov-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	Unknown	to	
Concomitant Medication(s):									
SOC:General disorders and administration site conditions									
202512GLO024845VN	VIET NAM 68 Years Male	**Pyrexia (Fever)***	Recovering	24-Dec-2025 1 month 13 days	AZD2936	Solution	750 milligram q3w Intravenous use	04-DEC-2025 to	Periodic Report Comments. Patient experienced event fever. Investigator states event related to DATOPOTAMAB DERUXTECAN, AZD2936 Company physician considers event unrelated to DATOPOTAMAB DERUXTECAN, AZD2936
						Solution	750 milligram q3w Intravenous use	12-NOV-2025 to 12-NOV-2025 1 day	
					DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	04-DEC-2025 to	
						Injection	6 milligram/kilogram Intravenous use	12-NOV-2025 to 12-NOV-2025 1 day	

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

Project ID: D926T

Study ID: D926TC00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Phase III, Randomised, Open-label, Global Study of Adjuvant Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig or Rilvegostomig Monotherapy Versus Standard of Care in Participants With Stage I Adenocarcinoma Non-small Cell Lung Cancer who are ctDNA-positive or Have High-risk Pathological Features, Following Complete Tumour Resection (TROPION Lung12)

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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) | | Captopril (C) | Colchicin (C) | Metformin (C) | Dexamethason (C) | Diphenhydramin (C) | Palonosetron HCL (C) | Paracetamol (C) | Iobitridol (C)									
SOC:Injury, poisoning and procedural complications									
202511GLO007274US	UNITED STATES Female	**Procedural haemorrhage (Intraoperative haemorrhage)** *	Fatal	03-Nov-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	to	
Concomitant Medication(s):									

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:Blood and lymphatic system disorders									
202410GLO024810TR	TURKEY 59.8 Years Female	**Neutropenia (Neutropenia)***	Recovered	27-Oct-2024 1 month 5 days	5-FLUOROURACIL	Infusion	392 milligram/sq. meter q3w Intravenous use	13-JAN-2025 to 14-FEB-2025 1 month 2 days	
						Infusion	600 milligram/sq. meter q3w Intravenous use	23-SEP-2024 to 22-NOV-2024 2 months	
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Desmont (C) | Diaformin (C) | Atorvastatin (C) | Kytril (C) | Fito (C) | Hametan (C) | Desal (C)									
202503GLO002123ES	SPAIN 69 Years Male	**Anaemia (Anemia)***	Recovered	03-Mar-2025 1 month 23 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	06-MAY-2025 to 17-JUN-2025 1 month 12 days	Periodic Report Comments. Patient experiencing Anemia Inv causality: RELATED CCA: NOT RELATED and Fever Inv causality: NOT RELATED CCA: NOT RELATED
						Injection	4 milligram/kilogram q3w Intravenous use	25-MAR-2025 to 25-MAR-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	09-JAN-2025 to 19-FEB-2025 1 month 11 days	

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	30-JAN-2025 to 30-JAN-2025 1 day	
Concomitant Medication(s): | Polaramine (C) | Paracetamol (C) | Ondansetron (C) | Atorvastatin (C) | Sitagliptin (C) | Famotidine (C) | Lantus (C)									
SOC:Cardiac disorders									
2023A191947	POLAND 60.6 Years Female	**Atrial fibrillation (Atrial fibrillation)***	Not Recovered	22-Aug-2023 8 weeks 6 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	21-JUN-2023 to 28-NOV-2023 23 weeks	Periodic Report Comment. Patient experienced atrial fibrilation serious and Investigator related to study therapy.
Concomitant Medication(s): | Neoparin (C) | Propranolol (C) | Oxycodon (C) | Lyrica (C) | Potassium nitrate (C) | Olanzapine (C) | Glucosum (C) | Clemastin (C) | Dexamethasone (C)									
SOC:Ear and labyrinth disorders									
202412GLO021186GB	UNITED KINGDOM 57 Years Female	**Vertigo (Vertigo)***	Recovered	23-Dec-2024 2 months 8 days	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	16-OCT-2024 to 16-OCT-2024 1 day	
						Injection	Intravenous use	22-NOV-2024 to 24-JAN-2025 2 months 3 days	
Concomitant Medication(s): | Perindopril (C) | Doxazosin (C) | Rivaroxaban (C) | Atorvastatin (C) | Sertraline (C) | Docusate (C) | Movicol (C) | Benzydamine (C) | Betamethasone (C) | Loperamide (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									
2023A075353	TAIWAN 63.2 Years Female	**Vomiting (Vomiting)***	Recovered	29-Mar-2023 17 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	13-APR-2023 to 13-APR-2023 1 day	Periodic Report Comment. Patient experience vomiting and hyponatremia serious and vomiting related to study therapy.
						Injection	6 milligram/kilogram q3w Intravenous use	13-MAR-2023 to 13-MAR-2023 1 day	
Concomitant Medication(s): | Dexamethasone (C) | Aig esomeprazole (C) | Metformin (C) | Acetaminophen (C) | Diphenhydramine HCL (C) | Palonosetron (C) | Anacle (C) | Ceftriaxone (C) | Asmofug (C) | Meropenem trihydrate (C) | Teicoplanin (C)									
2023A077764	UNITED STATES 81 Years Male	**Colitis (Colitis)***	Not Recovered	29-Mar-2023 4 weeks 6 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	03-MAY-2023 to 03-MAY-2023 1 day	Periodic Report Comment. Patient experience colitis and syncope serious and Investigator related to colitis .Comp causality not related.
						Injection	4 milligram/kilogram q3w Intravenous use	18-AUG-2023 to 29-SEP-2023 6 weeks 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	23-FEB-2023 to 23-FEB-2023 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	17-MAR-2023 to 17-MAR-2023 1 day	
Concomitant Medication(s): | LEUPROLIDE (C) | CHOLECALCIFEROL (C) | DENOSUMAB (C) | ALLOPURINOL (C) | ASPIRIN (C) | KENALOG (C) | REFRESH (C)									
202411GLO001694US	UNITED STATES 71 Years Female	**Stomatitis (Mucositis oral)***	Not Recovered	20-Oct-2024 4 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	17-OCT-2024 to 17-OCT-2024 1 day	
Concomitant Medication(s): | Latanoprost (C) | Metoprolol tartrate (C) | Dorzolamide (C) | Lisinopril (C) | Minivelle (C) | Vitamin D2 (C) | Triamcinolone acetonide (C) | Hydrocodone (C) | Artificial tears (C) | Ondansetron (C) | Prochlorperazine (C) | Acetaminophen (C) | Diphenhydramine HCL (C) | Dexamethasone (C) | Latanoprost (C) | Hydrocodone (C) | Artificial tear (C) | Famotidine (C) | Maalox (C) | Sodium Chloride 0.9% & Dextrose 5% (C) | Xylocaine (C) | Fluconazole (C) | Oxycodone (C) | Normal saline (C) | Nystatin (C)									
202411GLO006536US	UNITED STATES 71 Years Female	**Stomatitis (Mucositis oral)***	Not Recovered	20-Oct-2024 4 days	DATOPOTAMAB DERUXTECAN	Injection	490 milligram Intravenous use	17-OCT-2024 to 17-OCT-2024 1 day	
Concomitant Medication(s): | Latanoprost Preservative Free (C) | Metoprolol tartrate (C) | Dorzolamide (C) | Lisinopril (C) | Magic Mouthwash (Lidocaine 20mg/mL, Maalox, Benadryl 12.5mg/5mL) (C) | Minivelle (C) | Vitamin D2 (C) | Triamcinolone acetonide (C) | Hydrocodone 5mg Acetaminophen 325mg (C) | ARTIFICIAL TEARS (INGREDIENTS UNKNOWN) (C) | Acetaminophen (C) | Dexamethasone (C) | Diphenhydramine HCL (C) | Ondansetron (C) | Prochlorperazine (C) | Famotidine (C) | Hydromorphone (C) | MAALOX #1 (INGREDIENTS UNKNOWN) (C) | Sodium Chloride 0.9% & Dextrose 5% (C) | Xylocaine (C) | Fluconazole (C) | Oxycodone (C) | Normal saline (C) | Nystatin (C)									
202412GLO011852FR	FRANCE 74.9 Years Female	**Stomatitis (Mucositis oral)** Fatigue (Fatigue)*	Not Recovered	02-Dec-2024 1 day	CARBOPLATIN	Infusion	Intravenous use	02-DEC-2024 to 02-DEC-2024 1 day	Periodic Report Comments. Patient experienced fatigue, Mucositis oral,Inv, related to Datopotamab Deruxtecan, Inv,

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
					DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	02-DEC-2024 to 02-DEC-2024 1 day	related to bevacizumab, Inv, related to CARBOPLATIN, CCA : not related to Datopotamab Deruxtecan, CCA : not related to bevacizumab, CCA: not related to CARBOPLATIN;Periodic Report Comments. Patient has event: Mucositis oral, fatigue. For study therapy DATOPOTAMAB DERUXTECAN, CARBOPLATIN, BEVACIZUMAB Action Taken: Does not change. The investigator causality: related and Company causality: not related.;periodic report comment. patient experienced Mucositis oral, fatigue, inv: related to DATOPOTAMAB DERUXTECAN, CARBOPLATIN, BEVACIZUMAB, cca: not related to DATOPOTAMAB DERUXTECAN, CARBOPLATIN, BEVACIZUMAB.
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | BEVACIZUMAB (S) | Atenolol (C) | Paracetamol (C) | Solifenacine (C) | Venlafaxine (C) | Lansoprazole (C) | Oxazepam (C) | Lidocain (C)									
202412GLO017243ES	SPAIN 52.9 Years Female	**Stomatitis (Mucositis oral)***	Recovered	11-Dec-2024 9 days	DATOPOTAMAB DERUXTECAN	Injection Injection	3 milligram/kilogram Intravenous use 4 milligram/kilogram	14-FEB-2025 to 25-APR-2025 2 months 12 days 10-JAN-2025 to 10-JAN-2025	Periodic Report Comments. Patient experience Oral Mucositis. Investigator: Related to study therapy Dato-Dxd. CCA: Not related to Study therapy

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
							Intravenous use	1 day	
						Injection	6 milligram/kilogram Intravenous use	03-DEC-2024 to 03-DEC-2024 1 day	
Concomitant Medication(s): | CARBOPLATIN (S) | BEVACIZUMAB (S) | Lidocaine (C) | Sucralfate (C) | Nistatin (C) | Omeprazole (C) | Metoclopramide (C) | Movicol (C) | Fentanyl citrate (C) | Dexamethasone (C) | Dexchlorpheniramine (C) | Ondansetron (C) | Paracetamol (C)									
2024A040849	UNITED KINGDOM 64.1 Years Male	**Upper gastrointestinal haemorrhage (Upper gastrointestinal haemorrhage)** *	Fatal	16-Feb-2024 10 weeks 2 days	PREDNISONE	Tablet	5 milligram/kilogram q3w Oral use	06-DEC-2023 to 27-DEC-2023 3 weeks 1 day	Periodic Report Comments. Patient experienced acute upper gastro-intestinal haemorrhage. Inv: event not related to study therapy. CCA: not related.; Patient has event : Acute upper gastrointestinal haemorrhage. For study therapy Action taken : no change, Investigator Causality: not Related, related respectively. CC: Not Related. Outcome: Fatal.
						Tablet	5 milligram/kilogram q3w Oral use	07-FEB-2024 to 07-FEB-2024 1 day	
						Tablet	5 milligram/kilogram q3w Oral use	17-JAN-2024 to 17-JAN-2024 3 weeks	
						Tablet	5 milligram/kilogram q3w Oral use	29-DEC-2023 to 16-JAN-2024 2 weeks 5 days	

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
Concomitant Medication(s): DATOPOTAMAB DERUXTECAN (S) | | Alendronic acid (C) | Ag amlodipine (C) | Bisoprolol (C) | Betha (C) | Chlorhexidine (C) | Chlorphenamine (C) | Dexamethasone (C) | Hypromellose (C) | Metclam (C) | Ondansetron (C) | Paracetamol (C) | Ramipril (C)									
2024A161984	CANADA 63 Years Male	**Intestinal obstruction (Bowel obstruction)***	Not Recovered	13-Jul-2024 8 weeks 5 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	13-MAY-2024 to 13-MAY-2024 1 day	Periodic Report Comment. Patient experienced Small and large bowel obstruction; Inv: related to Datopotamab deruxtecan; CCA: not related to Datopotamab deruxtecan
						Injection	6 milligram/kilogram q3w Intravenous use	04-JUN-2024 to 04-JUN-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	16-AUG-2024 to 06-SEP-2024 22 days	
						Injection	6 milligram/kilogram q3w Intravenous use	26-JUN-2024 to 26-JUN-2024 1 day	
Concomitant Medication(s): | CLINDAMYCINE (C) | Hydrocortisone acetate (C) | MINOCYCLINE (C)									
202501GLO005338FR	FRANCE 63 Years Male	**Stomatitis (Stomatitis)***	Recovered	02-Jan-2025 28 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	06-DEC-2024 to 06-DEC-2024 1 day	Patient experienced STOMATITIS Investigator causality: RELATED with the study therapy Company causality was NOT RELATED

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
Concomitant Medication(s): | Amlodipine (C) | Irbesartan (C) | Actiskenan (C) | Movicol (C) | Paracetamol (C) | Denosumab (C)									
202501GLO005398FR	FRANCE 76 Years Male	**Stomatitis (Mucositis oral)***	Not Recovered	25-Dec-2024 9 days	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	17-DEC-2024 to	Periodic Report Comments. Patient experienced "Mucositis" . INV related to DATOPOTAMAB DERUXTECAN . Company not related to DATOPOTAMAB DERUXTECAN.
Concomitant Medication(s): | Kardegic (C) | Levothyrox (C)									
202501GLO011131TR	TURKEY 73 Years Female	**Constipation (Constipation)***	Recovered	13-Jan-2025 11 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	03-JAN-2025 to 03-JAN-2025 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	10-MAR-2025 to 24-APR-2025 1 month 15 days	
						Injection	6 milligram/kilogram q3w Intravenous use	24-JAN-2025 to 17-FEB-2025 25 days	
Concomitant Medication(s): | Azarga (C) | Hyzaar (C) | Cipram (C) | Calcium sandoz (C) | Dexamethasone (C) | Avil (C) | Pantoprazole (C) | Fosemazon (C) | Palonosetron (C) | Zyrtec (C) | Vomepram (C) | Partemol (C)									
202501GLO015723GB	UNITED KINGDOM	**Abdominal pain (Abdominal pain aggravated)***	Not Recovered	16-Jan-2025 3 months 23 days	DATOPOTAMAB DERUXTEC	Injection	3 milligram/kilogram q3w	26-FEB-2025 to 19-MAR-2025	Periodic Report Comments. Patient experienced Abdominal pain. Investigator: related,

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	
	55 Years Female				AN		Intravenous use	22 days		Company: related. Study procedure: not related
						Injection	3 milligram/kilogram q3w Intravenous use	30-JAN-2025 to 30-JAN-2025 1 day		
						Injection	4 milligram/kilogram q3w Intravenous use	24-DEC-2024 to 24-DEC-2024 1 day		
						Injection	6 milligram/kilogram q3w Intravenous use	25-SEP-2024 to 27-NOV-2024 2 months 3 days		
Concomitant Medication(s): | Lansoprazole (C) | Promethazine (C) | Amlodipine (C) | Gaviscon (C) | Bisacodyl (C) | Cyclizine (C) | Mst (C) | Betamethasone (C) | Hypromellose (C) | Ondansetron (C) | Dexamethason (C) | Chlorhexidine (C) | Clarithromycin (C) | Paracetamol (C) | Metoclopramide (C)										
202503GLO002132ES	SPAIN 69 Years Male	**Stomatitis (Mucositis oral)***	Recovered	04-Mar-2025 1 month 24 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	25-MAR-2025 to 17-JUN-2025 2 months 24 days	Periodic Report Comments. Patient experiencing MUCOSITIS Inv causality: RELATED CCA: NOT RELATED	
						Injection	6 milligram/kilogram q3w Intravenous use	09-JAN-2025 to 30-JAN-2025 22 days		

Blinded IBPR - AstraZeneca - Confidential & Proprietary

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
Concomitant Medication(s): | Polaramine (C) | Paracetamol (C) | Ondansetron (C) | Atorvastatin (C) | Sitagliptin (C) | Famotidine (C) | Mirtazapine (C)									
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	
						Injection	4 milligram/kilogram q3w Intravenous use	19-AUG-2025 to 30-SEP-2025 1 month 12 days	
						Injection	4 milligram/kilog	25-MAR-2025 to 25-MAR-2025	

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
							ram q3w Intravenous use	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	
						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)

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
202511GLO006046JP	JAPAN 70.8 Years Female	**Nausea (Nausea)***	Recovered	06-Nov-2025 nk	AZ_DS-1062A	Injection	6 milligram/kilogram q3w Intravenous use	05-NOV-2025 to 05-NOV-2025 1 day	Periodic Report Comments. Subject has event: Nausea, Investigator causality for study drug: Related, Sponsor causality: Not related
Concomitant Medication(s): | Amlodipine (C) | Fexofenadine (C) | Epinastine hydrochloride (C) | Hyaluronate sodium (C) | Latanoprost (C) | Heparinoid (C) | Restamin kowa (C) | Thyradin (C) | Flucort (C) | Loxoprofen (C) | Mucosta (C) | Azunol (C) | Ferrous citrate (C) | Aloxi (C) | Calonal (C) | Onetram (C) | Polaramine (C) | Ranmark (C) | Solucortef (C) | Tavegyl (C)									
202512GLO019851TR	TURKEY 63.8 Years Female	**Abdominal pain upper (Stomachache)***	Recovering	09-Oct-2025 2 years 6 months 20 days	DATOPOTAMAB DERUXTECAN	Injection	3 milligram/kilogram q3w Intravenous use	15-JAN-2025 to 16-DEC-2025 11 months 2 days	
						Injection	4 milligram/kilogram q3w Intravenous use	07-NOV-2023 to 10-DEC-2024 1 year 1 month 4 days	
						Injection	6 milligram/kilogram q3w Intravenous use	20-MAR-2023 to 16-OCT-2023 6 months 27 days	
Concomitant Medication(s): | Levotiron (C) | Benipin (C) | Pexola (C) | Redepra (C) | Piyeloseptyl (C) | Borea (C) | Pantpas (C) | Dexamethasone (C) | Enema (C) | Kytril (C) | Parol (C) | Panto (C) | Desal (C) | Megace (C) | Monurol (C) | Fucithalmic (C) | Zylet (C) | Ciprofloxacin (C) | Buscopan (C) | Eyestil (C) | Contramal (C) | Isotonic sodium chloride (C) | Arcotil (C) | E.s. enema (C) | Spazmol (C) | Metoclopramide hydrochloride (C) | Colchicum dispert (C)									

SOC:General disorders and administration site conditions

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
2023A197096	KOREA, REPUBLIC OF 76 Years Male	**Asthenia (Weakness generalised)***	Recovered	23-Aug-2023 31 weeks	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	18-JAN-2023 to 01-AUG-2023 28 weeks	
						Injection	6 milligram/kilogram q3w Intravenous use	18-SEP-2023 to 17-APR-2024 15 weeks 3 days	
Concomitant Medication(s):									
2024A160202	CHINA 73.5 Years Male	**Fatigue (Fatigue)***	Not Recovered	08-Jul-2024 5 weeks 5 days	DATOPOTAMAB DERUXTECAN	Injection	340 milligram/kilogram q3w Intravenous use	03-JUN-2024 to 11-JUL-2024 1 month 9 days	Periodic Report Comment. Patient experienced fatigue , related to DATOPOTAMAB DERUXTECAN, Company causality not related.
						Injection	340 milligram/kilogram q3w Intravenous use	19-JUN-2024 to 19-JUN-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	29-MAY-2024 to 29-MAY-2024 1 day	
Concomitant Medication(s): | Acetylsalicylate calcium | Clopidogrel bisulfate | Rosuvastatin calcium (C) | CORONABASON (C) | 2-Deoxy-d-glucose | Chlorphenamine | Diphenhydramine hydrochloride | Nystatin | Tetracycline (C) | Diphenhydramine hydrochloride (C) | Rosuvastatin calcium (C) | Esomeprazole sodium (C)									

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

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Study ID: D926UC00001

EudraCT No: 2023-509436-26-00

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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
SOC:Hepatobiliary disorders									
2024A022108	CANADA 40.1 Years Male	**Cholecystitis (Cholecystitis)***	Recovered	25-Jan-2024 3 weeks 6 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	05-APR-2024 to 05-APR-2024 1 day	Periodic Report Comment. The patient experienced cholecystitis. Inv: Related to study therapy. CCA: Not related to study therapy.
						Injection	6 milligram/kilogram q3w Intravenous use	06-SEP-2024 to 06-SEP-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	15-MAR-2024 to 15-MAR-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	29-DEC-2023 to 29-DEC-2023 1 day	

Concomitant Medication(s): | PANTOPRAZOLE (C) | ACETAMINOPHEN (C) | LEVOFLOXACIN (C) | STATEX (C) | BENADRYL (C) | DEXAMETHASONE (C) | PEPCID (C) | CEFTRIAXONE (C) | CETIRIZINE (C) | METRONIDAZOLE (C) | CEFEPIME, TAZOBACTAM (C) | DALTEPARIN (C) | HYDROMORPHONE (C) | DIAMORPHINE HCL (C) | URSODIOL (C) | VANCOMYCINE (C) | DIMENHYDRINATE (C) | CIPROFLOXACIN (C) | ONDANSETRON (C) | AMOXICLAV (C) | METOCLOPRAMIDE (C) | PANTOLOC (C) | SUCROL (C) | NABILONE (C) | TRAMADOL (C) | LEVAFLOX (C) | AVANCOMYCIN (C) | SULFATRIM (C) | PERSONNELLE HYDRALAX (C) | SUCRALAN (C) | ANDROGEL (C) | METHADONE HYDROCHLORIDE (C)

SOC:Immune system disorders

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
202502GLO016306JP	JAPAN 84 Years Male	**Anaphylactic reaction (Anaphylaxis)***	Recovered	19-Feb-2025 2 months 7 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram Intravenous use	13-DEC-2024 to 19-FEB-2025 2 months 7 days	

Concomitant Medication(s): | Vonoprazan fumarate (C) | Rebamipide (C) | Tamsulosin hydrochloride (C) | Dutasteride (C) | Sennosides (C) | Dexamethasone (C) | Magnesium oxide (C) | Acetaminophen (C) | Sennoside (C) | Bilastine (C)

SOC:Infections and infestations

2023A242823	CANADA 60.7 Years Female	**Pneumonia (Pneumonia)***	Not Recovered	19-Sep-2023 6 months 5 days	DATOPOTAMAB DERUXTECAN	Injection	3 milligram/kilogram q3w Intravenous use	14-MAR-2024 to 22-AUG-2024 5 months 9 days	Periodic Report Comment. Patient experience pneumoniae (lung infection) serious and Investigator related to study therapy. Company causality: Not related
						Injection	4 milligram/kilogram q3w Intravenous use	12-OCT-2023 to 16-FEB-2024 4 months 5 days	
						Injection	6 milligram/kilogram q3w Intravenous use	15-MAR-2023 to 14-SEP-2023 6 months	

Concomitant Medication(s): | Tylenol (C) | Rizatriptan (C) | Sertraline (C) | Amitriptyline (C) | Lorazepam (C) | Colchicine (C) | Avelox (C) | Zilactin-b (C) | Imodium (C) | Nifedipine (C) | Erythromycin (C) | Colace (C) | Dexamethasone (C) | Pantothenic acid (C) | Dexamethasone (C) | Tums (C) | Mouth wash (C) | Replens (C) | Zilactin (C) | Hydrasense (C) | Flarex (C) | Akynzeo (C) | Benadryl (C) | Moxifloxacin (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
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)

SOC:Investigations

202411GLO016936GB	UNITED KINGDOM 62 Years Male	**Amylase increased (Serum amylase increased)***	Recovered	18-Nov-2024 20 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram Intravenous use	27-NOV-2024 to 27-NOV-2024 1 day	Patient experienced serum amylase increased; INV; related to suspect; CCA; not related to study therapy.
						Injection	6 milligram/kilogram Intravenous use	30-OCT-2024 to 30-OCT-2024 1 day	

Concomitant Medication(s): | Irbesartan (C) | Rosuvastatin (C)

202511GLO016246IT	ITALY 61 Years Female	**Amylase increased (Amylase increased)***	Recovered	24-Sep-2025 4 months 11 days 11 hrs	DATOPOTAMAB DERUXTEC	Injection	6 milligram/kilogram q3w	12-MAY-2025 12:02 to 16-OCT-2025 15:29	

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

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Study ID: D926UC00001

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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
				58 min	AN		Intravenous use	5 months 4 days 3 hrs 27 min	
Concomitant Medication(s): | Carvedilolo (C) | Zirtec (C) | Chlorhexidine (C) | Sodium hyaluronate (C) | Clorfenamina (C) | Palonosetron (C) | Desametasone (C) | Paracetamol (C) | Corti-fluoral (C)									
202512GLO020883ES	SPAIN 70 Years Female	**Lymphocyte count decreased (Lymphocyte count decreased) ***	Recovered	19-Nov-2025 11 months 25 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram Unknown	16-JUN-2025 to	Periodic Report Comment. Investigator states event lymphocytes low count related to DATOPOTAMAB DERUXTECAN Company physician considers event lymphocytes low count not related to DATOPOTAMAB DERUXTECAN
						Injection	6 milligram/kilogram Unknown	26-NOV-2024 to 27-MAR-2025 4 months 2 days	
Concomitant Medication(s): | Atenolol (C) | Ramipril (C) | Simvastatin (C) | Euthyrox (C) | Esidrex (C) | Nistatin (C) | Sucralfate (C) | Lidocaine (C) | Omeprazole (C)									

SOC:Metabolism and nutrition disorders

202410GLO000857JP	JAPAN 75 Years Male	**Decreased appetite (Anorexia post chemotherapy)***	Recovering	28-Sep-2024 27 days	AZD2936	Solution	750 milligram/kilogram q3w Intravenous use	02-SEP-2024 to 16-DEC-2024 3 months 15 days	Patient experienced Anorexia, Inv: event related to DATOPOTAMAB DERUXTECAN ,AZD2936 CCA: not related
					DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	02-SEP-2024 to 16-DEC-2024 3 months 15 days	

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) | | Rezaltas (C) | Olmesartan od (C) | Spironolactone (C) | Clopidogrel (C) | Lansoprazole (C) | Magnesium oxide (C)									
202503GLO018997TR	TURKEY 59.2 Years Male	**Hypercalcaemia (Hypercalcemia)***	Not Recovered	20-Mar-2025 nk	DATOPOTAMAB DERUXTECAN	Injection	Intravenous use	to	
Concomitant Medication(s): | Plavix (C) | Durogesic (C) | NaCl (C) | GRONSIT (C) | Pandev (C) | Rastamol (C) | Resource Energy (C) | Resource protein (C) | Tramosel (C) | Vomepram (C) | Bactrim (C) | Fosit (C) | Kalinor (C) | Potassium chloride (C) | Morphine hydrochloride (C) | Parol (C) | Esmax (C) | Tazilix (C) | Zolcer (C) | Isotonic (C) | Dextrose (C) | Balaban (C)									
SOC:Nervous system disorders									
202506GLO009100GB	UNITED KINGDOM 70 Years Female	**Syncope (Syncope vasovagal)***	Recovered	10-Jun-2025 3 months 28 days 11 hrs 10 min	DATOPOTAMAB DERUXTECAN	Injection	300 milligram q3w Intravenous use	14-MAR-2025 11:13 to 23-APR-2025 12:35 1 month 9 days 1 hr 22 min	Periodic Report Comments. Patient experienced Syncope. Investigator: related to DATOPOTAMAB DERUXTECAN. Company physician: Not related to DATOPOTAMAB DERUXTECAN.
						Injection	460 milligram q3w Intravenous use	12-FEB-2025 12:50 to 12-FEB-2025 14:26 1 hr 36 min	
Concomitant Medication(s): | Amitriptyline (C) | Senna (C) | Atorvastatin (C) | Gabapentin (C) | Movicol (C) | Carbocisteine (C) | Omeprazole (C) | Benzydamine (C) | Betamethasone (C) | Lidocaine (C) | Metoclopramide (C) | Ondansetron (C) | Canesten (C) | Fluconazole (C) | Sucralfate (C) | Artificial tears (C) | Anusol (C) | Solifenacin (C) | Epimax (C) | Co-amoxiclav (C) | Hydrocortisone (C) | Sodium chloride (C) | Prednisolone (C) | Docusate sodium (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:Psychiatric disorders									
2024A156330	CANADA 80 Years Female	**Confusional state (Confusion)** *	Not Recovered	03-Jul-2024 33 weeks 6 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	28-MAY-2024 to 28-MAY-2024 1 day	Periodic Report Comment. Inv.: event was related to Datopotamab Deruxtecan. Company: event was not related to Datopotamab Deruxtecan.
						Injection	6 milligram/kilogram q3w Intravenous use	01-FEB-2024 to 01-FEB-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	07-MAY-2024 to 07-MAY-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	09-NOV-2023 to 09-NOV-2023 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	11-JAN-2024 to 11-JAN-2024 1 day	
						Injection	6 milligram/kilogram q3w Intravenous use	17-APR-2024 to 17-APR-2024 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	21-DEC-2023 to 21-DEC-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	30-NOV-2023 to 30-NOV-2023 1 day	

Concomitant Medication(s): | ATENOLOL (C) | HYDRACILLIN (C) | NIFEDIPINE (C) | TELMISARTAN (C) | ALORA (C) | JANUMET (C) | DUOTRAV (C) | SYNTHROID (C) | DIAMICRON (C) | JARDIANCE (C) | Clobetasol (C) | FLUCONAZOLE (C) | MAGNESIUM (C) | AZYNOR (C) | BENADRYL (C) | DEXAMETHASONE (C) | FAMOTIDINE (C) | TYLENOL (C) | Dexamethasone dipropionate (C) | DILAUDID (C)

SOC:Renal and urinary 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
202510GLO024691JP	JAPAN 66 Years Male	**Renal failure (Renal failure)***	Recovering	27-Oct-2025 nk	AZ_DS-1062A	Injection	6 milligram/kilogram q3w Intravenous use	24-JUN-2025 to 06-OCT-2025 3 months 13 days	Periodic Report Comments. Patient experienced event Renal failure. Investigator states event related to datopotamab deruxtecan. Company physician considers event related to datopotamab deruxtecan.

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
Concomitant Medication(s): | Febuxostat (C) | Dermovate (C) | Hirudoid (C) | Vtama (C) | White petrolatum (C) | Thyradin (C) | Zinc acetate (C) | Predonine (C) | Bonalon (C) | Corectim (C) | Hyaluronate na (C) | Azunol (C) | Calonal (C) | Aloxi (C) | Polaramine (C) | Tavegyl (C) | Loxonin (C) | Tramal od (C) | Novamin (C) | Fluorometholone (C) | Lansoprazole (C) | Levofloxacin (C) | Sodium hyaluronate (C) | Tarivid (C) | Olanzapine (C) | M magnesium oxide (C)									
SOC:Respiratory, thoracic and mediastinal disorders									
2023A078413	CANADA 68 Years Female	**Pulmonary embolism (Pulmonary embolism)***	Not Recovered	01-Apr-2023 1 month 5 days	DATOPOTAMAB DERUXTECAN	Injection	4 milligram/kilogram q3w Intravenous use	29-MAR-2023 to 29-MAR-2023 1 day	Periodic Report Comment. Patient experienced Pulmonary embolism serious and related to IP. company causality: no
						Injection	6 milligram/kilogram q3w Intravenous use	28-FEB-2023 to 28-FEB-2023 1 day	
Concomitant Medication(s): | Eliquis (C) | Lansoprazole (C) | Docusate sodium (C) | Senokot (C) | Statex (C) | Calcium carbonate (C) | Magnesium (C) | Glycerine (C) | Dexamethasone (C) | Synthroid (C) | Atorvastatin (C) | Vitamin d (C) | Tylenol (C) | Ondansetran (C) | Diphenhydramine (C) | Famotidine (C) | Acetaminophen (C) | Artificial tear (C) | Mouth wash (C) | Pantoloc (C) | Fragmin (C)									
202501GLO008104FR	FRANCE 60 Years Female	**Pulmonary embolism (Pulmonary embolism)***	Not Recovered	09-Jan-2025 nk	DURVALUMAB	Infusion	Intravenous use	to	
Concomitant Medication(s): | Innohep (C) | Alprazolam (C)									
SOC:Skin and subcutaneous tissue disorders									

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
202411GLO025826TR	TURKEY 59 Years Female	**Acute febrile neutrophilic dermatosis (Sweet's syndrome)***	Recovered	27-Nov-2024 2 months 5 days	DATOPOTAMAB DERUXTECAN	Injection	6 milligram/kilogram q3w Intravenous use	03-FEB-2025 to 03-FEB-2025 28 days	Periodic Report Comments. Subject experienced event "Sweet Syndrome": Inv. related to suspect Dato-DXd and not related to suspect 5-FU. Company not related to all suspects.
						Injection	6 milligram/kilogram q3w Intravenous use	04-NOV-2024 to 04-NOV-2024 28 days	
						Injection	6 milligram/kilogram q3w Intravenous use	09-DEC-2024 to 09-DEC-2024 28 days	
						Injection	6 milligram/kilogram q3w Intravenous use	10-FEB-2025 to 10-FEB-2025 28 days	
						Injection	6 milligram/kilogram q3w Intravenous use	13-NOV-2025 to 13-NOV-2025 28 days	
						Injection	6 milligram/kilogram q3w Intravenous use	14-OCT-2024 to 14-OCT-2024 28 days	
						Injection	6 milligram/kilogram q3w	18-NOV-2024 to 18-NOV-2024 28 days	

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
							Intravenous use		
						Injection	6 milligram/kilogram q3w Intravenous use	23-SEP-2024 to 23-SEP-2024 1 day	

Concomitant Medication(s): | 5-FLUOROURACIL (S) | Dexamethasone (C) | Oksapar (C) | Zarzio (C) | Folinic acid (C) | Sodium hyaluronate (C) | Hametan (C) | Rivanolum (C) | Atorvastatin (C) | Desloratadin (C) | Granisetron (C) | Pantoprazole (C) | Isotonic sodium chloride (C) | Sulbactam (C) | Fungostatin (C) | Levofloxacin (C) | Metoclopramide HCL (C) | Magnesium sulphate (C) | Furosemide (C) | Haloperidol (C) | Mycostatin (C)

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

Project ID: D933P

Study ID: D933IC00001

EudraCT No: 2018-001748-74

Study Design: Not Blinded

Study Description: D933IC00001 MAGELLAN POC Phase 1/2 NSCLC Study - New protocol title: A Phase IB, Open-Label, Multi-Center Study to Determine the Efficacy and Safety of Durvalumab and/or Novel Oncology Therapies, With or Without Chemotherapy, for First-Line Stage IV Non-Small Cell Lung Cancer (NSCLC) (MAGELLAN) Previous protocol title: A Phase IB, Open-Label, Randomized, Multi-Center Platform Study to Determine the Efficacy and Safety of Durvalumab (MEDI4736) in Combination With Novel Oncology Therapies, With or Without Chemotherapy, for First-Line Metastatic

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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:Psychiatric disorders									
202502GLO003073TH	THAILAND 78 Years Male	**Completed suicide (Accomplished suicide)***	Fatal	31-Jan-2025 19 days	DURVALUMAB	Infusion	Intravenous use	13-JAN-2025 to	
					PEMETREXED	Infusion	Intravenous use	13-JAN-2025 to	

Concomitant Medication(s): | PEMETREXED (S)

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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
SOC:Blood and lymphatic system disorders									
2024A160620	KOREA, REPUBLIC OF 73 Years Male	**Febrile neutropenia (Febrile neutropenia)** Septic shock (Septic shock)*	Recovered	10-Jul-2024 8 days	CAPECITABINE	Tablet	bid Intravenous use	03-JUL-2024 to 10-JUL-2024 8 days	Periodic Report Comment. Inv: Related to CAPECITABINE, TRASTUZUMAB DERUXTECAN; Rilvegostomig.with event febrile neutropenia and Rilvegostomig with event Septic shock not releated CCA: Not related to study therapy.; Periodic Report Comments. Patient experienced Febrile neutropenia and septic shock. Inv: Related to CAPECITABINE, TRASTUZUMAB DERUXTECAN; Rilvegostomig.with event febrile neutropenia and Rilvegostomig with event Septic shock not releated CCA: Not related to study therapy.
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	q3w Intravenous use	03-JUL-2024 to 03-JUL-2024 1 day	
					AZD2936	Solution	750 milligram qd Intravenous use	03-JUL-2024 to 03-JUL-2024 1 day	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | AZD2936 (S) | Cetamadol (C) | Motilitone (C) | Almagel (C) | Oxycodone (C) | Harmonilan (C) | Megestrol (C) | Morphine sulfate (C) | Granisetron (C) | Hydrocortisone (C) | Chlorpheniramine (C) | Udca (C) | Pethidine (C) | Albumine (C) | Esomeprazole (C) | Red blood cells (C) | Fentanyl (C) | Sod bicarbonate (C) | Calcium gluconate (C) | Magnesium sulfate (C) | Potassium chloride (C) | Humulin r (C) | Vaseline (C) | Addaven (C) | Thiamine (C) | Winuf (C) | Tamipro (C) | Furosemide (C) | Pot phosphate (C) | Spironolactone (C) | Smectite (C) | Smoflipid (C) | Fresh frozen plasma (C) | Lansoprazole (C) | Tranexamic acid (C) | Cryoprecipitate (C) | PeriOlimel (C) | Norepinephrine (C) | Platelets (C) | Plasma (C) | Tazoferan (C) | Remifentanil (C) | Ketamine (C) | Rocuronium bromide (C) | Glucose, sodium chloride and potassium chloride (C)									
202507GLO008120KR	KOREA, REPUBLIC OF	**Thrombocytopenia (Thrombocytopenia)***	Recovered	26-Jun-2025 4 months 15 days	TRASTUZUMAB DERUXTEC	Powder for solution for infusion	4.4 milligram/kilogram q3w	04-APR-2025 to 04-APR-2025	

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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
	76 Years Male	Neutropenia (Neutropenia)*			AN		Intravenous use	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	
						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	

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): | CAPECITABINE (S) | RILVEGOSTOMIG (S) | Megace (C) | Amaryl (C) | Tenelia (C) | Dexid (C) | Pravix (C) | Glupa (C) | Macperan (C) | Lopaine (C) | Tantum (C)									
SOC:Cardiac disorders									
2024A182849	CHINA 55 Years Male	**Myocardial injury (Myocardial injury)***	Not Recovered	09-Aug-2024 5 weeks	CAPECITABINE	Tablet	500 milligram/sq. meter Oral use	26-JUL-2024 to 01-AUG-2024 7 days	Periodic Report Comment. Patient experienced myocardial damage. Inv, related to trastuzumab deruxtecan, medi5752, capecitabine, CCA: not related to trastuzumab deruxtecan, medi5752, related to capecitabine.
						Tablet	750 milligram/sq. meter Oral use	05-JUL-2024 to 12-JUL-2024 1 week 1 day	
					MEDI5752	Infusion	500 milligram Intravenous use	05-JUL-2024 to 26-JUL-2024 3 weeks 1 day	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	05-JUL-2024 to 26-JUL-2024 3 weeks 1 day	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | MEDI5752 (S) | Celecoxib (C) | Vonoprazan fumarate (C) | Oxycodone (C) | Esomeprazole magnesium (C) | Lactulose (C) | Coenzyme Q10 (C) | Vastarel (C) | Vitamin C (C)									
202501GLO009534GB	UNITED KINGDOM	**Myocarditis (Myocarditis)***	Recovered	06-Jan-2025 7 months 10 days	TRASTUZUMAB DERUXTEC	Powder for solution for infusion	5.4 milligram/kilogram q3w	28-MAY-2024 to 10-DEC-2024	

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
	54 Years Male				AN		Intravenous use	6 months 13 days	
Concomitant Medication(s): | CAPECITABINE (S) | MEDI5752 (S) | Fluoxetine (C) | Metoclopramide (C) | Loperamide (C) | Levomepromazine (C) | Omeprazole (C) | Cyclizine (C) | Aprepitant (C) | Hydrocortisone (C) | Prednisolone (C)									
202502GLO012092ES	SPAIN 77 Years Male	**Myocarditis (Myocarditis)***	Recovered	13-Feb-2025 13 days 14 hrs 14 min	RILVEGOSTOMIG	Solution	750 milligram Intravenous use	30-JAN-2025 09:46 to 30-JAN-2025 10:48 1 hr 2 min	Periodic Report Comments. Patient experienced Myocarditis related to study therapy TRASTUZUMAB DERUXTECAN, cca not applicable.
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | CAPECITABINE (S) |									

SOC:Endocrine disorders

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
					MEDI5752	Infusion	500 milligram q3w Intravenous use	28-MAY-2024 to 10-DEC-2024 6 months 13 days	

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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
									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

Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | MEDI5752 (S) | Ondansetron (C) | Omeprazole (C) | Prednisolone (C) | Fluoxetine (C) | Metoclopramide (C) | Loperamide (C) | Levomepromazine (C) | Aprepitant (C) | Peptac (C)

SOC:Gastrointestinal disorders

2022A358989	UNITED STATES 67 Years Male	**Melaena (Melena)***	Fatal	22-Oct-2022 18 weeks 2 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	07-JUL-2022 to 07-JUL-2022 1 day	Periodic Report Comment. Patient experienced melena and esophageal hemorrhage, Melena: related to Trastuzumab Deruxtecan, Pembrolizumab and Esophageal hemorrhage not related to study therapy.

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 for infusion	200 milligram q3w	08-SEP-2022 to 08-SEP-2022	
							Intravenous use	1 day	
						Solution for infusion	200 milligram q3w	16-JUN-2022 to 16-JUN-2022	
							Intravenous use	1 day	
						Solution for infusion	200 milligram q3w	18-AUG-2022 to 18-AUG-2022	
							Intravenous use	1 day	
						Solution for infusion	200 milligram q3w	27-JUL-2022 to 27-JUL-2022	
							Intravenous use	1 day	
						Solution for infusion	200 milligram q3w	29-SEP-2022 to 29-SEP-2022	
							Intravenous use	1 day	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	6.4 milligram/kilogram q3w	16-JUN-2022 16:35 to 16-JUN-2022 18:05	
							Intravenous use	1 hr 30 min	
						Powder for solution for infusion	6.4 milligram/kilogram q3w	07-JUL-2022 13:55 to 07-JUL-2022 14:25	
							Intravenous use	30 min	

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	6.4 milligram/kilogram q3w Intravenous use	08-SEP-2022 14:07 to 08-SEP-2022 14:37 30 min	
						Powder for solution for infusion	6.4 milligram/kilogram q3w Intravenous use	18-AUG-2022 13:27 to 18-AUG-2022 13:57 30 min	
						Powder for solution for infusion	6.4 milligram/kilogram q3w Intravenous use	27-JUL-2022 17:16 to 27-JUL-2022 17:46 30 min	
						Powder for solution for infusion	6.4 milligram/kilogram q3w Intravenous use	29-SEP-2022 11:50 to 29-SEP-2022 12:20 30 min	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | COPAXONE (C) | PANTOPRAZOLE (C) | ZOFRAN (C) | PREDNISONE (C)									
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	

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
						Infusion	600 milligram/sq. meter Intravenous use	01-AUG-2024 to 18-SEP-2024 1 month 18 days	
					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)									
202410GLO028412US	UNITED STATES 49 Years Male	**Nausea (Nausea)***	Not Recovered	18-Oct-2024 2 months 18 days	MEDI5752	Infusion Intravenous use	250 milligram q3w	15-JAN-2025 to 26-FEB-2025 1 month 12 days	
						Infusion Intravenous use	250 milligram q3w	19-MAR-2025 to 02-JUL-2025 3 months 14 days	
						Infusion Intravenous use	500 milligram q3w	01-AUG-2024 to 13-DEC-2024 4 months 13 days	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | 5-FU (S) | | Clonazepam (C) | Wellbutrin (C) | Pantoprazole (C) | Oxycodone (C) | Acetaminophen (C) | Olanzapine (C) | Ondansetron (C) | Prochlorperazine (C)									
202412GLO007967CA	CANADA 38 Years Male	**Colitis (Typhlitis)***	Recovered	07-Dec-2024 2 months 19 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion Intravenous use	5.4 milligram/kilogram q3w	15-JAN-2025 to 26-FEB-2025 1 month 12 days	patient experienced severe typhlitis, Investigator- related to Medi5752, Trastuzumab Deruxtecan not related to Capecitabine
						Powder for solution for infusion Intravenous use	5.4 milligram/kilogram q3w	19-SEP-2024 to 20-NOV-2024 2 months 2 days	
Concomitant Medication(s): | MEDI5752 (S) | CAPECITABINE (S) | Ondansetron (C) | Dexamethasone (C) | Olanzapine (C) | Valacyclovir (C)									

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
2024A050338	GERMANY 65 Years Female	**Enteritis (Enteritis)***	Recovered	23-Feb-2024 29 days 11 hrs 33 min	5-FLUOROURACIL	Infusion	600 milligram/sq. meter q3w Intravenous use	14-FEB-2024 12: 55 to 19-FEB-2024 12:55 5 days	Periodic Report Comment. Patient experienced chemotherapy-induced enteritis, related to study therapy. Com causality: Related to Trastuzumab Deruxtecan, MEDI5752 and 5-Fluorouracil.
						Infusion	600 milligram/sq. meter q3w Intravenous use	24-JAN-2024 12: 27 to 29-JAN-2024 12:30 5 days 3 min	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	14-FEB-2024 11: 15 to 14-FEB-2024 12:47 1 hr 32 min	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	24-JAN-2024 10: 50 to 24-JAN-2024 11:21 1 day	
					MEDI 5752	Infusion	500 milligram/kilogram q3w Intravenous use	14-FEB-2024 09: 42 to 14-FEB-2024 10:42 1 hr	
						Infusion	500 milligram/kilogram q3w Intravenous use	24-JAN-2024 08: 45 to 24-JAN-2024 09:45 1 day	

Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | MEDI 5752 (S) | | Metamizol (C) | Tardyferon (C) | Pantoprazol (C) | Ciprofloxacin (C) | Metoclopramid (C) | Movicol (C) | Cetirizin (C) | Fosfomycin astro (C)

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
2024A110803	KOREA, REPUBLIC OF 66 Years Male	**Enterocolitis (Enterocolitis)***	Recovered	08-May-2024 14 weeks 1 day	CAPECITABINE	Tablet	500 milligram/sq. meter q3w Oral use	03-JUN-2024 to 03-JUN-2024 1 day	Periodic Report Comment. Patient experienced nonneutropenic enterocolitis. Inv related to study drug. CCA not related.
						Tablet	500 milligram/sq. meter q3w Oral use	20-MAY-2024 to 20-MAY-2024 1 day	
						Tablet	500 milligram/sq. meter q3w Oral use	21-MAY-2024 to 02-JUN-2024 13 days	
						Tablet	750 milligram/sq. meter q3w Oral use	30-JAN-2024 to 30-JAN-2024 1 day	
						Tablet	750 milligram/sq. meter q3w Oral use	03-APR-2024 to 03-APR-2024 1 day	
						Tablet	750 milligram/sq. meter q3w Oral use	04-APR-2024 to 16-APR-2024 1 week 6 days	
						Tablet	750 milligram/sq. meter q3w	06-MAR-2024 to 06-MAR-2024	

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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
							Oral use	1 day	
						Tablet	750 milligram/sq. meter q3w Oral use	08-MAY-2024 to 08-MAY-2024 1 day	
						Tablet	750 milligram/sq. meter q3w Oral use	13-FEB-2024 to 13-FEB-2024 1 day	
						Tablet	750 milligram/sq. meter q3w Oral use	13-MAR-2024 to 13-MAR-2024 1 day	
						Tablet	750 milligram/sq. meter q3w Oral use	14-MAR-2024 to 26-MAR-2024 1 week 6 days	
						Tablet	750 milligram/sq. meter q3w Oral use	17-APR-2024 to 17-APR-2024 1 day	
						Tablet	750 milligram/sq. meter q3w Oral use	21-FEB-2024 to 21-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
						Tablet	750 milligram/sq. meter q3w Oral use	22-FEB-2024 to 05-MAR-2024 1 week 6 days	
						Tablet	750 milligram/sq. meter q3w Oral use	24-APR-2024 to 08-MAY-2024 1 day	
						Tablet	750 milligram/sq. meter q3w Oral use	25-APR-2024 to 07-MAY-2024 1 day	
						Tablet	750 milligram/sq. meter q3w Oral use	27-MAR-2024 to 27-MAR-2024 1 day	
						Tablet	750 milligram/sq. meter q3w Oral use	31-JAN-2024 to 12-FEB-2024 1 week 6 days	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram Intravenous use	30-JAN-2024 to 20-MAY-2024 12 weeks 2 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
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | PEMBROLIZUMAB (S) | MOTILITONE (C) | BROMELAIN (C) | DIMETHICONE SOBHAN (C) | Pancreatin (C) | ALMAGEL (C) | ACETAMINOPHEN (C) | TRAMADOL (C) | ETHINYLESTRADIOL, MEGESTROL ACETATE, NORETHISTERONE (C) | MGO (C) | APO-LACTULOSE (C) | ACETYLCYSTEINE (C) | ACETYLSALICYLIC ACID, OXYCODONE HYDROCHLORIDE (C) | CLEAVEX (C) | HYDROCORTISONE, PRAMOCAINE (C) | AKNYL (C) | ZOLPIDEM (C) | ACH EZETIMIBE (C) | DIOVAN (C) | HERBEN (C) | PIDOGRIN (C) | VASTINAN (C) | LANSTON LFDT (C) | ATORVASTATIN (C) | Diovan (C) | Herben sr (C) | Pidogrin (C) | Vastinan (C) | Lanston lfdt (C) | Sodium (C) | Lacticare hc (C) | Zolpidem (C) | Megestrol (C) | Diclofenac (C) | Ezetimibe (C)									
2024A172652	CHINA 55 Years Male	**Flatulence (Flatulence)***	Recovered	27-Jul-2024 3 weeks 1 day	MEDI 5752	Infusion	500 milligram Intravenous use	05-JUL-2024 to 26-JUL-2024 3 weeks 1 day	Periodic Report Comment. Patient experienced Flatus,Inv, related to trastuzumab deruxtecan, Inv,related to medi5752, Inv, related to capecitabine, CCA: not related to trastuzumab deruxtecan, CCA: not related to medi5752, CCA: related to capecitabine
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	05-JUL-2024 to 26-JUL-2024 3 weeks 1 day	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | CAPECITABINE (S) | | Celecoxib (C) | Vonoprazan fumarate (C) | Esomeprazole magnesium (C) | Granisetron hydrochloride (C) | Oxycodone (C)									
2024A192672	NETHERLANDS 55 Years Male	**Immune-mediated enterocolitis (Immune-mediated colitis)***	Recovered	17-Aug-2024 1 week 1 day	5-FLUOROURACIL	Infusion	600 milligram/sq. meter q3w Intravenous use	09-AUG-2024 to 14-AUG-2024 6 days	Periodic Report Comments. Patient experienced Immune mediated colitis. Inv: event related to study therapy, CCA: not related.
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	09-AUG-2024 to 09-AUG-2024 1 day	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | MEDI 5752 (S) | | OXYCODON (C) | PARACETAMOL (C) | MACROGOL (C) | LORAZEPAM (C) | Metoclopramide HCL (C)									

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EudraCT No: 2019-004483-22

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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
202502GLO010454PL	POLAND 27 Years Male	**Colitis (Colitis)***	Recovered	07-Feb-2025 nk	RILVEGOSTOMIG	Solution	750 milligram q3w Intravenous use	09-JAN-2025 to 09-JAN-2025 1 day	Patient experienced colitis. Investigator: related. Company: not related
						Solution	750 milligram q3w Intravenous use	10-MAR-2025 to 10-MAR-2025 1 day	
						Solution	750 milligram q3w Intravenous use	22-APR-2025 to 22-APR-2025 1 day	
						Solution	750 milligram q3w Intravenous use	30-JAN-2025 to 30-JAN-2025 1 day	
						Solution	750 milligram q3w Intravenous use	31-MAR-2025 to 31-MAR-2025 1 day	
					ENHERTU	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	09-JAN-2025 to 09-JAN-2025 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	10-MAR-2025 to 10-MAR-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
						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	30-JAN-2025 to 30-JAN-2025 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	31-MAR-2025 to 31-MAR-2025 1 day	
Concomitant Medication(s): ENHERTU (S) | CAPECITABINE (S) | | Rimal (C) | Atossa (C) | Loperamide (C) | Sorbifer Durules (C) | Amlodipine (C) | KCl (C) | Encorton (C) | NaCl (C) | Optilyte (C) | Pantoprazole (C) | Solu medrol (C) | Paracetamol (C) | Kalium (C) | Nasen (C) | Ondansetron (C) | No-spa (C) | Alugastrin (C) | Spironol (C) | Tardyferon (C) | Pyralgin (C) | Trittico cr (C) | Reasec (C) | Calperos (C) | Hydroxizine (C) | Metocard (C) | Monover (C) | Vitamin d (C) | Ceftriakson (C) | Metronidazole (C) | Levox (C) | Bisocard (C) | Resource diabet plus (C) | Cetix (C) | Polpril (C) | Magnezin (C) | Red blood cells (C) | Fresh frozen plasma (C) | Torecan (C) | Amikin (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	09-MAY-2025 to 09-MAY-2025	

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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
							Intravenous use	1 day	
						Infusion	250 milligram q3w	11-FEB-2025 to 11-FEB-2025	
							Intravenous use	1 day	
						Infusion	250 milligram q3w	15-AUG-2025 to 15-AUG-2025	
							Intravenous use	1 day	
						Infusion	250 milligram q3w	17-APR-2025 to 17-APR-2025	
							Intravenous use	1 day	
						Infusion	250 milligram q3w	21-JAN-2025 to 21-JAN-2025	
							Intravenous use	1 day	
						Infusion	250 milligram q3w	25-JUL-2025 to 25-JUL-2025	
							Intravenous use	1 day	
						Infusion	250 milligram q3w	26-MAR-2025 to 26-MAR-2025	
							Intravenous use	1 day	
						Infusion	250 milligram q3w	31-DEC-2024 to 31-DEC-2024	
							Intravenous use	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	500 milligram q3w	07-AUG-2024 to 07-AUG-2024	
							Intravenous use	1 day	
						Infusion	500 milligram q3w	09-OCT-2024 to 09-OCT-2024	
							Intravenous use	1 day	
						Infusion	500 milligram q3w	11-DEC-2024 to 11-DEC-2024	
							Intravenous use	1 day	
						Infusion	500 milligram q3w	17-JUL-2024 to 17-JUL-2024	
							Intravenous use	1 day	
						Infusion	500 milligram q3w	19-SEP-2024 to 19-SEP-2024	
							Intravenous use	1 day	
						Infusion	500 milligram q3w	20-NOV-2024 to 20-NOV-2024	
							Intravenous use	1 day	
						Infusion	500 milligram q3w	26-JUN-2024 to 26-JUN-2024	
							Intravenous use	1 day	
						Infusion	500 milligram q3w	28-AUG-2024 to 28-AUG-2024	
							Intravenous use	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	500 milligram q3w Intravenous use	30-OCT-2024 to 30-OCT-2024 1 day	
					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	
						Powder for solution for infusion	4.4 milligram/kilogram q3w	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
							Intravenous use		
						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	
						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	

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	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	
						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	26-JUN-2024 to 26-JUN-2024	

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
							Intravenous use	1 day	

Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | CAPECITABINE (S) | Diphenhydramine hydrochloride (C) | Esomeprazole sodium (C)

SOC:General disorders and administration site conditions

202512GLO012226NL	NETHERLANDS 61 Years Male	**Pyrexia (Fever)***	Recovered	10-Dec-2025 1 year 4 months 14 days	MEDI5752	Infusion	250 milligram q3w Intravenous use	27-JUL-2024 to 19-NOV-2025 1 year 3 months 24 days	

Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | CAPECITABINE (S) | Acetylsalicylic acid (C) | Paracetamol (C) | Hydrocortisone (C) | Nifedipine (C) | Sucralfate (C) | Spironolactone (C) | Rosuvastatin (C) | Metoclopramide (C) | Kaliumchloride (C) | Folic acid (C) | Ferrous fumarate (C) | Esomeprazole (C) | Atomic (C) | Solu cortef (C) | Enalapril (C)

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)

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
202410GLO014256CA	CANADA 38 Years Male	**Hepatobiliary disease (Hepatobiliary disease)***	Recovered	16-Oct-2024 28 days	MEDI5752	Infusion	500 milligram Intravenous use	19-SEP-2024 to 09-OCT-2024 21 days	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | CAPECITABINE (S) | Ondansetron (C) | Dexamethasone (C) | Olanzapine (C) | Valacyclovir (C) | Methylprednisolone (C) | Ciprofloxacin (C) | Morphine sulfate (C) | Prednisone (C)									
202411GLO012368CA	CANADA 60 Years Male	**Autoimmune hepatitis (Hepatitis autoimmune)***	Fatal	13-Nov-2024 3 months 5 days 11 hrs 44 min	MEDI5752	Infusion	500 milligram q3w Intravenous use	07-AUG-2024 12:16 to 07-AUG-2024 13:16 1 hr	Periodic Report Comments. The patient experienced Hepatitis autoimmune disorder. Investigator: Related to Trastuzumab Deruxtecan, MEDI5752. Not related to Capecitabine. Company: Not related.
						Infusion	500 milligram q3w Intravenous use	28-AUG-2024 11:27 to 28-AUG-2024 12:27 1 hr	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	07-AUG-2024 14:17 to 07-AUG-2024 15:37 1 hr 20 min	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	28-AUG-2024 12:57 to 28-AUG-2024 13:27 30 min	

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) | | CAPECITABINE (S) | DURVALUMAB (S) | RILVEGOSTOMIG (S) | Volrustomig (S) | Pantoprazole (C) | Atrovastatin awa (C) | Nicotine (C) | Sb restore (C) | Anusol (C) | Glycerine (C) | Prednisone (C) | Atovaquone (C) | Piperacillin and tazobactam (C) | Potassium chloride (C) | Acetaminophen (C) | Lorazepam (C) | Heparin (C) | Polyethylene glycol (C) | Bisacodyl (C) | Methylprednisolone (C) | Famotidine (C) | Magnesium sulfate (C) | Midodrine (C) | Mycophenolate mofetil (C) | Multivitamins (C) | Calcium (C) | Vit d3 (C) | Fludrocortisone (C) | Fidaxomicin (C)									
202411GLO023484CA	CANADA 37 Years Male	**Cholangitis (Cholangitis)*** Sepsis (Sepsis)	Recovered	21-Nov-2024 128 days	CAPECITABINE	Tablet	750 milligram/sq. meter q3w Oral use	06-SEP-2024 to 06-SEP-2024 1 day	Periodic Report Comments. Periodic comment: Patient experience Cholangitis (biliary tract infection) and SEPSIS. Investigator: Related to T-DXd, Volrustomig and Capecitabine. CCA: related to Capecitabine, and Not Related to T-DXd and Volrustomig Action taken :T-DXd and Volrustomig No Change and Capecitabine: Not Applicable.
						Tablet	750 milligram/sq. meter q3w Oral use	16-JUL-2024 to 29-JUL-2024 14 days	
		Cholangitis (Cholangitis)* Sepsis (Sepsis)*	Recovered	21-Nov-2024 128 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	04-OCT-2024 to 04-OCT-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	06-SEP-2024 to 06-SEP-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	16-JUL-2024 to 16-JUL-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	5.4 milligram/kilogram q3w Intravenous use	25-OCT-2024 to 25-OCT-2024 1 day	
					MEDI5752	Infusion	500 milligram/kilogram Intravenous use	16-JUL-2022 to 25-OCT-2024 2 years 3 months 10 days	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | MEDI5752 (S) | | Insulin novolin (C) | Acetaminophen (C) | Perindopril erbumine (C) | Akynzeo (C) | Olanzapine (C) | Metoclopramide (C)									
2024A196081	ITALY 34 Years Male	**Hypertransaminasaemia (Hypertransaminasemia)***	Recovered	12-Aug-2024 1 week	5-FLUOROURACIL	Infusion	600 milligram/sq. meter q3w Intravenous use	05-AUG-2024 to 08-AUG-2024 4 days	Periodic Report Comment. The patient experienced HYPERTRANSAMINASEMIA .Inv: Related to TRASTUZUMAB DERUXTECAN,MEDI5752 and 5-FLUOROURACIL.CCA: Not related to TRASTUZUMAB DERUXTECAN,MEDI5752 and 5-FLUOROURACIL.
					MEDI 5752	Infusion	500 milligram q3w Intravenous use	05-AUG-2024 to 05-AUG-2024 1 day	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	05-AUG-2024 to 05-AUG-2024 1 day	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | MEDI 5752 (S) | | Ensure plus (C) | METHYLPREDNISOLONE (C) | GLUTATHIONE (C)									

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

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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
SOC:Infections and infestations									
2022A280786	BRAZIL 76 Years Male	**Gastroenteritis (Gastroenterocolitis)***	Recovered	02-Jul-2022 9 months 10 hrs 50 min	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	15-JUL-2022 08:50 to 15-JUL-2022 09:23 33 min	Periodic Report Comment. the patient experienced grade three gastroenterocolitis, related to Trastuzumab Deruxtecan and not related to Capecitabine.
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	08-APR-2022 09:50 to 08-APR-2022 10:20 30 min	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	18-MAR-2022 09:45 to 18-MAR-2022 10:15 30 min	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	20-MAY-2022 09:30 to 20-MAY-2022 10:00 30 min	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	25-FEB-2022 09:50 to 25-FEB-2022 10:30 40 min	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	29-APR-2022 09:10 to 29-APR-2022 09:40 30 min	

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	10-JUN-2022 09:10 to 10-JUN-2022 09:40	
							Intravenous use	30 min	
						Powder for solution for infusion	6.4 milligram/kilogram q3w	01-OCT-2021 13:10 to 01-OCT-2021 14:35	
							Intravenous use	1 hr 25 min	
						Powder for solution for infusion	6.4 milligram/kilogram q3w	03-DEC-2021 11:40 to 03-DEC-2021 12:15	
							Intravenous use	35 min	
						Powder for solution for infusion	6.4 milligram/kilogram q3w	12-NOV-2021 11:10 to 12-NOV-2021 11:40	
							Intravenous use	30 min	
						Powder for solution for infusion	6.4 milligram/kilogram q3w	13-JAN-2022 11:08 to 13-JAN-2022 11:55	
							Intravenous use	47 min	
						Powder for solution for infusion	6.4 milligram/kilogram q3w	22-OCT-2021 11:45 to 22-OCT-2021 12:50	
							Intravenous use	1 hr 5 min	
						Powder for solution for infusion	6.4 milligram/kilogram q3w	23-DEC-2021 12:45 to 23-DEC-2021 13:15	

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

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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
							Intravenous use	30 min	
						Powder for solution for infusion	6.4 milligram/kilogram q3w Intravenous use	03-FEB-2022 19:30 to 03-FEB-2022 20:00 30 min	
Concomitant Medication(s): | CAPECITABINE (S) | Pantoprazole sodium sesquihydrate (C) | Dipyrone (C) | Combodart (C) | Tadalafil (C) | Olanzapine (C)									
202411GLO011928DE	GERMANY 70 Years Female	**Sepsis (Sepsis)***	Fatal	14-Nov-2024 1 month 20 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	26-SEP-2024 to 07-NOV-2024 1 month 13 days	
Concomitant Medication(s): | CAPECITABINE (S) | MEDI5752 (S) | L-thyroxin (C) | Ramipril (C) | Ondansetron (C) | Dulcolax (C) | Bisacodyl (C)									
202502GLO010455GB	UNITED KINGDOM 56 Years Female	**Infection (Infection NOS)***	Recovered	12-Feb-2025 5 months 16 days	ENHERTU	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	28-AUG-2024 to 20-JUN-2025 9 months 24 days	Patient experienced Infection of unknown origin. Investigator: not reported. Company: not related
Concomitant Medication(s): | MEDI5752 (S) | CAPECITABINE (S) | Levothyroxine sodium (C) | Paracetamol (C) | Lansoprazole (C) | Olanzapine (C) | Aprepitant (C) | Tranexamic acid (C) | Oxycodone (C) | Dermol (C) | Codeine Phosphate (C) | Sodium acid phosphate (C) | Sando k (C) | Magnesium aspartate (C) | Loperamide (C)									
202510GLO001735PL	POLAND 51 Years Female	**Pneumonia (Pneumonia)***	Fatal	11-Sep-2025 7 months 16 days	ENHERTU	Powder for solution for infusion	5.4 milligram/kilogram q3w	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
							Intravenous use		
						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	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	27-JAN-2025 to 27-JAN-2025 1 day	

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Project ID: D967L

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EudraCT No: 2019-004483-22

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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
						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	
						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	

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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	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	
						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) | Ondansetron (C) | Pantoprazole (C) | Atossa (C) | Tardyferon (C) | Efferalgan codeine (C) | Ceftriaxon (C) | Biseptol (C) | Doreta (C)									
SOC:Investigations									
2022A250357	CHINA 59 Years Male	**White blood cell count decreased (White blood cell decreased)*** Neutrophil count decreased (Neutrophil count decreased)*	Recovered	06-Jul-2022 1 week	CAPECITABINE	Tablet Tablet	1000 milligram/sq. meter q3w Oral use 1000 milligram/sq. meter q3w Oral use	01-JUL-2022 to 01-JUL-2022 1 day 02-JUL-2022 to 03-JUL-2022 2 days	Periodic Report Comment. The patient experienced neutrophil counts decreased and white blood cell decreased. Inv: related, Comp: related

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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
						Tablet	1000 milligram/sq. meter q3w Oral use	29-JUN-2022 to 29-JUN-2022 1 day	
						Tablet	1000 milligram/sq. meter q3w Oral use	30-JUN-2022 to 30-JUN-2022 1 day	
						Tablet	1000 milligram/sq. meter q3w Oral use	04-JUL-2022 to 04-JUL-2022 1 day	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	6.4 milligram/kilogram q3w Intravenous use	29-JUN-2022 to 29-JUN-2022 1 day	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | PEMBROLIZUMAB (S) | Short peptide enteral nutrition powder (C) | Esomeprazole sodium (C) | Vitamin b6 f (C) | Abtei vitamin c (C) | Pantoprazole sodium (C)									
202411GLO019319DE	GERMANY 64 Years Male	**Blood creatinine increased (Creatinine increased)***	Not Recovered	27-Aug-2024 274 days	5-FLUOROURACIL	Infusion	Unknown	02-APR-2024 to 07-APR-2024 6 days	Periodic Report Comments. pt exp. event worsening of creatinin increase, serious event serious due hospitalization. invetigator: related and comapny caulsaity: not related
						Infusion	Unknown	04-JUN-2024 to 09-JUN-2024 6 days	

Blinded IBPR - AstraZeneca - Confidential & Proprietary

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

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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	Unknown	08-AUG-2024 to 13-AUG-2024 6 days	
						Infusion	Unknown	08-JAN-2024 to 13-JAN-2024 6 days	
						Infusion	Unknown	11-MAR-2024 to 16-MAR-2024 6 days	
						Infusion	Unknown	12-DEC-2024 to 17-DEC-2024 6 days	
						Infusion	Unknown	16-JUL-2024 to 21-JUL-2024 6 days	
						Infusion	Unknown	17-OCT-2024 to 22-OCT-2024 6 days	
						Infusion	Unknown	18-DEC-2023 to 23-DEC-2023 6 days	
						Infusion	Unknown	19-FEB-2024 to 24-FEB-2024 6 days	

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						Infusion	Unknown	21-NOV-2024 to 26-NOV-2024 6 days	
						Infusion	Unknown	23-APR-2024 to 28-APR-2024 6 days	
						Infusion	Unknown	25-JUN-2024 to 30-JUN-2024 6 days	
						Infusion	Unknown	26-SEP-2024 to 01-OCT-2024 6 days	
						Infusion	Unknown	27-AUG-2024 to 01-SEP-2024 6 days	
						Infusion	Unknown	27-NOV-2023 to 02-DEC-2023 6 days	
						Infusion	Unknown	29-JAN-2024 to 03-FEB-2024 6 days	
						Infusion	600 milligram/sq. meter	14-MAY-2024 to 19-MAY-2024 6 days	

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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
							Unknown		
					MEDI5752	Infusion	Unknown	02-APR-2024 to 02-APR-2024 1 day	
						Infusion	Unknown	04-JUN-2024 to 04-JUN-2024 1 day	
						Infusion	Unknown	08-AUG-2024 to 08-AUG-2024 1 day	
						Infusion	Unknown	08-JAN-2024 to 08-JAN-2024 1 day	
						Infusion	Unknown	11-MAR-2024 to 11-MAR-2024 1 day	
						Infusion	Unknown	14-MAY-2024 to 14-MAY-2024 1 day	
						Infusion	Unknown	16-JUL-2024 to 16-JUL-2024 1 day	

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						Infusion	Unknown	18-DEC-2023 to 18-DEC-2023 1 day	
						Infusion	Unknown	19-FEB-2024 to 19-FEB-2024 1 day	
						Infusion	Unknown	23-APR-2024 to 23-APR-2024 1 day	
						Infusion	Unknown	25-JUN-2024 to 25-JUN-2024 1 day	
						Infusion	Unknown	27-AUG-2024 to 27-AUG-2024 1 day	
						Infusion	Unknown	27-NOV-2023 to 27-NOV-2023 1 day	
						Infusion	Unknown	29-JAN-2024 to 29-JAN-2024 1 day	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w	02-APR-2024 to 02-APR-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
							Intravenous use		
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	04-JUN-2024 to 04-JUN-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	08-AUG-2024 to 08-AUG-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	08-JAN-2024 to 08-JAN-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	11-MAR-2024 to 11-MAR-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	14-MAY-2024 to 14-MAY-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	16-JUL-2024 to 16-JUL-2024 1 day	

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						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	17-OCT-2024 to 17-OCT-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	18-DEC-2023 to 18-DEC-2023 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	19-FEB-2024 to 19-FEB-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	21-NOV-2024 to 21-NOV-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	23-APR-2024 to 23-APR-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	25-JUN-2024 to 25-JUN-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w	26-SEP-2024 to 26-SEP-2024 1 day	

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							Intravenous use		
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	27-NOV-2023 to 27-NOV-2023 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	29-JAN-2024 to 29-JAN-2024 1 day	
						Powder for solution for infusion	5400 milligram/kilogram q3w Intravenous use	12-DEC-2024 to	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | MEDI5752 (S) | Metformin (C) | Doxazosin (C) | Allopurinol (C) | Amlodipin (C) | Ramipril (C) | Pantoprazol (C) | Novaminsulfon (C) | Metoprolol (C) | Ibuprofen (C)									
2024A151922	ITALY 68 Years Male	**Transaminases increased (Transaminases increased)***	Recovered	01-Jul-2024 1 week	MEDI 5752	Infusion	500 milligram Intravenous use	24-JUN-2024 to 24-JUN-2024 1 day	Periodic Report Comment. Patient experienced transaminase increase (ast/alt). Inv related to Medi5752 and not not related to Trastuzumab Deruxtecan, Capecitabine;

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									CCA: not related to study therapy.
Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | CAPECITABINE (S) | DOXAZOSIN (C) | OLMESARTAN (C) | AMLODIPINE (C) | CARVEDILOL (C) | PANTOPRAZOLE (C)									
2024A186525	CHINA 52 Years Female	**Platelet count decreased (Platelet count decreased)***	Recovered	14-Aug-2024 1 month 20 days	CAPECITABINE	Tablet	1000 milligram/sq. meter q3w Oral use	20-AUG-2024 to 22-AUG-2024 3 days	Periodic Report Comment. Patient experienced decreased platelet count. Inv: related to Trastuzumab Deruxtecan, Capecitabine and Volrustomig, Com causality not related
						Tablet	500 milligram/sq. meter q3w Oral use	28-AUG-2024 to 28-AUG-2024 1 day	
						Tablet	600 milligram/sq. meter q3w Oral use	19-AUG-2024 to 22-AUG-2024 4 days	
						Tablet	750 milligram/sq. meter q3w Oral use	11-DEC-2024 to 24-APR-2025 4 weeks 1 day	
						Tablet	750 milligram/sq. meter q3w Oral use	26-JUN-2024 to 04-DEC-2024 7 weeks 6 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
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	28-AUG-2024 to 10-OCT-2024 1 month 13 days	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	26-JUN-2024 to 07-AUG-2024 6 weeks 1 day	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | MEDI 5752 (S) | Recombinant human thrombopoietin (C) | Dexamethasone sodium phosphate (C) | Betamethasone sodium phosphate (C) | Metoclopramide hydrochloride (C) | Dolasetron mesylate (C) | Glucose and sodium chloride (C) | Esomeprazole sodium (C) | Aprepitant al (C) | Diphenhydramine hydrochloride (C)									
202504GLO027429BR	BRAZIL 63 Years Female	**Troponin I increased (Troponin I increased)***	Recovered	21-Apr-2025 1 month 11 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	11-MAR-2025 to 07-OCT-2025 6 months 27 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 DERUXTECAN, RILVEGOSTOMIG, not related to CAPECITABINE, cca: not related to TRASTUZUMAB DERUXTECAN, CAPECITABINE,

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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
									RILVEGOSTOMIG Action taken of TRASTUZUMAB UPDATED TO Dose reduced.; Periodic Report Comments. Patient experienced INCREASED OF TROPONIN I, inv: related to TRASTUZUMAB DERUXTECAN, RILVEGOSTOMIG, not related to CAPECITABINE, cca: not related to TRASTUZUMAB DERUXTECAN, CAPECITABINE, RILVEGOSTOMIG.

Concomitant Medication(s): | CAPECITABINE (S) | AZD2936 (S) | Olmesartan (C) | Metformin (C) | Linagliptin (C) | Linadib (C) | Glimepiride (C)

SOC:Metabolism and nutrition disorders

2024A209228	NETHERLANDS 46 Years Male	**Diabetic ketoacidosis (Diabetic ketoacidosis)***	Recovered	11-Sep-2024 1 month 4 days	MEDI5752	Infusion	500 milligram Intravenous use	08-AUG-2024 to 29-AUG-2024 22 days	Periodic Report Comment. Patient experienced diabetic keto-acidosis,Inv, not related to trastuzumab deruxtecan, Inv, related to medi5752, Inv, not related to capecitabine, CCA : not related to study therapy

Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | CAPECITABINE (S) | Tirosint (C) | Amlodipine (C) | Fosinopril (C) | Empagliflozin (C) | Gliclazide (C) | Metformine (C) | Loperamide (C) | Zolpidem (C) | Oxazepam (C) | Metoclopramide (C) | Rivaroxaban (C)

202504GLO005011CN	CHINA 79 Years Male	**Hypokalaemia (Hypokalemia)***	Recovered	05-Apr-2025 nk	RILVEGOSTOMIG	Solution	750 milligram q3w	03-MAR-2025 to 03-MAR-2025	Periodic Report Comments. Patient experienced HYPOKALEMIA .Inv, related

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
								1 day	to deruxtecan and capecitabine and rilvegostomig Inv, related to deruxtecan and capecitabine and rilvegostomig, CCA: related to deruxtecan and capecitabine and rilvegostomig ,
						Solution	750 milligram q3w	07-FEB-2025 to 07-FEB-2025	
								1 day	
						Solution	750 milligram q3w	15-JAN-2025 to 15-JAN-2025	
								1 day	
						Solution	750 milligram q3w	24-MAR-2025 to 24-MAR-2025	
								1 day	

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EudraCT No: 2019-004483-22

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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
									CCA : related to deruxtecan and capecitabine and rilvegostomig , CCA : not related to deruxtecan and capecitabine and rilvegostomig
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | CAPECITABINE (S) | | Amlodipine besylate (C) | Potassium chloride (C)									
202509GLO003458CN	CHINA 52 Years Female	**Malnutrition (Malnutrition)***	Recovered	03-Sep-2025 1 year 2 months 7 days 9 hrs 40 min	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	04-MAR-2025 18:28 to 04-MAR-2025 19:28 1 hr	Periodic Report Comments. Patient experienced vomiting. Inv: event related to Medi5752, Trastuzumab Deruxtecan and not related to capecitabine. CCA: not related.

Blinded IBPR - AstraZeneca - Confidential & Proprietary

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

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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
						Powder for solution for infusion	4.4 milligram/kilogram q3w	09-OCT-2024 12:45 to 09-OCT-2024 14:14	
							Intravenous use	1 hr 29 min	
						Powder for solution for infusion	4.4 milligram/kilogram q3w	11-DEC-2024 14:32 to 11-DEC-2024 16:01	
							Intravenous use	1 hr 29 min	
						Powder for solution for infusion	4.4 milligram/kilogram q3w	11-FEB-2025 14:08 to 11-FEB-2025 15:10	
							Intravenous use	1 hr 2 min	
						Powder for solution for infusion	4.4 milligram/kilogram q3w	17-APR-2025 13:43 to 17-APR-2025 14:44	
							Intravenous use	1 hr 1 min	
						Powder for solution for infusion	4.4 milligram/kilogram q3w	19-SEP-2024 13:36 to 19-SEP-2024 15:00	
							Intravenous use	1 hr 24 min	
						Powder for solution for infusion	4.4 milligram/kilogram q3w	20-NOV-2024 14:58 to 20-NOV-2024 16:25	
							Intravenous use	1 hr 27 min	
						Powder for solution for infusion	4.4 milligram/kilogram q3w	21-JAN-2025 14:12 to 21-JAN-2025 15:13	

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

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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
							Intravenous use	1 hr 1 min	
						Powder for solution for infusion	4.4 milligram/kilogram q3w	26-MAR-2025 14:28 to 26-MAR-2025 15:29	
							Intravenous use	1 hr 1 min	
						Powder for solution for infusion	4.4 milligram/kilogram q3w	28-AUG-2024 13:36 to 28-AUG-2024 15:09	
							Intravenous use	1 hr 33 min	
						Powder for solution for infusion	4.4 milligram/kilogram q3w	30-OCT-2024 13:39 to 30-OCT-2024 14:40	
							Intravenous use	1 hr 1 min	
						Powder for solution for infusion	4.4 milligram/kilogram q3w	31-DEC-2024 13:17 to 31-DEC-2024 14:45	
							Intravenous use	1 hr 28 min	
						Powder for solution for infusion	5.4 milligram/kilogram q3w	07-AUG-2024 13:50 to 07-AUG-2024 15:23	
							Intravenous use	1 hr 33 min	
						Powder for solution for infusion	5.4 milligram/kilogram q3w	17-JUL-2024 18:46 to 17-JUL-2024 20:15	
							Intravenous use	1 hr 29 min	

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

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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)

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						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	26-JUN-2024 14:20 to 26-JUN-2024 15:57 1 hr 37 min	
					MEDI5752	Infusion	250 milligram q3w Intravenous use	31-DEC-2024 to 17-APR-2025 3 months 18 days	
						Infusion	500 milligram q3w Intravenous use	26-JUN-2024 to 11-DEC-2024 5 months 16 days	
Concomitant Medication(s): | CAPECITABINE (S) | MEDI5752 (S) | Diphenhydramine hydrochloride (C) | Betamethasone sodium phosphate (C) | Metoclopramide dihydrochloride (C) | Dolasetron mesylate (C)									
202511GLO010721DE	GERMANY 53 Years Female	**Hypophagia (Oral intake reduced)***	Recovered with Sequelae	10-Nov-2025 8 months 16 days 11 hrs 55 min	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	24-FEB-2025 12:05 to 24-NOV-2025 14:23 9 months 2 hrs 18 min	Periodic Report Comments. Patient experienced event Insufficient oral food and fluid intake. Investigator states event related to TRASTUZUMAB DERUXTECAN, CAPECITABINE, AZD2936. Company physician considers event related to TRASTUZUMAB DERUXTECAN, CAPECITABINE, AZD2936.
					AZD2936	Solution	750 milligram q3w Intravenous use	24-FEB-2025 09:50 to 24-NOV-2025 13:11 9 months 3 hrs 21 min	
					CAPECITABINE	Tablet	521 milligram/sq. meter q3w Oral use	01-SEP-2025 to 05-SEP-2025 5 days	

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)

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						Tablet	521 milligram/sq. meter q3w Oral use	04-MAY-2025 to 04-MAY-2025 1 day	
						Tablet	521 milligram/sq. meter q3w Oral use	05-JUL-2025 to 06-JUL-2025 2 days	
						Tablet	521 milligram/sq. meter q3w Oral use	07-APR-2025 to 11-APR-2025 5 days	
						Tablet	521 milligram/sq. meter q3w Oral use	10-JUN-2025 to 15-JUN-2025 6 days	
						Tablet	521 milligram/sq. meter q3w Oral use	11-AUG-2025 to 15-AUG-2025 5 days	
						Tablet	521 milligram/sq. meter q3w Oral use	13-OCT-2025 to 14-OCT-2025 2 days	
						Tablet	521 milligram/sq. meter q3w	15-OCT-2025 to 15-OCT-2025	

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
							Oral use	1 day	
						Tablet	521 milligram/sq. meter q3w Oral use	16-AUG-2025 to 16-AUG-2025 1 day	
						Tablet	521 milligram/sq. meter q3w Oral use	16-OCT-2025 to 17-OCT-2025 2 days	
						Tablet	521 milligram/sq. meter q3w Oral use	17-MAR-2025 to 22-MAR-2025 6 days	
						Tablet	521 milligram/sq. meter q3w Oral use	19-MAY-2025 to 23-MAY-2025 5 days	
						Tablet	521 milligram/sq. meter q3w Oral use	21-JUL-2025 to 25-JUL-2025 5 days	
						Tablet	521 milligram/sq. meter q3w Oral use	22-SEP-2025 to 26-SEP-2025 5 days	

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

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						Tablet	521 milligram/sq. meter q3w Oral use	23-MAR-2025 to 23-MAR-2025 1 day	
						Tablet	521 milligram/sq. meter q3w Oral use	24-MAY-2025 to 24-MAY-2025 1 day	
						Tablet	521 milligram/sq. meter q3w Oral use	26-JUL-2025 to 26-JUL-2025 1 day	
						Tablet	521 milligram/sq. meter q3w Oral use	27-MAR-2025 to 27-MAR-2025 1 day	
						Tablet	521 milligram/sq. meter q3w Oral use	28-APR-2025 to 03-MAY-2025 6 days	
						Tablet	521 milligram/sq. meter q3w Oral use	30-JUN-2025 to 04-JUL-2025 5 days	
						Tablet	750 milligram/sq. meter q3w	24-FEB-2025 to 01-MAR-2025	

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							Oral use	6 days	
Concomitant Medication(s): | CAPECITABINE (S) | AZD2936 (S) | Magnesium (C) | Ondansetron (C) | Mcp (C) | Movicol (C) | Dexamethason (C) | Biotin (C) | Pantothenic acid (C) | Riboflavin (C) | Zinc (C) | Calcium (C) | Ferro sanol (C) | Innohep (C) | Cernevit (C) | Tracutil (C) | Riopan (C)									
202512GLO016969IT	ITALY 73 Years Female	**Hypercalcaemia (Hypercalcemia)***	Recovering	12-Dec-2025 nk	MEDI5752	Infusion	Intravenous use	to	Periodic Report Comments. The investigator did not provide a causality assessment for study therapy Medi5752, Trastuzumab Deruxtecan and the following event(s): hypercalcemia.
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	Intravenous use	to	
Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | Simvastatin (C) | Ezetimibe (C) | Levothyroxine (C) | Acetylsalicylic acid (C) | Levosulpiride (C) | Tramadol (C)									

SOC:Musculoskeletal and connective tissue disorders

202503GLO023339US	UNITED STATES 66 Years Male	**Back pain (Back pain aggravated)***	Not Recovered	28-Feb-2025 nk	5-FLUOROURACIL	Infusion	Intravenous use	to	
					DURVALUMAB	Infusion	Intravenous use	to	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | CAPECITABINE (S) | DURVALUMAB (S) | OXALIPLATIN (S) | CISPLATIN (S) | PEMBROLIZUMAB (S) | Rosuvastatin (C)									

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
SOC:Product issues									
202510GLO013392PL	POLAND 70 Years Male	**Device occlusion (Stent occlusion)***	Recovered	13-Oct-2025 7 months 4 days	CAPECITABINE	Tablet	750 milligram/sq. meter q3w Intravenous use	10-MAR-2025 to 18-MAR-2025 9 days	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | 5-FLUOROURACIL (S) | AZD2936 (S) | | Torecan (C) | Ondansetron (C) | No-spa (C) | Omeprazol (C) | Trittico (C) | Co prestarium (C) | Rosvera (C) | Mesopral (C)									
SOC:Renal and urinary disorders									
202409GLO002746CA	CANADA 60 Years Male	**Tubulointerstitial nephritis (Acute interstitial nephritis)***	Recovered	23-Sep-2024 1 month 15 days 11 hrs 3 min	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	07-AUG-2024 14:17 to 07-AUG-2024 15:37 1 hr 20 min	Periodic Report Comments. The patient experienced Acute Interstitial Nephritis Investigator: Not related to Capecitabine, related to Trastuzumab Deruxtecan, MEDI5752. Company: Not related.
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	28-AUG-2024 12:57 to 28-AUG-2024 13:27 30 min	
					MEDI5752	Infusion	500 milligram/kilogram q3w Intravenous use	07-AUG-2024 12:16 to 07-AUG-2024 13:16 1 hr	

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
						Infusion	500 milligram/kilogram q3w Intravenous use	28-AUG-2024 11:27 to 28-AUG-2024 12:27 1 hr	

Concomitant Medication(s): | MEDI5752 (S) | CAPECITABINE (S) | Pantoprazole (C) | Atorvastatin (C) | Nicotine (C) | Restore (C) | Anusol (C) | Glycerine (C) | Ursodiol (C) | Midodrine (C) | Cotrimoxazol (C) | Polyethylene glycol (C) | Bisacodyl (C)

SOC:Respiratory, thoracic and mediastinal disorders

202410GLO008793DE	GERMANY 70 Years Female	**Dyspnoea (Dyspnea)***	Recovered with Sequelae	27-Sep-2024 2 days	MEDI5752	Infusion	500 milligram q3w Intravenous use	07-NOV-2024 to 07-NOV-2024 1 day	Periodic Report Comments. patient experiences dyspnea, Related to study therapy, CCA: related, patient died.
						Infusion	500 milligram q3w Intravenous use	17-OCT-2024 to 17-OCT-2024 1 day	
						Infusion	500 milligram q3w Intravenous use	26-SEP-2024 to 26-SEP-2024 1 day	

Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | CAPECITABINE (S) | | L-thyroxin (C) | Ramipril (C) | Ondansetron (C) | Dulcolax (C)

202410GLO025077PL	POLAND 68 Years Male	**Autoimmune lung disease (Autoimmune pneumonitis)***	Fatal	20-Oct-2024 107 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	05-AUG-2024 to 05-AUG-2024 1 day	

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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	05-JUL-2024 to	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	08-OCT-2024 to 08-OCT-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	18-SEP-2024 to 18-SEP-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	27-AUG-2024 to 27-AUG-2024 1 day	
					MEDI5752	Infusion	500 milligram Intravenous use	05-JUL-2024 to 14-SEP-2024 2 months 10 days	
Concomitant Medication(s): | CAPECITABINE (S) | MEDI5752 (S) | Aspirin (C) | Adadut (C) | Silodosin aurovitas (C) | Nedal (C) | Lapixen (C) | Ondansetron (C) | Elocom (C) | Encorton (C) | Belogent (C)									
202411GLO026916KR	KOREA, REPUBLIC OF 67 Years Male	**Interstitial lung disease (Interstitial lung disease)***	Not Recovered	05-Nov-2024 1 year 17 days	PEMBROLIZUMAB	Solution for infusion	200 milligram q3w Intravenous use	20-OCT-2023 to 18-OCT-2024 11 months 29 days	Patient experiencing interstitial lung disease, cca not related to study therapy.

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) | CAPECITABINE (S) | | Macperan (C) | Esroban (C)									
202412GLO011637KR	KOREA, REPUBLIC OF 50 Years Male	**Interstitial lung disease (Interstitial lung disease)***	Not Recovered	03-Dec-2024 3 months 26 days 10 hrs 42 min	MEDI5752	Infusion	500 milligram q3w Intravenous use	06-AUG-2024 13: 18 to 19-NOV-2024 14:50 3 months 13 days 1 hr 32 min	Periodic Report Comments. Patient experienced Interstitial Lung Diseas Inv: event related to Trastuzumab deruxtecan and MEDI5752, not related to Capecitabine. CCA: not related.
Concomitant Medication(s): | TRASTUZUMAB DERUXTECAN (S) | CAPECITABINE (S) | Synthyroxine (C) | Ebastel (C) | Desowen (C) | Xyzal (C) | Fexuclue (C) | Sancuso (C) | Rapison (C) | Tridol (C) | Tramol (C) | Gaster (C) | K cab (C) | Mucosta (C) | Solondo (C) | Septrin (C) | Trajenta (C) | Diamicron (C) | Glupa (C) | Urea (C) | Duloctin (C) | Nexium IV (C) | Synacthen Deposito (C)									
SOC:Skin and subcutaneous tissue disorders									
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	

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
					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	
					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	

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

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: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	24-SEP-2024 to	Periodic Report Comments. Patient experienced anaemia and platelet count decreased , investigator assessed causality with TRASTUZUMAB DERUXTECAN as related, with MEDI5752 as not related. CCA: not related with study therapy, Darolutamide and Prednisolone.
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 Powder for solution for infusion Powder for solution for infusion	3.2 milligram/kilogram q3w Intravenous use 3.2 milligram/kilogram q3w Intravenous use 3.2 milligram/kilogram q3w Intravenous use	05-AUG-2025 to 05-AUG-2025 1 day 08-APR-2025 to 08-APR-2025 1 day 27-AUG-2025 to 27-AUG-2025 1 day	Periodic Report Comments. Patient experienced anemia and neutropenia. Investigator Causality: Not Related CC: Not Related. TRASTUZUMAB DERUXTECAN Anemia. Investigator Causality: Related CC: Not Related. AZD2936 Neutropenia.;Periodic Report Comments. Patient experienced anemia and neutropenia. Anemia Investigator Causality: Related CC: Not Related. TRASTUZUMAB DERUXTECAN. Investigator Causality: not Related CC: Not Related. AZD2936. Neutropenia Investigator Causality: Related CC: Not Related.

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	TRASTUZUMAB DERUXTECAN. Investigator Causality: not Related CC: Not Related. AZD2936.
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	27-FEB-2025 to 27-FEB-2025 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	29-MAY-2025 to 29-MAY-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)									
202505GLO017984PH	PHILIPPINES 76 Years Male	**Neutropenia (Neutropenia)***	Not 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	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	27-FEB-2025 to 07-MAY-2025 2 months 11 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
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	Periodic Report Comments. Patient experienced neutropenia. Inv: related to trastuzumab deruxtecan. Not related to Rilvegostomig. CCA Not related.
Concomitant Medication(s): | MEDI5752 (S) | Eurodin (C) | Tamsulosin (C) | Through (C) | Tranexamic acid (C)									
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									
2024A023573	MALAYSIA 54 Years Male	**Thyroiditis (Thyroiditis)***	Recovered with Sequelae	29-Jan-2024 3 weeks	MEDI5752	Infusion	500 milligram q3w Intravenous use	08-JAN-2024 to 29-JAN-2024 3 weeks 1 day	Periodic Report Comment. Patient experienced hyperthyroidism serious and Investigator related to Medi5752. CCA: Not related to trastuzumab deruxtecan and Medi5752.

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
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | 20/20 eye drop (C) | Loratadine (C) | Acide fusidique (C) | Piriton (C)									
202507GLO001819PH	PHILIPPINES 65 Years Male	**Hypothyroidism (Hypothyroidism)***	Recovering	01-Jul-2025 5 months 17 days	AZD2936	Solution Intravenous use	750 milligram q3w	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 Intravenous use	750 milligram q3w	22-JUL-2025 to 12-AUG-2025 22 days	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Insulin lispro (C)									
SOC:Gastrointestinal disorders									
202511GLO006162PH	PHILIPPINES 39 Years Female	**Vomiting (Vomiting)***	Recovered	02-Nov-2025 6 days	AZD2936	Solution Intravenous use	750 milligram	09-DEC-2025 to 09-DEC-2025 1 day	Periodic Report Comments. Patient has event: Event: Vomitting, Action taken with Rilvegostomig: No Change, Investigator causality: related, Company Causality: not related
						Solution Intravenous use	750 milligram	18-NOV-2025 to 18-NOV-2025 1 day	
						Solution Intravenous use	750 milligram	28-OCT-2025 to 28-OCT-2025 1 day	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Ascorbic acid (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
202511GLO006254PH	PHILIPPINES 39 Years Female	**Nausea (Nausea)***	Recovered	05-Nov-2025 7 days 12 hrs 50 min	AZD2936	Solution	750 milligram Intravenous use	09-DEC-2025 to 09-DEC-2025 1 day	Periodic Report Comments. Patient experienced event - nausea. Investigator states event related to Trastuzumab Deruxtecan and Azd2936. Company physician considers event related to Trastuzumab Deruxtecan and Azd2936.
						Solution	750 milligram Intravenous use	18-NOV-2025 to 18-NOV-2025 1 day	
						Solution	750 milligram q3w Intravenous use	28-OCT-2025 11:10 to 28-OCT-2025 12:40 1 hr 30 min	

Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Ascorbic acid (C) | Diphenhydramine (C) | Dexamethasone (C) | Ondansetron (C)

SOC:General disorders and administration site conditions

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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 1 day 10 hrs 20 min	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	16-SEP-2025 13:40 to 16-SEP-2025 15:15 1 hr 35 min	Periodic Report Comments. Patient experienced Sudden cardiac death, Investigator assessed causality with TRASTUZUMAB DERUXTECAN and AZD2936 as Related. CCA: Not related with TRASTUZUMAB DERUXTECAN and AZD2936.
					AZD2936	Solution	750 milligram q3w Intravenous use	16-SEP-2025 11:10 to 16-SEP-2025 12:40 1 hr 30 min	

Concomitant Medication(s): | AZD2936 (S) | Digoxin (C) | Apixaban (C) | Diphenhydramine (C) | Dexamethasone (C) | Ondansetron (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:Infections and infestations									
202409GLO015045MY	MALAYSIA 56 Years Male	**Upper respiratory tract infection (URTI (upper respiratory tract infection))***	Recovered	06-Oct-2024 20 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram Intravenous use	17-SEP-2024 to 31-DEC-2024 3 months 15 days	
Concomitant Medication(s): | MEDI5752 (S) | Thymol (C) | Hydrocortisone (C) | Aqueous (C) | Thyroxine (C)									
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)									
202502GLO010495PH	PHILIPPINES 62 Years Male	**Pneumonia (Obstructive pneumonia)***	Recovered	12-Feb-2025 nk	MEDI5752	Infusion	Intravenous use	to	Periodic Report Comments. Patient experienced Obstructive pneumonia Inv causality: NOT REPORTED CCA: NOT RELATED
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | DURVALUMAB (S)									
202505GLO002377PH	PHILIPPINES 58 Years Female	**Pneumonia (Lung infection)***	Fatal	03-May-2025 7 months 10	TRASTUZUMAB DERUXTEC	Powder for solution for infusion	5.4 milligram/kilogram q3w	02-APR-2025 to 23-APR-2025	

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
				days	AN		Intravenous use	22 days	
						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)									
202501GLO008482KR	KOREA, REPUBLIC OF 63 Years Male	**Ejection fraction decreased (Ejection fraction decreased)***	Recovered	09-Jan-2025 1 year 5 days	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	03-MAY-2024 to 03-MAY-2024 1 day	Periodic Report Comments. Patient experienced event – ejection fraction decreased. Investigator states event related trastuzumab Deruxtecan and not related to MEDI5752. Company physician considers event not related trastuzumab Deruxtecan,

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
									MEDI5752.
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	05-JUL-2024 to 05-JUL-2024 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	06-SEP-2024 to 06-SEP-2024 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	07-NOV-2024 to 07-NOV-2024 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	09-APR-2024 to 09-APR-2024 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	14-JUN-2024 to 14-JUN-2024 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	16-AUG-2024 to 16-AUG-2024 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w	17-OCT-2024 to 17-OCT-2024	

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
								1 day	
							Intravenous use		
						Powder for solution for infusion	4.4 milligram/kilogram q3w	20-DEC-2024 to 20-DEC-2024	
								1 day	
							Intravenous use		
						Powder for solution for infusion	4.4 milligram/kilogram q3w	21-MAR-2024 to 21-MAR-2024	
								1 day	
							Intravenous use		
						Powder for solution for infusion	4.4 milligram/kilogram q3w	24-MAY-2024 to 24-MAY-2024	
								1 day	
							Intravenous use		
						Powder for solution for infusion	4.4 milligram/kilogram q3w	26-JUL-2024 to 26-JUL-2024	
								1 day	
							Intravenous use		
						Powder for solution for infusion	4.4 milligram/kilogram q3w	27-SEP-2024 to 27-SEP-2024	
								1 day	
							Intravenous use		
						Powder for solution for infusion	4.4 milligram/kilogram q3w	28-NOV-2024 to 28-NOV-2024	
								1 day	
							Intravenous use		

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	05-JAN-2024 to 05-JAN-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	25-JAN-2024 to 25-JAN-2024 1 day	
Concomitant Medication(s): | MEDI5752 (S) | Heparin (C) | Peniramin (C) | Lacticare (C) | Dermatop (C) | Solondo (C)									
202509GLO028355PL	POLAND 74 Years Female	**Troponin increased (Troponin increased)***	Recovering	18-Sep-2025 1 month 12 days 9 hrs 15 min	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	05-AUG-2025 14:45 to 29-DEC-2025 12:30 4 months 23 days 21 hrs 45 min	Periodic Report Comments. Patient experienced events Hypokalemia and Elevated troponin levels. Investigator states event Hypokalemia not related to TRASTUZUMAB DERUXTECAN and event Troponin increased related to TRASTUZUMAB DERUXTECAN. Both events not related to TRASTUZUMAB DERUXTECAN and AZD2936. CCC- not related.
Concomitant Medication(s): | AZD2936 (S) | Indapen (C) | Toramid (C) | Acurenal (C) | Roswera (C) | Acard (C) | Sevredol (C) | Lyrica (C) | Primacor (C) | Kalipoz (C) | Ondansetron kabi (C) | Dexaven (C) | Metoclopramid (C) | Oxydolor (C) | Doreta sr (C)									

SOC:Metabolism and nutrition disorders

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
2024A135605	KOREA, REPUBLIC OF 61 Years Female	**Diabetic ketoacidosis (Diabetic ketoacidosis)***	Recovered	08-Jun-2024 4 months 21 days	MEDI5752	Infusion	500 milligram Intravenous use	02-MAY-2024 to 02-MAY-2024 1 day	Periodic Report Comment. The patient experienced DIABETIC KETOACIDOSIS.Inv: Related to MEDI5752,Not related to Trastuzumab deruxtecan and Fever not related to study therapy. CCA: Not related to study therapy.
						Infusion	500 milligram Intravenous use	08-FEB-2024 to 08-FEB-2024 1 day	
						Infusion	500 milligram Intravenous use	09-APR-2024 to 09-APR-2024 1 day	
						Infusion	500 milligram Intravenous use	19-JAN-2024 to 19-JAN-2024 1 day	
						Infusion	500 milligram Intravenous use	23-MAY-2024 to 23-MAY-2024 1 day	

Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Kynex 2 (C) | Emend (C) | Aloxi (C) | Lopaine (C) | Lanston (C) | Methysol (C) | Peridex (C) | Topisol (C) | Macperan (C) | Lacticare hc (C) | Megace (C) | Tantum (C) | Norzyme (C) | Heparin (C) | Ursa (C) | Tresiba flextouch (C) | Solondo (C)

SOC:Renal and urinary disorders

202511GLO029495PL	POLAND 74 Years Female	**Acute kidney injury (Acute renal failure)***	Recovered	17-Nov-2025 3 months 13 days	RILVEGOS TOMIG	Solution	750 milligram Unknown	05-AUG-2025 to 07-NOV-2025 3 months 3 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
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Indapen (C) | Toramid (C) | Acurenal (C) | Metoclopramide (C) | Oxydolor (C) | Dexaven (C) | Kalipoz (C) | Acard (C) | Sevredol (C) | Roswera (C) | Hydrocoll (C) | Primacor (C) | Ondansetron kabi (C)									
SOC:Respiratory, thoracic and mediastinal disorders									
202411GLO014184PH	PHILIPPINES 58 Years Female	**Epistaxis (Epistaxis)***	Recovered	12-Nov-2024 1 month 18 days 11 hrs 20 min	TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	06-NOV-2024 15:10 to 12-MAR-2025 4 months 5 days 8 hrs 50 min	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	15-OCT-2024 14:10 to 15-OCT-2024 14:40 30 min	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	24-SEP-2024 12:40 to 24-SEP-2024 14:10 1 hr 30 min	
Concomitant Medication(s): | MEDI5752 (S) | Losartan (C) | Folic acid (C)									
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:

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
						Infusion	500 milligram q3w Intravenous use	07-OCT-2024 to 07-OCT-2024 1 day	RELATED to Trastuzumab Deruxtecan NOT RELATED to MEDI5752 CCC: NOT RELATED
						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	
						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.

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
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Minerals (C) | Fluticasone (C) | Losartan (C) | Diphenhydramine (C) | Levocetirizine (C) | Folic acid (C) | Erythropoietin (C)									
202412GLO023048PH	PHILIPPINES 66 Years Male	**Immune-mediated lung disease (Immune-mediated pneumonitis)***	Recovered	20-Aug-2024 14 days	MEDI5752	Infusion Intravenous use	500 milligram q3w 1 day	07-AUG-2024 to 07-AUG-2024	Periodic Report Comments. Patient experienced immune check point pneumonitis Inv causality: RELATED to Medi5752 NOT RELATED to Trastuzumab Deruxtecan CCC: NOT RELATED
						Infusion Intravenous use	500 milligram q3w 1 day	07-OCT-2024 to 07-OCT-2024	
						Infusion Intravenous use	500 milligram q3w 1 day	18-SEP-2024 to 18-SEP-2024	
						Infusion Intravenous use	500 milligram q3w 1 day	20-NOV-2024 to 20-NOV-2024	
						Infusion Intravenous use	500 milligram q3w 1 day	29-AUG-2024 to 29-AUG-2024	
						Infusion Intravenous use	500 milligram q3w 1 day	29-OCT-2024 to 29-OCT-2024	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | Salmeterol and Fluticasone (C) | Acetylcysteine (C) | Losartan (C) | Palonosetron (C) | Ondansetron (C) | Diphenhydramine (C) | Levocetirizine (C) | Ferroven iron + folic acid (C) | Epoetin alfa (C) | Lactulose (C) | Prednisone (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
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	5.4 milligram/kilogram q3w Intravenous use	02-MAY-2024 to 02-MAY-2024 1 day	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.
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	11-APR-2024 16:05 to 11-APR-2024 16:35 30 min	
						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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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
202507GLO000729TW	TAIWAN 77 Years Male	**Pneumonitis (Pneumonitis)***	Not Recovered	24-Jun-2025 7 months 6 days	AZD2936	Solution	750 milligram q3w 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)									

SOC:Skin and subcutaneous tissue disorders

2024A043166	KOREA, REPUBLIC OF 61 Years Female	**Urticaria (Urticaria)***	Recovered	28-Jan-2024 10 days	MEDI 5752	Infusion	500 milligram q3w Intravenous use	19-JAN-2024 to 23-MAY-2024 4 months 5 days	Periodic Report Comment. Patient experienced urticaria. Investigator related to study therapy. CCA: related.;Periodic Report Comments. Patient experienced urticaria. Investigator related to study therapy.
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	3.2 milligram/kilogram q3w Intravenous use	22-JUL-2024 to 23-APR-2025 9 months 2 days	

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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
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	09-APR-2024 to 23-MAY-2024 1 month 15 days	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	21-MAR-2024 to 21-MAR-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	08-FEB-2024 to 08-FEB-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	19-JAN-2024 to 19-JAN-2024 1 day	
Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | EMEND (C) | KYTRIL (C) | MACPERAN (C) | Nasea od (C) | SANCUSO (C)									
2024A043189	KOREA, REPUBLIC OF 63 Years Male	**Urticaria (Urticaria)***	Not Recovered	19-Jan-2024 15 days	MEDI5752	Infusion	500 milligram q3w	09-APR-2024 to 05-JUL-2024 2 months 27 days	Periodic Report Comment. Patient experienced urticaria. Inv. related to study therapy. CCA: related to study therapy.
						Infusion	500 milligram q3w Intravenous use	05-JAN-2024 to 05-JAN-2024 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
						Infusion	500 milligram q3w Intravenous use	25-JAN-2024 to 25-JAN-2024 1 day	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	4.4 milligram	07-NOV-2024 to 07-NOV-2024 1 day	
						Powder for solution for infusion	4.4 milligram	28-NOV-2024 to 28-NOV-2024 1 day	
						Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	21-MAR-2024 to 17-OCT-2024 6 months 27 days	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	05-JAN-2024 to 05-JAN-2024 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	25-JAN-2024 to 25-JAN-2024 1 day	

Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | CRESTOR (C) | EZETROL (C) | MACPERAN (C) | LANSTON (C) | SANCAGO (C) | Nasea od (C) | EMEND (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
2024A146295	TAIWAN 65 Years Female	**Stevens-Johnson syndrome (Stevens Johnson syndrome)***	Recovered	22-Jun-2024 9 weeks 2 days	CARBOPLATIN	Infusion	Intravenous use	16-MAY-2024 to 13-JUN-2024 4 weeks 1 day	Periodic Report Comment. Patient experienced stevens johnson syndrome. INV: Related CCA: not related to all suspects.
						Infusion	Intravenous use	18-APR-2024 to 18-APR-2024 1 day	
					MEDI 5752	Infusion	500 milligram q3w Intravenous use	18-APR-2024 to 14-JUN-2024 8 weeks 2 days	
					TRASTUZUMAB DERUXTECAN	Powder for solution for infusion	4.4 milligram/kilogram q3w Intravenous use	16-MAY-2024 to 13-JUN-2024 4 weeks 1 day	
						Powder for solution for infusion	5.4 milligram/kilogram q3w Intravenous use	18-APR-2024 to 18-APR-2024 1 day	

Concomitant Medication(s): TRASTUZUMAB DERUXTECAN (S) | | MEDI 5752 (S) | ACETAMINOPHEN (C) | Medicon a (C) | AMBROXOL (C) | MEGESTROL (C) | FOSTER (C) | MONTELUKAST (C) | Alinamin f (C) | FEXOFENADINE (C) | SINBABY (C) | PREDNISOLONE (C) | FLUOCINOLONE (C) | ESOMEPRAZOLE (C) | DIFLUCORTOLONE (C)

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

Project ID: D9804

Study ID: D9804C00001

EudraCT No:

Study Design: Not Blinded

Study Description: A Master Protocol for an Open-Label, Multi-Drug, Multi-Center, Phase II Platform Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Preliminary Anti-Tumor Activity of Novel Agents or Combinations as Perioperative Treatment in Participants with Locally Advanced Resectable Gastroesophageal Adenocarcinoma

Case Number	Country Age Gender	Main Adverse Event PT (LLT) Other Adverse Event/s PT (LLT) * denotes a SUSAR	Case Outcome Main Event 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									
202512GLO024280GE	GEORGIA Unknown	**Gastric haemorrhage (Gastric hemorrhage)***	Recovered	24-Dec-2025 1 month 3 days 22 hrs 30 min	5-FLUOROURACIL	Infusion	2600 milligram/sq. meter	04-DEC-2025 20:12 to 05-DEC-2025 20:12	
							Unknown	1 day	
						Infusion	2600 milligram/sq. meter	20-NOV-2025 01:30 to 21-NOV-2025 01:30	
							Unknown	1 day	
					DOCETAXEL	Infusion	50 milligram/sq. meter	04-DEC-2025 14:48 to 04-DEC-2025 15:48	
							Unknown	1 hr	
						Infusion	50 milligram/sq. meter	20-NOV-2025 19:52 to 20-NOV-2025 20:52	
							Unknown	1 hr	
					OXALIPLATIN	Infusion	85 milligram/sq. meter	04-DEC-2025 15:57 to 04-DEC-2025 17:57	
							Unknown	2 hrs	
						Infusion	85 milligram/sq. meter	19-NOV-2025 21:00 to 19-NOV-2025 23:00	
							Unknown	2 hrs	

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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): RILVEGOSTOMIG (S) | | OXALIPLATIN (S) | LEUCOVORIN CALCIUM (S) | DOCETAXEL (S) | Rivaroxaban (C) | Filgrastim (C)									
SOC:Injury, poisoning and procedural complications									
202512GLO021251ES	SPAIN 64 Years Male	**Infusion related reaction (Infusion reaction)***	Recovered	17-Dec-2025 2 days	DOCETAXEL	Infusion	50 milligram/sq. meter Unknown	16-DEC-2025 to 16-DEC-2025 1 day	
Concomitant Medication(s): AZD2936 (S) | 5-FLUOROURACIL (S) | OXALIPLATIN (S) | | LEUCOVORIN (S) | Actocortin (C) | Imidapril (C) | Amlodipine (C) | Dolutegravir (C) | Lamivudina (C)									

Total count of Cases: 682

Total count of SUSARs: 768

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
Product issues
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.