

ETHICS COMMITTEE DOSSIER

Protocol Title	A prospective, observational, multicenter, post marketing surveillance study to assess safety of Durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC)
Development Phase of Study	Post Marketing surveillance_Observational
Protocol No.	D9106R00007
Sponsor	AstraZeneca
Name of IRB/ IEC/ EC: Address:	Institutional Review Board Tata Medical Centre
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Clinical Study Protocol Version1.0. Dated 22-Dec-2024

Study Code	D9106R00007
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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation or special term	Explanation
NSCLC	Non-Small Cell Lung Cancer
ADR	Adverse Drug Reaction
AE	Adverse Events
AESI	Adverse Event of Special Interest
ALK	Anaplastic Lymphoma Kinase
APTT	Activated Partial Thromboplastin Time
cCRT	concurrent chemoradiotherapy
CDSCO	Central Drugs Standard Control Organisation
CRO	Clinical Research Organization
CTLA-4	cytotoxic T Lymphocyte-Associated antigen 4
DC	Dendritic Cell
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic Case Report Form
EGFR	Epidermal Growth Factor Receptor
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GPP	Good Pharmacoepidemiology Practice
HIV	Human Immunodeficiency Virus
ICF	Informed Consent Form
ICH	International Council for Harmonisation
ICI	Immune Checkpoint Inhibitors
IEC	Independent Ethics Committee
IgG1	Immunoglobulin G1
INR	International Normalized Ratio
IRB	Institutional Review Board
ISPE	International Society for Pharmacoepidemiology
LFT	Liver Function Test

Abbreviation or special term	Explanation
NCCN	National Comprehensive Cancer Network
NK	Natural Killer
NSCLC	Non-Small Cell Lung Cancer
PD-1	Programmed cell Death protein-1
PD-L1	Programmed Death-Ligand 1
PMS	Post Marketing Surveillance
PT	Preferred Term
q3w	once every 3 weeks
q4w	once every 4 weeks
SAE	Serious Adverse Events
SAP	Statistical Analysis Plan
sCRT	sequential chemoradiotherapy
SOC	System Organ Class
SoC	Standard of Care
TEAE	Treatment Emergent Adverse Event
TSH	Thyroid Stimulating Hormone

RESPONSIBLE PARTIES

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PROTOCOL SYNOPSIS

A Prospective, observational, multicenter, post marketing surveillance study to assess safety of durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC)

Background/Rationale:

Lung cancer is the leading cause of cancer-related deaths worldwide with non-small cell lung cancer (NSCLC) accounting for 85% of all lung cancers. Surgery is the most effective treatment for patients with resectable NSCLC. However, only 20% to 35% can be treated through resection. ¹ Peri-operative immunotherapy has the potential benefits of both neoadjuvant & adjuvant therapy and helps to improve survival outcomes as well as reduce micrometastases. Recently, immunotherapy has also been established as a valuable component of treatment for resectable NSCLC with pembrolizumab, atezolizumab, and nivolumab all approved by the US FDA for use in this setting. Of these, neoadjuvant nivolumab has received approval from CDSCO for use in India. Perioperative immunotherapy has been incorporated into the NCCN Clinical Practice Guidelines for Oncology (NCCN Guidelines) and is categorized into adjuvant and neoadjuvant immunotherapy approaches [2,3].

Neoadjuvant immunotherapy aims to enhance systemic immunity against tumour antigens, eliminating micrometastatic tumour deposits that would otherwise be the source of postsurgical relapse. Furthermore, while the primary tumour is in place, neoadjuvant therapy leverages higher levels of endogenous tumour antigen present in the primary tumour to enhance T cell priming [4]. Adjuvant therapy plays an important role in eliminating micrometastases and preventing recurrence [5].

The Indian Health Authority has granted conditional approval of durvalumab in combination with chemotherapy as neoadjuvant therapy followed by durvalumab monotherapy after surgery for use in patients with resectable (tumors $\geq$ 4 cm and/or node positive) NSCLC and no known EGFR mutations and ALK rearrangements

AstraZeneca is mandated to conduct a study evaluating the safety of durvalumab in patients with resectable NSCLC, as administered by physicians in standard clinical practice settings as per the CDSCO approval. This study aims to confirm the known safety profile and identify previously unrecognized adverse reactions of durvalumab in the treatment of resectable NSCLC among Indian patients, in compliance with the requirements of the Indian Health Authority.

Objectives:

Primary objective	Outcome measure
To assess the safety of Durvalumab (IMFINZI) in resectable non-small cell lung cancer (NSCLC) patients in India	- Frequency and proportion of patients with Grade 3/4 possibly related adverse events (PRAEs)*

	- Frequency and proportion of patients with treatment emergent adverse events & serious adverse events (SAEs) and , mortality - Time to occurrence of first AEs and first SAEs * PRAEs as assessed per the WHO-UMC criteria
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Methods:

Study design:

This will be a single-arm, multicenter, prospective, observational, real-world study and the data source is the patients' medical record at each site. A total of 78 patients will be enrolled in the study.

Eligible patients with newly diagnosed, previously untreated, resectable NSCLC (tumors ≥ 4 cm and/or node positive) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements will be included.

This study will be conducted according to each site's routine clinical practice for the treatment of resectable NSCLC. Patients will undergo routine biopsies and staging investigations; and will be offered durvalumab as neoadjuvant and/or adjuvant therapy in accordance with the approved prescribing information and as per the institutional standard at the discretion of the Investigator. Patients accepting this treatment approach will be offered enrolment into this study. Patients will be made aware that their therapy and subsequent management will not be impacted as a result of their enrolment. Patients will be provided with an informed consent form (ICF) that describes the data to be collected, and the purpose of the study. There will be no protocol-mandated procedures in the present study.

The **treatment period** for an individual patient will be calculated from the date of the first dose of durvalumab until:

- Date of last dose of durvalumab + 90 days **or**
- Date of first dose of subsequent anti-cancer therapy; **whichever is earlier**

Patient data will be gathered for about 90 days for safety assessment since the last dose of the study drug, until withdrawal of consent, lost to follow-up, or death, whichever comes first. The enrolled patients should be followed up at least once after taking the study drug. Safety follow-up will be conducted for all AEs occurring during the study period.

The total number of visits and the visit time will be determined at the discretion of the investigator based on the patient's condition. Patients' demographic, disease status, investigations, durvalumab dosing and other treatment data at baseline and throughout the study period will be collected and recorded in eCRF, along with outcome measures such as incidence of TEAE including SAEs and death (Refer Since this is an observational study, there will be no protocol-mandated investigations. Data related to the below mentioned assessments (if available) will be collected at the following timepoints corresponding to treatment schedule:

Table 1).

Data Source(s):

The data source of this study is the patient's medical records in each site and collected data will be recorded and gathered in case report form (eCRF). Participation in this study is not intended to change the routine treatment patients receive, as determined by their prescribing physicians (Investigators); all treatment decisions, type and timing of disease monitoring are at the discretion of treating physician and patient.

Study Population:

Inclusion criteria

1. Patients with newly diagnosed previously untreated resectable NSCLC (tumors ≥ 4 cm and/or node positive) and no known EGFR mutations or ALK rearrangements prescribed with durvalumab as per local prescriber information.
2. Provision of signed, written and dated informed consent
3. Male or female patients aged 18 years or older

Exclusion criteria

1. Presence of unresectable or metastatic disease.
2. Prior treatment with durvalumab for any other indications
3. Requires concurrent treatment for cancers other than resectable NSCLC
4. Concurrently participating in any other clinical trial
5. Patients with active or prior autoimmune disease or with medical conditions that required systemic corticosteroids or immunosuppressants
6. Any condition that, in the opinion of the investigator, would interfere with the patient's participation in the study.

Exposure(s):

Patients who fit the eligibility criteria and are assessed by their physicians as qualifying for therapy with durvalumab and have not received any previous treatment for their NSCLC will be considered for enrolment in the present study. Durvalumab will be administered as per each site's routine clinical practice and in accordance with the approved prescribing information.

Exposure will be defined in terms of total and actual exposure. The total exposure (duration of treatment) will be calculated using the start and stop dates of Durvalumab and the intended dosing interval (or intervals if dosing is not regular

Dose interruptions and dose reductions will also be monitored and captured in the eCRF.

Outcome(s):

Frequency and proportion of patients with treatment emergent adverse events (AEs) (Grade 3/4 PRAEs & all-grade AEs) including immune mediated adverse events& treatment emergent serious adverse events (SAEs), and deaths. The AEs will be characterised based on the time point of occurrence- before & after surgery. Additionallytime to occurrence of first AEs and first SAEs will also be noted.

Sample Size Estimations:

The primary endpoint of the trial is to demonstrate the safety profile of durvalumab in routine clinical practice as assessed by the incidence of Grade 3/4 possibly related AEs observed during the trial.

Based on the durvalumab data generated from the results of AEGEAN trial [18], the incidence rate of Grade 3/4 AEs which were at least possibly related, is 33%. A sample size of 70 will be needed to estimate a 33% AE rate (grade 3 or 4, possibly related) with 11% margin of error leading to a 95% confidence interval of 22% to 44%. With a dropout rate of 10%, the total sample size is 78.

Statistical Analysis:

Statistical software SAS® version 9.4 or higher (SAS Institute Inc, Cary, North Carolina) will be used for the analyses. The safety analysis population will include all patients who sign the ICF and receive at least one dose of durvalumab.

In general, the variables will be summarized by using standard descriptive statistics. Continuous variables will be summarized with the number (n) of non-missing observations, mean, standard deviation, median, and minimum and maximum, unless otherwise specified. For categorical data, descriptive statistics will be presented with the number and percentage of subjects in the various categories of the endpoint. Detailed methodology for summary and statistical analyses of data collected in this study will be documented in the SAP, which will be dated, filed and maintained by the sponsor.

AMENDMENT HISTORY

Date	Section of study protocol	Amendment or update	Reason
		N/A	

MILESTONES

Milestones	Planned dates
Study protocol approved	Q4 2024
First subject/patient in (or database start date)	Q1 2025
Last subject/patient in (or database end date)	Q2 2026
Last subject/patient last visit	Q1 2028
Final database lock	Q3 2028
Clinical study report approved	Q4 2028

1. BACKGROUND AND RATIONALE

1.1 Background

According to GLOBOCAN 2022, lung cancer was the most frequently diagnosed cancer in 2022, responsible for almost 2.5 million new cases, or one in eight cancers worldwide (12.4% of all cancers globally) and is also the leading cause of cancer death (18.7% of the total cancer deaths). Lung cancer is most frequent cancer in men (both cases and deaths). Biologically, lung cancers are a group of heterogeneous diseases categorically divided into non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC). NSCLC is predominant, representing 85% of the cases, while SCLC comprises 15% of total lung cancer cases. Furthermore, depending on the cell of origin, lung cancers of NSCLC histology are classified into two major subtypes: lung adenocarcinoma and lung squamous carcinoma [7]

For lung cancer, as in any other cancer, an accurate diagnosis is crucial to provide the patients with the best possible treatment. Lung cancer staging is necessary to determine the prognosis, to evaluate the available treatment options, and to allow accurate representation in clinical trials [8].

Surgery is the most effective treatment for patients with resectable NSCLC. However, only 20% to 35% can be treated through resection [1]. In addition to TNM staging, the presence of driver mutations [such as alterations in the epidermal growth factor receptor (*EGFR*) gene and anaplastic lymphoma kinase (*ALK*) rearrangements] is another important factor to be considered during treatment selection. In patients with no known driver mutations, immunotherapy with checkpoint inhibitors has revolutionized the treatment [8].

Immunotherapy in cancer

Recently, immunotherapy has been established as a valuable component of treatment for resectable NSCLC. Perioperative immunotherapy has been incorporated into the NCCN Clinical Practice Guidelines for Oncology (NCCN Guidelines) and is categorized into neoadjuvant and adjuvant immunotherapy approaches [2]. Neoadjuvant immunotherapy aims to enhance systemic immunity against tumor antigens, eliminating micrometastatic tumor deposits that would otherwise be the source of postsurgical relapse. Furthermore, while the primary tumor is in place, neoadjuvant therapy leverages higher levels of endogenous tumor antigen present in the primary tumor to enhance T cell priming [4]. Adjuvant therapy plays an important role in eliminating micrometastases and preventing recurrence [5]. The huge number of genetic and epigenetic changes that are inherent to most cancer cells provide plenty of tumour-associated antigens that the host immune system can recognize, thereby requiring tumours to develop specific immune resistance mechanisms. An important immune resistance mechanism involves immune-inhibitory pathways, termed immune checkpoints, which normally mediate immune tolerance and mitigate collateral tissue damage [10].

Immune Checkpoints and Immune Checkpoint Inhibitors (ICIs)

Immune checkpoints regulate immune activation, preventing autoimmunity and limiting tissue damage. Tumors exploit these mechanisms to evade immune responses by suppressing tumor-

specific lymphocyte activation. Blocking these inhibitory signals reactivates antitumor immunity, forming the basis of modern immunotherapies using monoclonal antibodies or recombinant receptors. While effective, this approach may trigger autoimmune reactions [11].

PD-1, an inhibitory receptor, regulates T-cell responses and is expressed on various immune cells in the tumor microenvironment (TME), including monocytes, dendritic cells, NK cells, T cells, and B cells. Its ligands, PD-L1 and PD-L2, are expressed by tumor and immune cells. PD-L1 suppresses T-cell migration and proliferation by binding PD-1 and B7.1, hindering tumor cell killing and facilitating immune escape [12, 13, 14].

Antibodies targeting immune inhibitory receptors, such as CTLA-4, PD-1, and PD-L have been the most widely used immunotherapeutic agents in the last decade. An increasing number of studies report that immune checkpoint inhibitors may be of significant therapeutic value.

After the FDA's 2011 approval of the CTLA-4 inhibitor (ipilimumab), six additional ICIs have received FDA clearance, including 3 PD-1 inhibitors (nivolumab, pembrolizumab, and cemiplimab) and 3 PD-L1 inhibitors (atezolizumab, avelumab, and durvalumab). Oncologists frequently use these ICIs in their routine treatment for about 15 different tumor types, and they have demonstrated impressive success [14]. Durvalumab, one such novel antibody against PD-L1, is currently being evaluated in the present study.

Durvalumab

On February 16, 2018, the Food and Drug Administration approved durvalumab (Imfinzi, AstraZeneca Inc.) for patients with unresectable stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. Durvalumab is a human immunoglobulin G1 (IgG1) monoclonal antibody and is a highly selective PD-L1 blocking antibody. It is highly selective for PD-L1 and does not bind to PD-L2, which plays a role in controlling inflammation in normal tissue, and which might potentially decrease the immune-related toxicity associated with the PD-L2 interaction. When used in conjunction with chemotherapy and radiation treatment, durvalumab is an appealing new approach to targeting the immune system pre- and post-surgery, thus enhancing survival rates [15].

In the phase III, placebo-controlled PACIFIC trial of patients with unresectable, stage III non-small-cell lung cancer (NSCLC) whose disease had not progressed after platinum-based CRT, administration of durvalumab for up to 12 months improved overall survival and progression-free survival. The degree of benefit with durvalumab versus placebo remained consistent at subsequent updates. Furthermore, durvalumab exhibited a manageable safety profile and did not detrimentally affect patient-reported outcomes compared with placebo. Durvalumab received global approvals on the basis of these findings, establishing consolidation durvalumab after CRT (the PACIFIC regimen) as standard of care (SoC) for patients with unresectable, stage III NSCLC [16].

In the recent AEGEAN trial, perioperative durvalumab plus neoadjuvant chemotherapy was associated with significantly better results with regard to the two primary end points of event-free survival and pathological complete response. Regarding resectable NSCLC, findings from the AEGEAN trial and other recent trials (i.e., CheckMate-816, IMpower010, KEYNOTE-091,

Neotorch, and KEYNOTE-671) have confirmed the benefits of immunotherapy given as neoadjuvant treatment in combination with chemotherapy, as adjuvant treatment, or both [17, 1817].

1.2 Rationale

This will be an observational post-marketing study of durvalumab (IMFINZI®) to be conducted in compliance with a condition of approval specified by the Indian Health Authority.

Approval in India has been granted for the use of durvalumab in combination with chemotherapy as neoadjuvant therapy followed by durvalumab monotherapy after surgery for use in patients with resectable (tumors ≥ 4 cm and/or node positive) NSCLC and no known EGFR mutations and ALK rearrangements. As a condition of approval, AstraZeneca is mandated to conduct a study evaluating the safety of durvalumab in patients with resectable NSCLC, as administered by physicians in standard clinical practice settings.

This study aims to confirm the known safety profile and identify previously unrecognized adverse reactions of durvalumab (if any) in the treatment of resectable NSCLC among Indian patients, in compliance with the requirements of the Indian Health Authority.

2. OBJECTIVES

2.1 Primary Objective

To assess the safety of Durvalumab (IMFINZI) in resectable non-small cell lung cancer (NSCLC) patients in India

3. METHODOLOGY

3.1 Study Design – General Aspects

This will be a single-arm, multicenter, prospective, observational, real-world study and the data source is the patients' medical record at each site. A total of 78 patients will be enrolled in the study.

Eligible patients with previously untreated resectable NSCLC (tumors ≥ 4 cm and/or node positive) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

This study will be conducted according to each site's routine clinical practice for the treatment of resectable NSCLC. Patients will undergo routine biopsies and staging investigations; and will be offered Durvalumab as neoadjuvant and/or adjuvant therapy in accordance with the approved prescribing information and as per the institutional standard at the discretion of the Investigator. Patients accepting this treatment approach will be offered enrolment into this study. Patients will be provided with an informed consent form (ICF) that describes the data to

be collected, and the purpose of the study. There will be no protocol-mandated procedures in the present study.

The **treatment period** for an individual patient will be calculated from the date of the first dose of durvalumab until:

- Date of last dose of Durvalumab + 90 days **or**
- Date of first dose of subsequent anti-cancer therapy; **whichever is earlier**

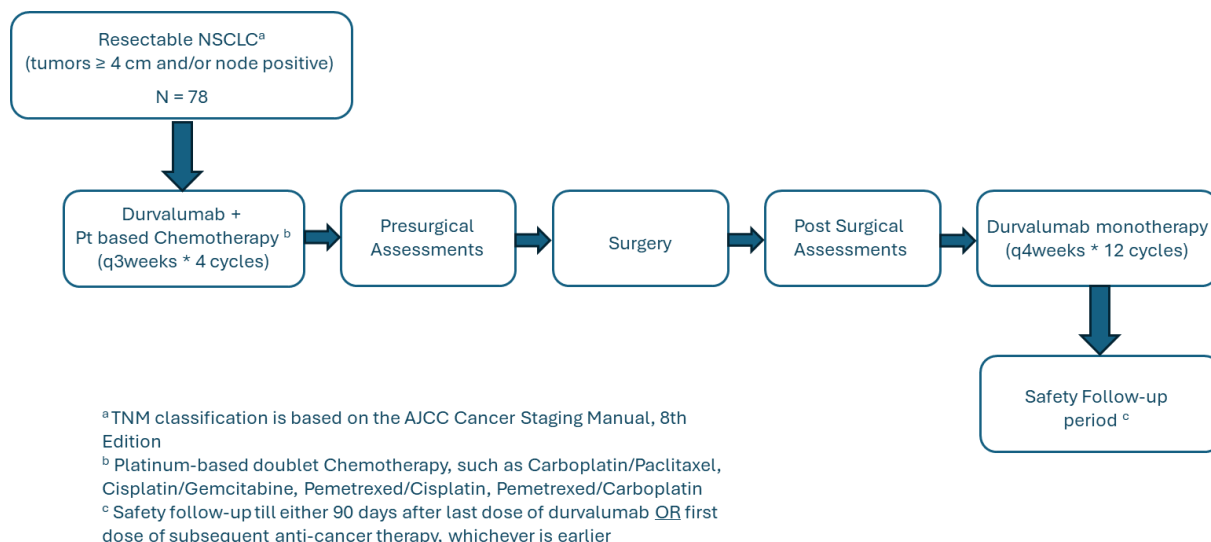
Patient data will be gathered for about 90 days for safety assessment since the last dose of the study drug, until withdrawal of consent, lost to follow-up, or death, whichever comes first. The enrolled patients should be followed up at least once after taking the study drug. Safety follow-up will be conducted for all AEs occurring during the study period.

Duration of exposure before & after surgery, dose reduction & dose interruption will also be monitored

The total number of visits and the visit time will be determined at the discretion of the investigator based on the patient's condition. Patients' demographic, disease status, investigations, durvalumab dosing and other treatment data at baseline and throughout the study period will be collected and recorded in CRF, along with outcome measures such as incidence of TEAE, SAEs and mortality All AE which are not treatment emergent will also be captured in the CRF and listed as part of the study reporting.(Refer [Since this](#) is an observational study, there will be no protocol-mandated investigations.Data related to the below mentioned assessments (if available) will be collected at the following timepoints corresponding to treatment schedule:

Table 1).

Figure 1 Study Design



3.1.1 Data Sources

All data collected in this study is intended to capture the real-world treatment patterns and outcomes of patients with resectable NSCLC. An electronic case report form (eCRF) will be used for data collection. The eCRF must be signed by the investigator. The signature serves to attest that the information contained on the eCRF is true. At all times, the investigator has the final responsibility for the accuracy and authenticity of all clinical and laboratory data entered into the eCRFs.

The investigator or authorized medical staff will record clinical and treatment data from patients' existing medical records into an eCRF following each patient's standard of care clinic visit.

3.2 Study Population

Indian patients with previously untreated resectable (tumors ≥ 4 cm and/or node positive) NSCLC and with no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements will be enrolled from a geographically representative population from clinics/ hospitals across the country. Resectable NSCLC patients whose treatment decision with Durvalumab has been made by their treating physician and meet the eligibility criteria will be invited to participate in the study.

3.3 Inclusion Criteria

Patients must meet all of the following inclusion criteria to be eligible for enrolment into the study:

1. Patients with newly diagnosed previously untreated resectable NSCLC (tumors ≥ 4 cm and/or node positive) and no known EGFR mutations or ALK rearrangements prescribed with durvalumab as per local prescriber information.
2. Provision of signed, written and dated informed consent
3. Male or female patients aged 18 years or older

3.4 Exclusion Criteria

Patients meeting any of the following criteria will not be included in the study:

1. Presence of unresectable or metastatic disease.
2. Prior treatment with durvalumab for any other indications
3. Requires concurrent treatment for cancers other than resectable NSCLC
4. Concurrently participating in any other clinical trial
5. Patients with active or prior autoimmune disease or with medical conditions that required systemic corticosteroids or immunosuppressants
6. Any condition that, in the opinion of the investigator, would interfere with the patient's participation in the study.

3.5 Participant Follow-up

Patient data will be collected for safety assessment for 90 days since the last dose of the study drug, until start of new therapy, until withdrawal of consent, lost to follow-up, or death, whichever comes first. The enrolled patients should be followed up at least once after taking the study drug. Safety follow-up will be conducted for all AEs occurring during the study period.

Patients are free to discontinue the study at any time without giving their reasons. Already collected data will be analyzed for this study unless patients refuse.

A patient must be withdrawn in the event of any of the following:

- Newly diagnosed malignant neoplasm other than resectable NSCLC to be treated during prospective data collection
- Administrative or other reasons

4. VARIABLES AND EPIDEMIOLOGICAL MEASUREMENTS

Objectives:

The present study will confirm the known safety profile or identify previously unrecognized adverse reactions of Durvalumab for the treatment of resectable NSCLC in Indian patients in accordance with the requirements of the Indian Health Authority.

Primary objective	Outcome measure
To assess the safety of Durvalumab (IMFINZI) in resectable non-small cell lung cancer (NSCLC) patients in India	- Frequency and proportion of patients with Grade 3/4 possibly related adverse events (PRTEAEs)* - Frequency and proportion of patients with treatment emergent adverse events (TEAE) & serious adverse events (SAEs), , mortality. - Time to occurrence of first AEs and first SAEs - * PRAEs as assessed per the WHO-UMC criteria

All those AEs which are not treatment emergent will be listed as part of the study reporting. As this is a single arm study, the obligations to assess confounders or effect modifiers as in comparative studies is not required.

4.1 Exposures

Patients who fit the eligibility criteria and are assessed by their physicians as qualifying for therapy with durvalumab and have not received any previous treatment for their NSCLC will be considered for enrolment in the present study. Durvalumab will be administered as per each site's routine clinical practice and in accordance with the approved prescribing information

For adult patients with previously untreated resectable NSCLC and no known EGFR mutations and ALK rearrangements, durvalumab is indicated for use in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by durvalumab continued as a single agent as adjuvant treatment after surgery. Off-label use of durvalumab is not permitted for patients in the present study.

Exposure (i.e. duration of treatment) will be defined as follows:

Total (or intended) exposure

The total (or intended) exposure (i.e. duration of treatment) of a patient to Durvalumab is calculated using the start and stop dates of Durvalumab and the intended dosing interval (or intervals if dosing is not regular). For a dosing period, the total (or intended) exposure is calculated as the number of days from date A to date B (i.e. B-A+1) where

- A is the date of first dose of Durvalumab in the dosing period.
- B is the earliest of:

- the date of death,
- the date of discontinuation, and
- the date when the last non-zero dose of Durvalumab was received (e.g. > 0 mg of durvalumab or > 0 Gy of a radiation therapy) plus C, where C is equal to the scheduled number of days between doses minus one.

Actual exposure

Actual exposure will be measured by the number of cycles received. A cycle corresponds to a period of 3 weeks in neoadjuvant period, and 4 weeks in the adjuvant period. If a cycle is prolonged due to toxicity, this should still be counted as one cycle. A cycle will be counted if treatment is started even if the full dose is not delivered.

Missed doses

Missed doses will be recorded in the eCRF as a dose interruption.

Patients who permanently discontinue during a dose interruption

If a patient permanently discontinues study treatment during a dose interruption, then the date of last administration of study medication recorded on eCRF.

4.2 Outcomes

- Frequency and proportion of patients with Grade 3/4 possibly related adverse events (PRAEs)
- Frequency and proportion of patients with treatment emergent adverse events (TEAEs) including immune mediated adverse events & serious adverse events (SAEs) Reactions), , mortality The AEs will be characterised based on the time point of occurrence- before & after surgery. Additionally time to occurrence of first AEs and first SAEs will also be noted.

4.3 Other Variables and Covariates

Age, sex and other baseline characteristics may be considered as covariates.

5. STATISTICAL ANALYSIS PLAN

5.1 Statistical Methods – General Aspects

The safety analysis population will include all patients who sign the ICF and receive at least one dose of durvalumab.

In general, the variables will be summarized by using standard descriptive statistics. Continuous variables will be summarized with the number (n) of non-missing observations, mean, standard deviation, median, and minimum and maximum, unless otherwise specified. For categorical data, descriptive statistics will be presented with the number and percentage of

subjects in the various categories of the endpoint. Detailed methodology for summary and statistical analyses of data collected in this study will be documented in the SAP, which will be dated, filed and maintained by the sponsor.

Statistical software SAS® version 9.4 or higher (SAS Institute Inc, Cary, North Carolina) will be used for the analyses.

5.1.1 Primary Objective

Safety and tolerability will be assessed in terms of AEs (including SAEs), deaths, laboratory data, vital signs, ECGs and exposure. Data from all cycles of treatment will be combined in the presentation of safety data. For AEs, on treatment (or treatment-emergent AEs) will be defined as any AEs that started after dosing or prior to dosing and which worsens following exposure to the treatment.

Adverse events observed up until 90 days following discontinuation of the last dose of study intervention or until the initiation of the first subsequent therapy following discontinuation of treatment (whichever occurs first) will be used for the reporting of the AE summary tables. AE summary tables will also be presented by treatment period- neoadjuvant, surgery, post-surgery and adjuvant periods.

Safety data will be summarised descriptively by MedDRA by system organ Class and preferred term, by seriousness, by causality, and by maximum NCI CTCAE Grade (v5.0).

The frequency and proportion of patients with Grade 3/4 possibly related adverse events (AEs) will be presented, along with the 95% confidence interval, using the Clopper–Pearson method.

The frequency and proportion of patients with AEs(including PRAEs, TEAE, SAE including immune mediated adverse events and deaths will also be presented along with the 95% confidence interval using the Clopper–Pearson method.

Detailed tables will be prepared on the AEs with reference to their seriousness and grades (CTCAE v5.0), the SOC and PTs involved, causal relations actions taken Laboratory data, data on vital signs and ECGs and duration of treatment exposure will be tabulated and presented.

5.2 Time to occurrence of AEs and SAEs: Time to occurrence of first AEs and first SAE will be estimated using Kaplan-Meier method. Median time to the events will be estimated and presented for each type of AE included under the set of primary endpoints. In the present context, the median time to an AE will be interpreted as the time at which 50% of the patients have experienced their first

AE. The presentation will also include a graphical display of the time-to-event probability. Bias

5.2.1 Methods to Minimize Bias

This post-marketing surveillance study is a non-interventional study in patients who initiated durvalumab in usual clinical practice. Given the conditions where additional tests and questionnaires cannot be performed, the type of safety data available for collection may be limited, compared with other non-interventional clinical trials where additional assessment is available. There might be information bias by extracting data from medical records, missing data, and risk selection bias by loss to follow-up. Moreover, reporting bias (more severe AEs are recorded in the medical data), treatment bias (sicker patients get newer treatments), no control group to compare and contextualize against background events in similar patients, lack of actual medication adherence measurements, unmeasured confounding that affects safety other than durvalumab will also be limiting factors of this study.

To minimize any biases involved, careful study design, standardized monitoring and reporting procedures will be undertaken.

5.2.2 Adjustment for Multiple Comparisons

Not applicable for this observational safety study protocol.

5.2.3 Strengths and Limitations

Single-arm studies are simpler to design, and conduct compared to randomized controlled trials (RCTs). They are typically faster and less resource-intensive since they do not require a control group. Single-arm studies can make use of historical control data to provide a contextual understanding of safety and adverse event rates. However, such studies are beset with certain limitations, which must be guarded against.

The absence of a control group makes it harder to contextualize and interpret the findings. Selection bias could occur if the patients enrolled in the study are not representative of the broader population. This can lead to an underestimation or overestimation of the frequency of AEs, as the selected population may not reflect how the treatment would perform in a more general population. In single-arm studies, there may be a tendency to either under-report or over-report AEs, especially if participants or investigators have preconceived expectations about the treatment's safety. Absence of a control group to compare the incidence of AEs, makes it difficult to determine whether the observed AEs are due to the intervention or part of the natural course of the disease or other external factors.

Without a control group, any observed AEs might be attributed to the treatment even when they could have occurred independently, or baseline incidence rates for certain AEs are not properly accounted for. Attrition bias (censoring) arises if patients drop out of the study or are lost to follow-up before experiencing an AE, and their data are excluded from the analysis. The Kaplan

Meier estimator proceeds under the assumption of non-informative censoring. Failure to account for changes over time such as advancements in patient management, detection techniques, or the natural progression of the condition can introduce bias.

The source data described in this protocol contain the inherent limitation of any current NIS, real world study. These studies have the potential for missing, inaccurate, or incomplete data. The limitations of the observational nature can result in methodological challenges in attributing causality to outcomes. The patient selection and the diagnostic or monitoring procedures are those applied per the usual treatment paradigm of the treating physician and not dictated by the protocol. Heterogeneous patient populations could make the interpretation of the outcomes difficult.

5.3 Interim Analyses

No Interim Analyses are planned for this study.

5.4 Sample Size Calculations

The primary endpoint of the trial is to demonstrate the safety profile of durvalumab in routine clinical practice as assessed by the incidence of Grade 3/4 possibly related AEs observed during the trial.

Based on the durvalumab data generated from the results of AEGEAN trial [8], the incidence rate of Grade 3/4 AEs which were at least possibly related, is 33%. A sample size of 70 will be needed to estimate a 33% AE rate (grade 3 or 4, possibly related) with 11% margin of error leading to a 95% confidence interval of 22% to 44%. With a dropout rate of 10%, the total sample size is 78.

6. STUDY CONDUCT AND REGULATORY DETAILS

6.1 Study Conduct

6.1.1 Study Flow Chart and Plan

Since this is an observational study, there will be no protocol-mandated investigations. Data related to the below mentioned assessments (if available) will be collected at the following timepoints corresponding to treatment schedule:

Table 1 Data Entry Schedule

Data Collection and Entry ¹	Baseline/ Screening	Neoadjuvant therapy period	Pre- Surgery	Surgery	Post- Surgery	Adjuvant therapy period	Follow-up period
Visits	Visit 1	C1 to C4 (q3weeks)				C5 to C16 (q4weeks)	End of Study/ EOS ²
Informed Consent	X						
Inclusion/ Exclusion Criteria	X		X				
Patient Demographics, Medical History	X				X		
Disease medical history & Baseline disease status (including EGFR/ALK status)	X						
Concomitant Medications	X	X	X	X	X	X	X
Physical examination and Vital signs	X	X				X	X
ECOG Performance Status	X						X
Clinical & Radiological Assessments ³	X	X	X		X	X	X
RECIST 1.1 assessment	X		X		X	X	X
ECG ⁴	As clinically indicated						
Laboratory assessments ⁵	X	X				X	X
NSCLC Treatment details ⁶		X				X	X
AE and SAE Reporting ⁷	X	X	X	X	X	X	X

- 1 Data is collected in accordance with normal SoC visits, enter all data available per Data Entry Schedule into the eCRF. Any information collected between treatment cycles (e.g. AE/ SAE reporting) can be entered under ‘Unscheduled visit’.
- 2 Enter data at SoC visits where any subsequent NSCLC therapy is prescribed, and at End of Study (EOS), where EOS is defined as:
 - a. 90 days from last dose of durvalumab OR
 - b. first dose of subsequent anti-cancer therapy; whichever is earlier
- 3 Clinical & Radiological assessments: overall clinical response as judged by Investigator, at intervals per standard of care schedule: imaging assessment (e.g., MRI/CT/ PET scans), clinical progression, and clinical biomarkers.

- 4 ECG: any ECG assessments done at baseline and during durvalumab treatment as per SoC will be entered in the eCRF
- 5 Laboratory assessments: any laboratory assessments performed at baseline and during durvalumab treatment as per SoC, including but not limited to clinical chemistry, haematology, APTT and INR, TSH, Urinalysis, Hepatitis B&C, HIV, Pregnancy tests etc will be noted in the eCRF.
Laboratory tests for liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment will be taken as per Investigator's discretion.
- 6 NSCLC Treatment: all treatments given in line with SoC including surgery, radiation and systemic chemotherapy in both neoadjuvant/adjuvant settings, prior to, during, and post durvalumab treatment. Also include any other additional medications such as Folic acid/ Vitamin B12.
- 7 AE/SAE reporting: begins when the patient signs the informed consent form (ICF) till up to 90 calendar days following the last administration of durvalumab, or till first dose of subsequent anti-cancer therapy, whichever is earlier. All AEs that occur after surgery regardless of decision to start adjuvant treatment must be reported.
No drug will be provided as part of the study.

6.1.2 Procedures

Since this is a post marketing, real-world observational study, there will be no protocol-mandated assessments or procedures for the entire duration of the study. The investigator or authorized medical staff will record clinical and treatment data from patients' existing medical records into an eCRF following each standard of care clinic visit.

6.1.3 Procedures for Voluntary withdrawal/discontinuation

The reason(s) for discontinuation will be recorded for all patients who wish to discontinue, and they will be assessed by the Investigator according to current practice.

Patients who discontinue durvalumab, withdraw consent, or cannot be followed up prior to the visit schedule outlined in Table 1 will be considered lost to follow-up from the PMS after at least 3 attempts are made to contact the patient.

Patients who do not follow the treatment guidelines as per the durvalumab product label will be discontinued from the PMS. Patients who restart treatment will not be eligible to be re-enrolled in the PMS.

6.1.4 Procedures for early termination of study

Should AstraZeneca decide to discontinue the study prior to what was established in this protocol, the investigator, and relevant authorities should receive written notice describing the reasons why the study was terminated at an earlier date. The investigator will immediately notify the patients taking part in the study; they will continue to receive their treatment according to usual clinical practice.

6.1.5 Data Collection

The following data will be used for analysis in this PMS study.

Patient Demographics & Medical History

Patient's date of birth, gender, height, weight, presence of pregnancy and breastfeeding in case of female patients as well pregnancy status of female partners in case of male patients.

Medical history, concurrent disease, and date and type of anti-meningococcal vaccination including boosters.

Disease medical history & Baseline disease status (including EGFR/ALK status)

Patient's disease history such as staging information, ECOG performance status and EGFR/ALK status (if known), will be collected from their medical records.

Concomitant Medications

Information about any concomitant medications taken by the patients will be recorded, including drug name, daily dose, route and indication. Any data available regarding Pre-randomization medications such as Folic acid or Vitamin B12 will also be noted in the eCRF.

Physical examination and Vital signs

Any results of physical examinations conducted, or vital signs recorded (especially body weight) as per Table 1 will be noted in the eCRF.

ECG

ECG readings taken over the duration of the study, especially at baseline, pre-surgery and post-surgery will be noted from the patient medical records.

Clinical & Radiological Assessments

All clinical and radiological assessments performed to evaluate the disease status or overall clinical response as judged by Investigator, at intervals per standard of care imaging assessment (e.g., MRI/CT/ PET scans) on clinical progression, and clinical biomarkers will be noted in the eCRF according to the research visit schedule outlined in Table 1.

Laboratory assessments

Results of any laboratory tests performed at baseline and during durvalumab treatment as per SoC, including but not limited to clinical chemistry, haematology, APTT and INR, TSH, Urinalysis, Hepatitis B&C, HIV, Pregnancy tests etc will be noted in the eCRF.

Results for clinical chemistry tests such as LFTs, electrolytes, full blood count, and creatinine must be available before commencing an infusion and reviewed by the Investigator prior to dosing. Laboratory tests for liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment will be taken as per Investigator's discretion.

NSCLC Treatment details

All treatments given in line with SoC including surgery, radiation and systemic chemotherapy in both neoadjuvant/adjuvant settings, prior to, during, and post durvalumab treatment. Details to be noted include total dose, total duration of treatment, ongoing or discontinuation status of treatment, reason for discontinuation of treatment/ reason for change dose of treatment.

AE and SAE Reporting

The following items will also be collected for patients enrolled in the PMS:

Occurrence of adverse events for patients on durvalumab will be assessed by the Investigator. When an adverse event (see [Section 6.3](#)) occurs, information on the following items will be collected; adverse event term, onset date, resolution date, seriousness, severity, causal relationship with the study drug, action taken for the study drug, outcome, action taken for adverse event, doctor's comment, etc.

All patients enrolled in PMS will be followed up as per the visit schedule outlined in Table 1, or withdrawal from the PMS (see [Sections 6.1.3](#) and [6.1.4](#)). Appropriate follow up information will be sought to determine outcome of safety events.

6.1.6 Quality Control

Data Entry

Data will be entered in the eCRF system at the Investigator's site. The Investigator will be responsible for entering data into the eCRF and according to the Investigator Instructions Manual. The Investigator Instructions Manual will also provide the site with data entry instructions.

Data entered in the eCRF will be immediately saved to a central database and changes tracked to provide an audit trail. All data collected via the eCRF will be reviewed by remote data monitors for clarity and completeness. Missing or unclear data will be queried according to the approved specifications. When data have been entered reviewed and edited, the Investigator will be notified to sign the eCRF electronically as per the agreed project process and data will be locked to prevent further editing. A copy of the eCRF will be archived at the Investigator's site.

Monitoring

This study will be monitored according to the SOPs and study's monitoring plan. The Investigator will allocate adequate time for such monitoring activities. The Investigator will also ensure that the monitor or other compliance or quality assurance reviewer is given access to all the above noted study-related documents and study related facilities (e.g. pharmacy, diagnostic laboratory, etc.), and has adequate space to conduct the monitoring visit.

Contacts with the sites to:

- Provide information and support to the investigator(s)
- Confirm that the research team is complying with the protocol and that data are recorded in the eCRFs

- Ensure that the subject informed consent forms are signed and stored at the investigator's site
- Ensure that the eCRFs are completed properly and with quality compliance.

Signals like a high rejection rate at a site can indicate low protocol compliance by investigators. If such signals appear, or if CRO or sponsor representative suspects suboptimal protocol compliance by a site investigator, specific steps would be taken to assess the situation and implement corrective action plans.

Training of Study Site Personnel

The Principal Investigator will ensure that appropriate training relevant to the Observational Study is given to investigational staff, and that any new information relevant to the performance of this Observational Study is forwarded to the staff involved.

6.2 Protection of Human Subjects

The PMS study will be performed in accordance with ethical principles that are consistent with the Declaration of Helsinki, ICH GCPs, ISPE GPP and the applicable legislation on Non-Interventional Studies and/or Observational Studies.

The Investigator will perform the study in accordance with the regulations and guidelines governing medical practice and ethics in the country of the study and in accordance with currently acceptable techniques and know-how.

The final protocol and the final version of the Informed Consent Form must be approved or given a favourable opinion in writing by the Institutional Review Board (IRB)/Independent Ethics Committee (IEC).

The Ethics Committee/IRB/IEC must also approve any amendment to the protocol according to local regulations.

6.2.1 Subject Informed Consent

The Investigator at each site will ensure that the subject is given full and adequate oral and written information about the nature, purpose, possible risk and benefit of the study. Subjects must also be notified that they are free to discontinue from the study at any time. The subjects should be given the opportunity to ask questions and allowed time to consider the information provided.

The signed and dated subject informed consent must be obtained before any specific procedure for the study is performed, including:

- Interview with the investigator
- Fulfil the questionnaires
- CRFs completion.

The Investigator must store the original, signed ICF. A copy of the signed ICF must be given to the subject.

6.2.2 Confidentiality of Study/Subject Data

The ICF will incorporate wording that complies with relevant data protection and privacy legislation. Pursuant to this wording, subjects will authorise the collection, use and disclosure of their personal data by the Investigator and by those persons who need that information for the purposes of the study.

The ICF will explain that study data will be stored in a computer database, maintaining confidentiality in accordance with the local law for Data Protection.

The ICF will also explain that for quality check purposes, a monitor of AstraZeneca or a monitor of company representing AstraZeneca, will require direct access to the signed subject informed consent forms. In case source data verification will be planned as quality check, the ICF will explain that for data verification purposes, monitor of AstraZeneca or a monitor of company representing AstraZeneca may require direct access to source documents that are part of the hospital or practice records relevant to the study.

6.3 Collection and Reporting of Adverse Events/Adverse Drug Reactions/Special Situations

6.3.1 Definition of Adverse Events (AE)

An AE is the development of any untoward medical occurrence in a patient or clinical study participant administered a medicinal product, and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (e.g., an abnormal laboratory finding), symptom (for example nausea, chest pain), or disease temporally associated with the use of a medicinal product, whether it's considered related to the medicinal product. The term AE is used to include both serious and non-serious AEs.

6.3.2 Definition of Serious Adverse Events (SAE)

A serious adverse event is an AE occurring during any study phase, that fulfills one or more of the following criteria:

- Results in death
- Is immediately life-threatening (life-threatening in this context refers to a reaction in which the participant was at risk of death at the time of the reaction; it does not refer to a reaction that hypothetically might have caused death if more severe)
- Requires in-patient hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity

- Is a congenital anomaly or birth defect
- Is an important medical event that may jeopardise the participant or may require intervention to prevent one of the outcomes listed above. Medical and scientific judgement should be exercised in deciding whether other situations should be considered an SAE.

Any suspected transmission via a medicinal product of an infectious agent is also considered an SAE and may be subject to expedited reporting requirements in some countries. Any organism, virus or infectious particle (for example Prion Protein Transmitting Transmissible Spongiform Encephalopathy), pathogenic or non-pathogenic, is considered an infectious agent.

Comment to Seriousness Assessment for Invasive and Malignant Cancers:

The above instruction applies only when the malignant tumour event in question is a new malignant tumour (i.e., it is not the tumour for which entry into the study is a criterion and that is being treated by the IP under study and is not the development of new or progression of existing metastasis to the tumour under study). Malignant tumours that – as part of normal, if rare, progression – undergo transformation (e.g., Richter's transformation of B cell chronic lymphocytic leukemia into diffuse large B cell lymphoma) should not be considered a new malignant tumour.

6.3.3 Definition of Adverse Drug Reactions (ADR)

An Adverse Drug Reaction (ADR) is an Adverse Event suspected to be causally related to the medicinal product.

When assessing causality consider the following factors when deciding if there is a 'reasonable possibility' that an AE may have been caused by the medicinal product.

- Time Course. Exposure to suspect drug. Has the participant received the suspect drug? Did the AE occur in a reasonable temporal relationship to the administration of the suspect drug?
- Consistency with known drug profile. Was the AE consistent with the previous knowledge of the suspect drug (pharmacology and toxicology) or drugs of the same pharmacological class? Or could the AE be anticipated from its pharmacological properties?
- De-challenge experience. Did the AE resolve or improve on stopping or reducing the dose of the suspect drug?
- No alternative cause. The AE cannot be reasonably explained by another aetiology such as the underlying disease, other drugs, other host, or environmental factors.

- Re-challenge experience. Did the AE reoccur if the suspected drug was reintroduced after having been stopped? AstraZeneca would not normally recommend or support a re challenge.
- Laboratory tests. A specific laboratory investigation (if performed) has confirmed the relationship.

In difficult cases, other factors could be considered such as:

- Is this a recognised feature of overdose of the drug?
- Is there a known mechanism?

6.4.4 PRAE (Possibly Related Adverse Event)

- A possibly related adverse event (PRAE) is defined as an AE (excluding any AE occurring after initiation of subsequent anti-cancer therapy and also excluding AE which occur more than 90days after the last dose of study treatment), where the WHO UMC causality assessment will be used.

Table 2 Causality assessment

Causality term	Assessment criteria*
Certain	Event or laboratory test abnormality, with plausible time relationship to drug intake Cannot be explained by disease or other drugs Response to withdrawal plausible (pharmacologically, pathologically) Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon) Rechallenge satisfactory, if necessary
Probable/ Likely	Event or laboratory test abnormality, with reasonable time relationship to drug intake Unlikely to be attributed to disease or other drugs Response to withdrawal clinically reasonable Rechallenge not required
Possible	Event or laboratory test abnormality, with reasonable time relationship to drug intake Could also be explained by disease or other drugs Information on drug withdrawal may be lacking or unclear

Causality term	Assessment criteria*
Unlikely	Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) Disease or other drugs provide plausible explanations
Conditional/ Unclassified	Event or laboratory test abnormality More data for proper assessment needed, or Additional data under examination
Unassessable/ Unclassifiable	Report suggesting an adverse reaction. Cannot be judged because information is insufficient or contradictory. Data cannot be supplemented or verified

*All points should be complied with reasonably

Severity/ Grades

Severity of AEs will be assessed by using the CTCAE v5.0 grading system. The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline:

Grade 1 Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.

Grade 2 Moderate; minimal, local or noninvasive intervention indicated; limiting ageappropriate instrumental ADL[#].

Grade 3 Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL^{##}.

Grade 4 Life-threatening consequences; urgent intervention indicated.

Grade 5 Death related to AE.

Notes:

A Semi-colon indicates ‘or’ within the description of the grade.

Grade 5 (Death) is not appropriate for some AEs and therefore is not an option.

Activities of Daily Living (ADL)

[#]Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.

^{##}Self-care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.

6.3.4 Collection of Adverse Events

All AEs, including those with a fatal outcome **MUST** be recorded in the eCRF.

For each AE, the following variables will be collected;

- AE term
- The date when the AE started and, if available, when the AE stopped
- Intensity
- CTCAE grade
- Whether the AE is serious or not
- Investigator causality rating against the medicinal product (yes or no)
- Action taken with regard to medicinal product
- Whether the AE caused participant's withdrawal from the study (yes or no)?
- Outcome

In addition, the following variables will be collected for SAEs:

- Date AE met criteria for SAE
- Date investigator became aware of SAE
- AE description
- AE is serious due to
- Date of hospitalisation
- Date of discharge
- Probable cause of death
- Date of death
- Autopsy performed
- Causality assessment in relation to study procedure(s)
- Causality assessment to other medication

It is important to distinguish between serious and severe AEs. Severity is a measure of intensity whereas seriousness is defined by the criteria in Sections 6.3.2. An AE of severe intensity need not necessarily be considered serious. For example, nausea that persists for several hours may be considered severe nausea, but not a SAE unless it meets one of the criteria shown in Section 6.3.2. On the other hand, a stroke that results in only a limited degree of disability may be considered a mild stroke but would be a SAE if it satisfies one of the criteria shown in Section 6.3.2.

Any ADR which is not required to be collected, as specified in this protocol, may be reported according to local regulations **including the study protocol number**.

Time period for collection of adverse events

Adverse Events will be collected from the time of starting Durvalumab therapy throughout the treatment period until

- i) 90 days after the last dose of Durvalumab, OR
- ii) Date of first dose of subsequent anti-cancer therapy; whichever is earlier

6.3.5 Collection of Special Situations

Special situations are situations of relevance for monitoring the safety of AstraZeneca products and which may or may not be associated with an AE. In general, special situations must be collected and reported, even if no AE occurred.

- Exposure to product during pregnancy
- Exposure to product via breastmilk
- Overdose
- Medication error and potential medication error
- Off label use
- Drug Abuse
- Drug Misuse
- Occupational exposure
- Lack of efficacy and disease progression

Special situations will be collected on the AE page or on event specific forms in the eCRF. ICSRs with special situations are to be collected even in the absence of an AE, to ensure regulatory reporting and surveillance requirements.

Reporting of Adverse Events

The Investigators or other site personnel will inform the appropriate AstraZeneca representatives within one day i.e., immediately but **no later than 24 hours** of when he or she becomes aware of:

- All AEs with a fatal outcome
- All other serious adverse events
- All non-serious ADR (related non-serious AEs as assessed by the reporter)
- Special situations

The designated AstraZeneca representative works with the Investigator to ensure that all the necessary information is provided to the AstraZeneca Patient Safety data entry site **within 2 calendar days** of initial receipt for fatal and life-threatening events, **within 2 calendar days** of initial receipt for all other serious AEs and **within 5 calendar days** for special situations without AE and non-serious ADRs.

For all collected AEs and special situations, where important or relevant information is missing, active follow-up is undertaken immediately. Investigators or other site personnel inform AstraZeneca representatives of any follow-up information within the same timeframe as the original report.

All collected adverse events will be summarised in the final study report.

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8. APPENDICES

Not Applicable

9. SIGNATURES

ASTRAZENECA SIGNATURE(S)

A prospective, observational, multicenter, post marketing surveillance study to assess safety of Durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC)

This Observational Study Protocol has been subjected to an internal AstraZeneca review.
I agree to the terms of this Study protocol.

AstraZeneca representative

Shashank

*Electronically signed by: Shashank
Reason: I approve this document
Date: Dec 22, 2024 15:00 GMT+5.5*

22-Dec-2024

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Date
(Day Month Year)

This document contains confidential information, which should not be copied, referred to, released or published without written approval from AstraZeneca. Investigators are cautioned that the information in this protocol may be subject to change and revision.

ASTRAZENECA SIGNATURE(S)

A prospective, observational, multicenter, post marketing surveillance study to assess safety of Durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC)

This Observational Study Protocol has been subjected to an internal AstraZeneca review.
I agree to the terms of this Study protocol.

AstraZeneca representative



*Electronically signed by: Hardik
Vasnawala
Reason: I approve this document
Date: Dec 23, 2024 09:21 GMT+5.5*

23-Dec-2024

Dr Hardik Vasnawala

(Study Director)

Director - Medical Affairs

AstraZeneca Pharma India Ltd.

Block N1, 12th Floor,

Manyata Embassy Business Park,

Bangalore, Karnataka 560045

hardik.vasnawala@astrazeneca.com

Date

(Day Month Year)

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AstraZeneca representative

Bharath HS

Electronically signed by: Bharath HS
Reason: I have reviewed this document
Date: Dec 23, 2024 09:25 GMT+5.5

23-Dec-2024

Dr Bharath HS

(Study Delivery Team Leader)

Trials, Publications & Medical Excellence
Lead

AstraZeneca Pharma India Ltd.

Block N1, 12th Floor,

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Bangalore, Karnataka 560045

bharath.hs@astrazeneca.com

Date

(Day Month Year)

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Durvalumab PMS protocol Version 1.0 _22 DEC 2024_ Signoff

Final Audit Report

2024-12-23

Created:	2024-12-22 (Eastern European Time)
By:	Jinu Johnson (jinu.johnson@astrazeneca.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAHGPqEVeY2ceqhE-g9HdaYmS0n27LdRwp

"Durvalumab PMS protocol Version 1.0 _22 DEC 2024_ Signoff" History

-  Document created by Jinu Johnson (jinu.johnson@astrazeneca.com)
2024-12-22 - 12:12:00 PM GMT+3
-  Document emailed to Hardik Vasnawala (hardik.vasnawala@astrazeneca.com) for signature
2024-12-22 - 12:15:10 PM GMT+3
-  Document emailed to Bharath HS (bharath.hs@astrazeneca.com) for signature
2024-12-22 - 12:15:10 PM GMT+3
-  Document emailed to drshashank.srinivasan@astrazeneca.com for signature
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-  drshashank.srinivasan@astrazeneca.com authenticated with Adobe Acrobat Sign.
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2024-12-22 - 12:28:07 PM GMT+3
-  Signer drshashank.srinivasan@astrazeneca.com entered name at signing as Shashank
2024-12-22 - 12:30:03 PM GMT+3
-  drshashank.srinivasan@astrazeneca.com authenticated with Adobe Acrobat Sign.
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-  Document e-signed by Shashank (drshashank.srinivasan@astrazeneca.com)
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 Email viewed by Hardik Vasnawala (hardik.vasnawala@astrazeneca.com)

2024-12-23 - 6:50:01 AM GMT+3

✓ Hardik Vasnawala (hardik.vasnawala@astrazeneca.com) authenticated with Adobe Acrobat Sign.

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2024-12-23 - 6:51:10 AM GMT+3

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Signing reason: I have reviewed this document

Signature Date: 2024-12-23 - 6:55:39 AM GMT+3 - Time Source: server

✓ Agreement completed.

2024-12-23 - 6:55:39 AM GMT+3

Consent Letter

Tata Medical Center

14 Major Arterial Road (EW)
Newtown, Rajarhat, Kolkata - 700 160
Tel.: + 91 33 66057000, Email : info@tmckolkata.com
www.tmckolkata.com



Date :31-Jan-2026

To,

Dr. Bharat HS
(Study Delivery Team Leader) Lead-Trials,
Publications & Medical Excellence,
AstraZeneca Pharma India Ltd.
Block N1, 12th Floor, Manyata Embassy Business Park
Rachenahalli, Outer Ring Road,
Bangalore- 560045

Sub: Consent for Participation in Study

**Study Title: A Prospective, Observational, Multicenter, Post Marketing
Surveillance Study To Assess Safety Of Durvalumab In Indian Adult Patients
With Resectable Non-Small Cell Lung Cancer (NSCLC)**

Study Code: D9106R00007

Dear Dr. Bharat,

I have reviewed the above-mentioned study protocol and I do hereby agree to participate in the study, subject to fulfilment of all required terms and conditions.

The study will be conducted at Tata Medical Center, 14 MAR(E-W)Newtown, Rajarhat, Kolkata-700160 under my supervision.

With regards,

Dr Somnath Roy
Tata Medical Center,
14 MAR(E-W) Newtown, Rajarhat
Kolkata-700160

Declaration Letter

Tata Medical Center

14 Major Arterial Road (EW)
Newtown, Rajarhat, Kolkata - 700 160
Tel.: + 91 33 66057000, Email : info@tmckolkata.com
www.tmckolkata.com

TATA MEDICAL CENTER

Date: 31-Jan-2026

To,

**The Drug Controller General (India)
Directorate General of Health Services,
FDA Bhavan, CHEB Campus
Kotla Road, New Delhi-110002**

Subject: Declaration regarding the site facilities for the conduct of study

Study Title: A Prospective, Observational, Multicenter, Post Marketing Surveillance Study To Assess Safety Of Durvalumab In Indian Adult Patients With Resectable Non-Small Cell Lung Cancer (NSCLC)

Study Code: D9106R00007

Dear Sir,

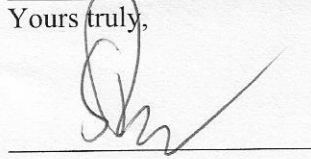
I would hereby like to declare that at Tata Medical Center, 14 MAR(E-W) Newtown, Rajarhat, Kolkata-700160, the following facilities are available to conduct the above-mentioned study.

No. of Beds in Hospital	Hospital Details	Type of ICU & No. of Beds in ICU	24 Hrs Emergency Department Available	Type of Ethics committee	Address of Ethics committee & Reg. Number
437	Private	ICU & HDU; 25	Yes	Institutional Review Board	Address: Tata Medical Center, Phase 2, 1 st Floor 14 MAR(E-W) Newtown, Rajarhat Kolkata-700160 Reg.Number: ECR/269/Inst/WB/2013/RR-19

Other Facilities available for conduct the clinical study at the site

- IP storage facility
- Trained & dedicated staff for the conduct of trial
- Archival facility

Yours truly,


Dr Somnath Roy
Tata Medical Center,
14 MAR(E-W) Newtown, Rajarhat
Kolkata-700160

Investigator Undertaking

Date: 14-Feb-2026

Undertaking by the Investigator

1. Full name, address and title of the Principal Investigator [or Investigator(s) when there is no Principal Investigator]

Full Name: Dr. Somnath Roy

Title: Senior Consultant of Medial Oncology

Address: 14 MAR(E-W), Newtown, Rajarhat, Kolkata-700160

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted:

Name: Tata Medical Center

Address: 14 MAR(E-W), Newtown, Rajarhat, Kolkata-700160

Education, training and experience that qualify the Investigator for the clinical trial (attach details including Medical Council registration number, or any other statement(s) of qualification(s).

Qualifications: CV Enclosed

MRC No: WB-61923

3. Name and address of all clinical laboratory facilities to be used in the study:

Local Laboratory Name and address: Department of Laboratories(North & South Lab)

Address: 14 MAR(E-W), Newtown, Rajarhat, Kolkata-700160

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

Name: Institutional Review Board

Address: Tata Medical Center, Phase 2; 1st Floor; 14 MAR(E-W), Newtown, Rajarhat, Kolkata-700160,

ECR Number: ECR/269/Inst/WB/2013/RR-19

5. Names of the other members of the research team (Co- or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation(s):

Name: Dr. Prashant Pandey

Role: Sub Investigator

Designation: Consultant Of Medical Oncology

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator:

Protocol Title: A Prospective, Observational, Multicenter, Post Marketing Surveillance Study To Assess Safety Of Durvalumab In Indian Adult Patients With Resectable Non-Small Cell Lung Cancer (NSCLC)

Protocol Code/ No.: D9106R00007

Version and date: Version 1.0 dated 22 December 2024

7. Commitments:

- I. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct of the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.
- II. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.
- III. I agree to personally conduct or supervise the clinical trial at my site.
- IV. I agree to inform all trial Subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.
- V. I agree to report to the Sponsors all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.
- VI. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

- VII. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
- VIII. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, Ethics Committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
- IX. I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.
- X. I agree to inform all serious adverse events to the Central Licensing Authority, Sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event.
- XI. The report of the serious adverse event after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.
- XII. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.
- XIII. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

Signature of Investigator with date and stamp:

 16/2/26

Dr. Somnath Roy
MD, DM (Med Oncol), ECMO
Consultant Medical Oncologist
TATA MEDICAL CENTER, KOLKATA

Informed Consent Form

English ICD version 1.0 dated 09-Mar-2026

STUDY INFORMATION AND INFORMED CONSENT FORM

Study Code:	D9106R00007	Site No:	
Sponsor:	AstraZeneca Pharma India Limited	Subject Id:	
Principal Investigator:			
Study Title:	A prospective, observational, multicenter, post marketing surveillance study to assess safety of Durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC)		

There are [3] parts to this document:

Part I: the “**Study Information**” essential to your decision to take part in the clinical study,

Part II: your “**Consent Form**” which summarises what you may agree to,

Part III: supplementary information in the “Additional information for patients” Section, including a glossary.

PART I: STUDY INFORMATION

D9106R00007, Durvalumab Post Marketing Safety Study

Observational Study to Assess the Safety of Durvalumab in Indian Adults with Removable Lung Cancer

Dear Madam/Sir,

You are invited to take part in this study because you have recently been diagnosed with a type of lung cancer called resectable (removable) non-small cell lung cancer (NSCLC). You have accepted the recommended treatment approach, which includes durvalumab in combination with chemotherapy as pre-operative therapy, followed by durvalumab monotherapy after surgery. This treatment is designed to help shrink the tumour and reduce the risk of cancer from returning.

We are conducting this study to evaluate the safety of durvalumab in patients with resectable NSCLC. In this post-marketing study, your treatment will continue as decided by your doctor, and we will only collect your data. Participation requires your written consent. Before you decide whether you want to participate in this study, you will be given an explanation about what the study involves.

The overall description of this study, including the collection, storage, and use of your data and documentation, etc. has been reviewed in your country by an independent Ethics Committee to ensure that the rights, safety, and well-being of study patients are protected.

Your condition may or may not improve if you join the study. However, the information we get from this study might help other patients with the same condition in the future.

1 What is this study about?

Durvalumab is a type of medicine known as immunotherapy. It works by helping your body's immune system recognize and attack cancer cells. Some cancer cells protect themselves by using a signal called PD-L1 which "switch off" the immune system. Durvalumab blocks this signal, helping your immune system find and destroy the cancer cells.

We are doing this study to learn more about how safe durvalumab is when used for the treatment of removable NSCLC, a type of lung cancer. This type of cancer occurs when uncontrolled cells multiply in your lungs and form a tumour. Pre-operative therapy, like the combination of durvalumab and platinum chemotherapy, is given before surgery to help shrink the tumour and enhance the body's defence. After surgery is done to remove a tumour, some small cancer cells that are too small to be detected by MRI, CT, or PET scans may remain. These residual cells can sometimes survive and cause the cancer to return later. After surgery, durvalumab monotherapy is given to strengthen the body's ability to fight against residual cancer cells and to reduce the risk of cancer from coming back.

The aim of the study is to make sure that durvalumab is safe, as shown in earlier studies, while also looking out for any new or unexpected side effects. Durvalumab has been in the market since 2017 and is approved by the United States Food and Drug Administration (USFDA). .

About 78 patients will participate in this study. The total duration of the study will be from the date of the first dose of durvalumab until the date of the last dose of durvalumab +90 days or the date of the first dose of subsequent anti-cancer therapy, until withdrawal of consent, lost to follow-up, or death, whichever is earlier.

2 Do I have to take part?

You have a choice whether or not you would like to participate.

Please take as much time as you need to decide whether or not you would like to participate in this study. It may be helpful to talk with your friends and family as you make this decision.

If you join the study, you can leave it at any time (see "section 14" for more details). Leaving will not affect your care. If you choose to leave the study, please let your study doctor know as soon as possible.

Please consider the study time commitments and responsibilities as a research patient when you are deciding to take part.

If you don't join the study, you will continue to receive care for your lung cancer. Your study doctor or treating physician will talk to you about other possible drugs, their risks, and benefits.

3 What will happen if I join the study?

Because this is an observational study, no medications or other treatments are provided to you by the Sponsor as part of this study.

You will be required to continue with your routine doctor's appointments and to take your regular medication as prescribed by your doctor.

Before you join the study drug you will undergo a series of tests. This is called screening. If you meet the screening criteria, you may enter the study. If you don't meet the screening criteria, the reasons will be explained. Your study doctor or treating physician will talk to you about other possible treatments/options.

You will undergo routine biopsies and staging investigations and will be offered durvalumab as pre-operative and post-operative therapy in accordance with the approved prescribing information by your doctor. We will collect your data throughout the study. You will be in the study from the date of the first dose of durvalumab until the date of the last dose of durvalumab +90 days or the date of the first dose of subsequent anti-cancer therapy, until the withdrawal of consent, lost to follow-up or death, whichever is earlier. Your participation in the study may need to be longer to get better answers to the study questions.

The total number of visits and the visit time will be determined at the discretion of the investigator based on the patient's condition.

During the routine visits, information will be collected for the study, and this might add some extra time to your routine visit.

If you cannot come to a visit, you must tell your study doctor.

Please note that the study, and your participation in the study, may be stopped earlier than expected, for example for scientific or safety reasons (see "Section 9" for more details).

4 What are the required tests and procedures?

While you are on the study, we will need to take your medical data from your records. As part of the standard of care examinations, the data from the following tests and procedures will be recorded:

Patient Demographics & Medical History

Your date of birth, gender, height, weight, presence of pregnancy and breastfeeding in case of female patients, and pregnancy status of female partners in case of male patients will be collected. Also, medical history of any other disease and date and type of anti-meningococcal vaccination, including boosters, will be collected. Disease medical history & baseline disease status (including EGFR/ALK status). Your disease history, such as staging information, ECOG performance status (your ability to function in daily life), and EGFR/ALK status (to check for the presence of change in the gene), if available, will be collected from your medical records.

Concomitant Medications

Information about any ongoing medications you have been taking will be noted from your medical records, including drug name, daily dose, route, and indication.

Physical examination and Vital signs

Any results of physical examinations conducted, or vital signs (especially body weight) recorded by your study doctor will be noted.

ECG

ECG readings taken over the duration of the study, especially at baseline, pre-surgery, and post-surgery, will be noted from your medical records.

Clinical & Radiological Assessments

All clinical and radiological assessments, such as MRI/CT/PET, performed to evaluate the disease status or overall clinical response, and RECIST 1.1 assessments, which assess the response of the tumour to treatment in clinical trials, whenever available, will be recorded for the study.

Laboratory assessments

Results of any laboratory tests performed at baseline and during durvalumab treatment as per prescribed treatment, including but not limited to clinical chemistry, haematology, kidney function test, liver function test, thyroid levels, urinalysis, Hepatitis B and C, HIV, pregnancy tests, etc., will be noted.

NSCLC Treatment details

All treatments given in line with the prescribed treatment, including surgery and chemotherapy before and after surgery, will be recorded. Details to be noted will include the total dose, total duration of treatment, ongoing or discontinuation status of

treatment, and reason for discontinuation of treatment/ reason for changing the dose of treatment.

Safety assessment

The occurrence of any side effect you might be experiencing, however small it may be, will be assessed by your study doctor. When a side effect occurs, information on the following items will be collected: what the side effect is, when it started and ended, how serious it is, how bad it felt, whether it is related to the study drug, what is done about the drug because of the side effect, what happened afterwards, what steps were taken regarding the side effect, and any comments from the doctor.

The complete list of study tests and procedures, including their detailed schedule is available in the “Part III: Additional information for patients”.

5. What are the optional tests and procedures?

Since this is an observational study, we will only collect data from your medical records. There will be no additional or optional tests or procedures.

6. What are the risks of joining the study?

This study will only capture the routine medical treatment provided to you by your doctor. There is no immediate clinical benefit for you. However, the information we get from this study may help us to describe how lung cancer patients are managed in real-life practice and to increase our knowledge about the disease and its symptoms. This will hopefully help us to better treat patients with lung cancer in the future.

Since Durvalumab is an immunotherapy that helps the immune system fight cancer. Since it activates the immune system, it may sometimes cause the immune system to affect normal organs and may cause some unwanted effects.

Common Side Effects

- Low red blood cell count (anaemia)
- Nausea
- Constipation
- Tiredness
- Muscle or bone pain
- Skin rash

Possible Immune-Related Side Effects

Durvalumab may cause inflammation in different organs, including:

- Lungs (cough, shortness of breath)

- Liver (yellowing of skin/eyes, abnormal liver tests)
- Intestines (diarrhea, stomach pain)
- Hormone glands (thyroid or adrenal problems causing fatigue, dizziness, or weight changes)
- Kidneys
- Skin

These side effects may occur during or after treatment. Most can be treated if detected early, but some may be serious and require hospitalization or stopping treatment. Rarely, severe complications may be life-threatening.

Side Effects of Other Treatments

If you receive chemotherapy, surgery, or radiation therapy as part of routine care, these treatments may cause additional side effects such as nausea, hair loss, infections, bleeding, pain, breathing problems, or fatigue. Your doctor will explain these risks separately.

Risks of Routine Tests

Routine blood tests may cause mild pain or bruising. ECG may cause mild skin irritation. No major risks are expected from these procedures. There is a risk that your lung cancer will not get better or even get worse during the study.

It's important to note that any side effects you experience may be related to the treatment you have chosen and are not a result of participating in this study. This study is purely observational and involves only recording your routine medical data provided by your doctor. Also, since the study is non-interventional, it will not change how your doctor manages your treatment.

To read more about risks, turn to the additional risk information provided in the "Additional information for patients".

7. Are there any other considerations or risks I need to know about?

Special Warnings

- Durvalumab may cause immune-related side effects that can affect organs such as the lungs, liver, intestines, kidneys, hormone glands, skin, heart, or nervous system.
- These reactions can occur during treatment or even after treatment has stopped.
- Some side effects may become serious if not treated early.

- You should inform your doctor immediately if you experience new or worsening symptoms such as breathing difficulty, persistent diarrhea, yellowing of the skin/eyes, severe fatigue, chest pain, confusion, or severe rash.

Other Medicines, Food, and Drinks

- You should inform your doctor about all medicines you are taking, including prescription drugs, over-the-counter medicines, herbal products, and supplements.
- Some medicines (especially steroids or medicines that affect the immune system) may need medical supervision while you are receiving durvalumab.
- Do not start any new medicine without discussing it with your doctor.
- There are no specific food or drink restrictions, but you should follow your doctor's dietary advice during treatment.

Driving, Machinery, Sports, and Activities

- Durvalumab may cause tiredness, dizziness, or weakness.
- If you feel unwell, tired, or dizzy, you should avoid driving, operating machinery, or performing activities requiring full alertness.
- There are no specific restrictions on sports or activities, but you should follow your doctor's advice based on your condition and overall health.

Pregnancy, contraception, and breast-feeding

Because the effects of durvalumab on an unborn child or infant are not known you (or your female partner if you are a male) must not get pregnant or breastfeed a child during the study.

The study doctor can discuss acceptable birth control methods with you.

For female patients:

If you become pregnant, you must tell the study doctor straight away. You will have to stop taking the study drug immediately until you have spoken to your study doctor. You will be asked to provide information about you and your baby. This may involve a separate consent to allow us to monitor your baby's health and development.

For male patients whose partners become pregnant:

If your partner becomes pregnant, you must tell the study doctor immediately. Your partner will be asked, under a separate consent, to provide information about their health and your baby's health.

Fasting

No specific fasting is required for participation in this study unless advised by your treating doctor for routine medical tests or procedures.

Vaccinations

- Inform your doctor before receiving any vaccine.
- Live vaccines should generally be avoided during treatment with durvalumab and for a period after treatment, as advised by your doctor.
- Inactivated (non-live) vaccines may be given if recommended by your doctor.

Blood Donation

You should not donate blood or blood products during treatment and for a period after the last dose of durvalumab, as advised by your doctor.

8. What are the possible benefits of taking part?

The information the study Sponsor receives from this study may help to better treat patients with lung cancer in the future.

It is not certain that you will directly benefit from the participation in the study. Your participation may, however, help other patients in the future by improving the knowledge of disease and improving medical care. We do not know if taking part will help your condition, but we hope that it will.

9. What happens if something changes while I am in the study, e.g. if new information is found?

Changes may happen in the study that could make you change your mind about continuing to take part in the study. If something changes, we will tell you as soon as possible.

You can choose to leave the study at any time. For more details, see section 14 below.

The study doctor can also choose to take you out of the study if they believe that it is best for you.

Your participation in the study also stops when the Sponsor, Indian health authorities, the ethics or regulatory agencies decide that the study must be stopped.

10. What happens if I am harmed or injured during the study?

Since this is an observational study, it does not involve any experimental treatments or procedures beyond the routine medical care provided by your doctor. Therefore, the risk of harm or injury from participating in the study is extremely low. Your doctor will continue to provide the necessary care and manage your treatment as usual. If you have any concerns, you can contact the study team or your doctor for further assistance.

If there is an emergency, call your study doctor as soon as you can. All relevant contact details can be found in part III: "Additional information for patients".

If you become ill or are injured while you are in this research study, you must tell your study doctor straight away.

Injuries that have been caused by the study drug, tests, or procedures are called 'research injuries'. Injuries caused by your usual medical care or your lung cancer are not research injuries.

If you have medical insurance, please check with your insurance company that taking part in this research study will not affect your coverage.

By signing this form, you do not give up any legal right you may have.

11. What will happen to my data gathered in the study?

a. Which data are collected?

To conduct the study, the Study site will have to collect and register information about your identity, such as your medical condition and medical history (this may include information from your physicians / available in your medical records), your lifestyle, your demographics (age, gender, ethnic and racial background), clinical chemistry, haematology, kidney function test, liver function test, thyroid levels, urinalysis, Hepatitis B&C, HIV, pregnancy tests etc will be noted along with the medicines you are taking for any other disease. Also, ECG and data generated from the imaging techniques like MRI/PET/CT will be collected. The treatment you will receive, along with your response to the treatment and side effects or any discomfort you may have, will be collected.

b. What is my data needed for?

Your data is needed for the Sponsor to generate post-marketing safety evidence on the use of durvalumab to fulfil the post-approval regulatory commitment to the Indian Health Authority. Therefore, the data will be used as planned in this study as well as within related research activities necessary for the drug development programme in to better

understand the studied disease and associated health problems. They may further be used to publish research results in scientific journals or use them for educational purposes.

c. Who can access my data?

Only at the study site, your name and contact details will be accessible to the study doctor and the study team to conduct the study. Non-medical personnel acting on behalf of the Sponsor and being bound by a duty of confidentiality as well as Health authorities and Ethics Committees may also be given access to this data only to verify that the study is carried out in compliance with legal and quality requirements. Some of your data may be accessed remotely, where allowed.

The study site will share your data with the Sponsor but only after they have been coded (which means that your name, contact details or health insurance number, have been replaced by a code. For more information about coding, see details at the end of this document in part III: “Additional information for patients”.

The Sponsor may share your coded data with its Research partners and Service providers for the purposes of the drug development programme.

In order to ensure proper conduct and accurate results of the study and to get permission to market the drug, the Sponsor will share your coded data with authorities and possibly with Ethics Committees. They may also be shared with scientific journals, so the study results can be reviewed by independent scientists and to ensure the accuracy of results.

In none of these cases your identity will be revealed.

Some of the above-mentioned persons may be located outside your country. If this other country does not have equivalent personal data protection standards as your country, appropriate Safeguards (such as contracts and technical Security measures) will be adopted to protect and maintain the confidentiality of your data as further described at the end of the document in part III: “Additional information for patients”.

In case another organisation takes over development or commercialisation of the study drug, your coded data may be transmitted to them. They will then have to protect your data in the same way as described herein.

d. Who else may have access to my contact information and why?

Your name or contact details may be shared with service providers to collect information on your survival status.

The service providers must keep your name or contact details private and will NOT share any information that can directly identify you with the Sponsor.

e. How long will my coded data be kept?

The study site and the Sponsor are obliged to keep all study data for 15 years after the end of the study, to comply with study sites and Sponsor's legal obligations. You can find out more about how the sponsor keeps personal information at www.astrazenecapersonaldataretention.com. Your coded data will then be deleted or anonymised.

For more details about anonymizing, see part 1 section 11g: What does anonymised data mean?".

f. What are my rights under data protection law?

You have the right to review which of your data is collected and being used; you can also ask for a copy of this data, ask for restriction of use of this data, or ask to have incorrect data rectified.

To ensure the scientific integrity of the study, you will not be able to review some of the data or receive a copy of it until the study ends.

To exercise these restricted rights, please contact preferably the study doctor.

g. What does anonymised data mean?

Health authorities as well as pharmaceutical companies believe that access to clinical studies data advances clinical science and medical knowledge and is in the best interest of patients and public health, provided that patient privacy is protected. Therefore, the Sponsor may generate and share internally or with other researchers an anonymised set of your data collected in the study (e.g., on www.vivli.org). This means your coded data will be stripped of your Patient code as well as of any other information that could reasonably be used to identify you, such as your date of birth.

12. What are the costs of taking part?

Participating in this study will not cost you anything more than the costs related to your routine appointments with your doctor. You will not be paid for being in this study. The cost of the study drug and lab investigations will not be covered through the study.

13. How to find out more after the study?

Trial Result Summaries are a short and easy to understand summary of the results of this study. These will be added to www.trialssummaries.com within 1 year of the last study patients last site visit. You can visit www.trialssummaries.com website anytime to sign up to be notified via email when the trial results summary of your study is available. Or please let your study doctor know if you need a printed copy of the document.

Information in technical language related to study protocol and the results will be posted on <http://astrazenecaclinicaltrials> and <http://www.clinicaltrials.gov>. A description of this study is also available on <http://ctri.nic.in>. These websites do not contain any information about you.

14. What will happen if I want to quit the study?

Your participation in the study is voluntary which means you can stop your participation at any time. If you want to stop taking the study drug, want to have a modified visit schedule or if you want to stop your participation, you should tell the study doctor and discuss available options.

If you stop participating in the study be aware that this is a “study discontinuation”, and not a withdrawal of / objection to consent for processing personal data, the study doctor will stop the collection of your data, but your previously collected data will be kept and used to guarantee the validity of the study and to comply with regulatory requirements, as allowed by law. The study doctor will then invite you to have an end of study examination to check your wellbeing. If you don't show up at a planned visit, the study doctor will try to reach you. This is important for study results. It is not mandatory but would be helpful for the study if you explain to your study doctor why you wish to stop your participation, in particular if you have experienced discomforts.

We will continue to use your data and collected samples as originally consented, unless you would like your data not to be used after you quit the study. In such a case, you must inform the study doctor, but your coded data previously collected will be kept as required by clinical regulations.

15. Who can answer any questions I may have?

Remember, there are no silly questions! Feel free to ask at ANY TIME! It is your right to be fully informed before deciding to take part in this study. You can contact the study doctor at any time at the address indicated in part III: “Additional information for patients”.

PART II: CONSENT FORM

D9106R00007, Durvalumab

A prospective, observational, multicenter, post marketing surveillance study to assess the safety of Durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC)

Subject's Initials:			
Subject's Name:			
Date of Birth (dd-mm-yyyy):		Age (years):	
Address of the Subject:			
Qualification:			
Occupation: (Please tick as appropriate)	Student ☐ Self-Employed ☐ Service ☐ Housewife ☐ Others _____		
Annual Income of the subject:			
Name and address of the nominee(s) and his/her relation to the Subject:			

Please sign this consent form only after you have had a chance to ask questions and have received acceptable answers to all of your questions. By signing this page, you will be confirming the following statements:

Sl. No	Please provide your initials (short signature or signature) or thumb impression (as applicable) against each one of the following statements to confirm your consent to these statements.	
(i)	I confirm that I have read and understood the Study Information and Informed Consent Form dated, Version Number for the above study and have had the opportunity to ask questions.	[]
(ii)	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[]
(iii)	I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee, and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	[]
(iv)	I agree not to restrict the use of any data or results that arise from this study, provided such a use is only for scientific purpose(s)	[]
(v)	I agree to take part in the above study.	[]

INFORMED CONSENT FORM

Signature (Or Thumb impression) of the Date of Signature subject/Legally Acceptable Representative (LAR)

Signatory's Name (Name of the subject or LAR who has signed)

Where a subject is not able to give informed consent (e.g., an unconscious person or a minor or those suffering from severe mental illness or disability), the same may be obtained from a legally acceptable representative (a legally acceptable representative is a person who is able to give consent for or authorise an intervention in the patient as provided by the law(s) of India).

Relationship of legally acceptable representative to subject

Signature of the Investigator

Date of Signature

Study Investigator's Name

If the Subject or his/her legally acceptable representative is unable to read/write - an impartial witness should be present during the entire informed consent process who must append his/her signatures to the consent form.

Impartial witness is a person who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form, and any other written information supplied to the subject.

Signature of Impartial Witness

Date of Signature

Name of Impartial Witness

Copy of the Patient Information Sheet (Adult Study Participant Master Information) and duly filled Informed Consent Form shall be handed over to the subject or his/her legally acceptable representative.

PART III: ADDITIONAL INFORMATION FOR PATIENTS

1. Contact details

Study doctor	Study Coordinator (e.g. nurse appointed to the study)
Phone No.	Phone No.
Address	Address
Email address	Email address

Name of EC Member Secretary	
Phone No. of EC Member Secretary	

2. Detailed list of visits and Test/Procedures

There is no protocol mandate in the present study, so you will not have any separate investigation apart from the treatment you are undergoing. We will collect information about your health from the first dose of durvalumab until the date of the last dose of durvalumab + 90 days or the date of the first dose of subsequent anti-cancer therapy, until withdrawal of consent, loss to follow-up, or death, whichever is earlier. During the study, we will record any side-effects you may have, like fatigue, musculoskeletal pain, constipation, decreased appetite, nausea, peripheral oedema, urinary tract infection, or any unknown side effects. The number and timing of visits will depend on the doctor's judgment based on the patient's condition. Information such as the patient's age, disease status, test results, durvalumab doses, and other treatments will be collected at the start and throughout the study.

3. Detailed Study Tests and Procedures Schedules

Here is the outline of what to expect at

Baseline/Screening

At the baseline, you will undergo the initial procedures to assess your eligibility for the study. This includes signing the informed consent form, verifying inclusion/exclusion criteria, and recording details about demographics, medical history, and the medicines you are taking will be recorded, and the patient will have a physical examination, vital sign checks, ECOG performance status assessment, and baseline clinical and

radiological imaging. Initial tumour measurements will be documented according to RECIST 1.1 guidelines, which provide a standardized set of rules for response assessment of the treatment, and necessary laboratory assessments will be conducted.

Neoadjuvant Therapy Period

Regular assessments will include recording concomitant medications, recording physical examinations, and vital sign checks. Clinical and radiological assessments will be performed to monitor treatment response, and laboratory assessments will help track therapy-related changes. Any adverse events (AEs) or serious adverse events (SAEs) will be carefully documented.

Pre-Surgery Phase

In preparation for surgery, eligibility criteria may be rechecked if necessary. Updated records of concomitant medications and clinical/radiological assessments, including RECIST 1.1 evaluations, will be recorded. The pre-surgery phase will focus on ensuring the patient is optimally prepared for the surgical procedure. Safety monitoring for AEs and SAEs continues during this phase.

Surgery Phase

The surgery phase involves the actual surgical intervention to remove the tumour. During this time, any necessary perioperative medications will be documented. Safety monitoring will focus on identifying surgery-related AEs or SAEs.

Post-Surgery Phase

Post-surgery, patients will undergo health monitoring to assess recovery and surgical outcomes. This includes recording concomitant medications, conducting physical examinations, and performing vital sign checks. Clinical and radiological assessments will evaluate the surgical success and any residual disease, while RECIST 1.1 evaluations and laboratory tests will provide further insights. Monitoring for AEs and SAEs remains a priority during this phase.

Durvalumab monotherapy Period

The adjuvant therapy period focuses on reducing the risk of disease recurrence. Patients will continue to receive treatment with regular evaluations, including updates on concomitant medications, physical examinations, clinical and radiological assessments, RECIST 1.1 tumour evaluations, and laboratory monitoring. Safety monitoring remains critical, with detailed documentation of any AEs or SAEs.

Follow-Up Period

In the follow-up period, patients will be monitored long-term to detect any recurrence or late complications. Clinical and radiological assessments, along with RECIST 1.1 evaluations, will continue. Concomitant medication updates and AE/SAE reporting will also be done throughout this phase till 90 days after the last dose of the treatment or the first day of the start of another treatment, until the withdrawal of consent, loss to follow-up, or death, whichever is earlier.

The table describing what to expect at each visit:

Data Collection and Entry	Baseline/ Screening	Neoadjuvant therapy period	Pre- Surgery	Surgery	Post- Surgery	Adjuvant therapy period	Follow-up period
Informed Consent	X						
Screening	X		X				
Pregnancy test ^a	X						
Patient Demographics and Medical History	X				X		
Disease medical history & Baseline disease status (including EGFR/ALK status)	X						
Medicine you are taking.	X	X	X	X	X	X	X
Physical examination and Vital signs	X	X				X	X
ECOG Performance Status	X						X
Clinical & Radiological Assessments	X	X	X		X	X	X
RECIST 1.1 assessment	X		X		X	X	X
ECG	As clinically indicated						
Laboratory assessments	X	X				X	X
NSCLC Treatment details		X				X	X
AE and SAE Reporting	X	X	X	X	X	X	X

^a Women of childbearing potential only

4. Complete List of Risks, Side Effects, and Discomforts

Since this is an observational study, there are no side effects or risks directly associated with participation in this study.

Durvalumab is an immunotherapy that helps the immune system fight cancer. Because it activates the immune system, it may sometimes cause the immune system to affect normal organs.

Common Side Effects

- Low red blood cell count (anemia)
- Nausea

- Constipation
- Tiredness
- Muscle or bone pain
- Skin rash

Possible Immune-Related Side Effects

Durvalumab may cause inflammation in different organs, including:

- Lungs (cough, shortness of breath)
- Liver (yellowing of skin/eyes, abnormal liver tests)
- Intestines (diarrhea, stomach pain)
- Hormone glands (thyroid or adrenal problems causing fatigue, dizziness, or weight changes)
- Kidneys
- Skin

These side effects may occur during or after treatment. Most can be treated if detected early, but some may be serious and require hospitalization or stopping treatment. Rarely, severe complications may be life-threatening.

Side Effects of Other Treatments

If you receive chemotherapy, surgery, or radiation therapy as part of routine care, these treatments may cause additional side effects such as nausea, hair loss, infections, bleeding, pain, breathing problems, or fatigue. Your doctor will explain these risks separately.

Risks of Routine Tests

Routine blood tests may cause mild pain or bruising. ECG may cause mild skin irritation. No major risks are expected from these procedures.

5. Complete List of Personal Data collected

All data, as described in Part I Section 11a, will be collected during the study.

6. Glossary

Your coded data	All your data collected at the study site, with your name and contact details, have been replaced by a code. This is done by the study doctor who keeps the link between your name/contact details and the code to ensure your safety and confidentiality. Coded information cannot identify you unless your study doctor provides your name or contact details, where allowed by applicable law.
Sponsor details	Sponsor: AstraZeneca Pharma India Ltd. The sponsor has the overall responsibility for a clinical study.
Study site details	The place where the clinical study is taking place and where you will have to go for the planned visits.
Health authorities	Authorities who supervise the study, who approve the commercialisation of the drug or who receive the adverse events reporting, whether in your country or in other countries.
Research partners	Any organisation which collaborates with the sponsor within the drug development programme or for future research.
Service providers	Any organisation bound to the sponsor by a contract, which may conduct activities on behalf of the sponsor under its strict instructions. This may include other researchers including so- called “contracted research organisations” (CROs) and IT companies hosting clinical data or providing IT services including developing new systems and services.

Safeguards	Appropriate safeguards will be implemented to protect coded data during and after the study and may include that: – Access to the coded data will be limited to specific individuals subject to confidentiality obligations (including the obligation to not attempt to re-identify individuals/decode the clinical data). – The coded data will be protected with security measures to avoid data alteration, loss and unauthorised accesses and further de-identification techniques may be applied. – A data protection impact assessment (DPIA) will apply to identify and mitigate privacy risks, if any, associated with each scientific research. – When required by applicable law, scientific research is subject to the approval of Ethics Committees. – The coded data will not be shared for direct marketing purposes or other purposes that are not legal duties or are not considered scientific research according to the applicable data protection legislation. In particular, it will not be used to make decisions about future services available to you, such as insurance.
Security measures: How is my data protected in other countries?	The processing of your data starts at the study site. Your data will then be transferred to several data experts to be verified and for results to be calculated. In addition to having your data coded, your data is also protected by high standard technical security means such as strong access control and encryption. Within the sponsor group, your coded data are protected by Binding Corporate Rules (BCR). You can find more information about the Sponsors BCRs here: www.astrazenecabindingcorporaterules.com. You may obtain further information as well as a copy of these measures by asking your study doctor.

Restricted rights	Please note that the rights provided by the GDPR and UK Privacy Law to get data discarded (i.e., the right to be forgotten) do not apply to such studies.
Scientific research	Scientific research includes technological development and demonstration, fundamental research, applied research and privately funded research as well as studies conducted in the public interest in the area of public health. This means that we may use the data to advance our understanding of how to make new medicines, medical devices, diagnostic products, tools and/or other therapies, to treat diseases. We may also use this data to improve the design and execution of future clinical studies, services and drugs, for outcome research activities and to aid in pricing and reimbursement activities.
Deposit in scientific databases	To do more powerful research, it is helpful for researchers to share data by placing data into one or more scientific databases. Researchers can then study the data combined from several research projects and learn even more about health and disease. Researchers with an approved scientific research project may be able to see and use your coded data, along with that from many other people. Your name and other information that could directly identify you (such as address or social security number) will never be placed into such a scientific database. Researchers will always have a duty to protect your privacy and to keep your information confidential.

CORE STUDY ICD IN ENGLISH VERSION NO. 1.0 DATED
09-Mar-2026 TRANSLATED IN HINDI ON 16-Mar-2026

अध्ययन जानकारी और सूचित सहमति प्रपत्र

अध्ययन कोड:	डी9106आर00007	साइट क्रमांक:	
प्रायोजक:	एस्ट्राजेनेका फार्मा इंडिया लिमिटेड	व्यक्तिपात्र आईडी:	
मुख्य अन्वेषक:			
अध्ययन का शीर्षक:	रिसेक्टेबल (हटाने योग्य) गैर-छोटे कोशिका वाले फेफड़े का कैंसर (एनएससीएलसी) से पीड़ित भारतीय वयस्क रोगी में डूर्वालुमाब की सुरक्षा का आकलन करने के लिए एक संभावित, अवलोकन संबंधी, बहुकेंद्रीय, विपणन-पश्चात निगरानी अध्ययन।		

इस दस्तावेज़ के [3] भाग हैं:

- भाग I: नैदानिक अध्ययन में भाग लेने के आपके निर्णय के लिए आवश्यक "अध्ययन जानकारी",
- भाग II: आपका "सहमति प्रपत्र" जिसमें संक्षेप में बताया गया है कि आप किन बातों पर सहमत हो सकते हैं,
- भाग III: "रोगियों के लिए अतिरिक्त जानकारी" अनुभाग में पूरक जानकारी दी गई है, जिसमें शब्दावली भी शामिल है।

भाग I: अध्ययन जानकारी

डी9106आर00007, इर्वालुमाब पोस्ट मार्केटिंग सुरक्षा अध्ययन

फेफड़ों के कैंसर से पीड़ित भारतीय वयस्कों में इर्वालुमाब की सुरक्षा का आकलन करने के लिए
अवलोकन अध्ययन

प्रिय श्रीमती / श्रीमान,

आपको इस अध्ययन में भाग लेने के लिए आमंत्रित किया जाता है क्योंकि हाल ही में आपको फेफड़ों के कैंसर के एक प्रकार का निदान हुआ है जिसे रिसेक्टेबल (हटाने योग्य) गैर-छोटे कोशिका वाले फेफड़े का कैंसर (एनएससीएलसी) कहा जाता है। आपने अनुशंसित उपचार पद्धति को स्वीकार कर लिया है, जिसमें शल्य चिकित्सा-के पहले उपचार के रूप में कीमोचिकित्सा के साथ इर्वालुमाब का संयोजन और सर्जरी के बाद इर्वालुमाब मोनोचिकित्सा शामिल है। इस उपचार का उद्देश्य ट्यूमर को सिकोड़ने और कैंसर के दोबारा होने के जोखिम को कम करने में मदद करना है। इर्वालुमाब

हम रिसेक्टेबल एनएससीएलसी वाले रोगियों में इयूरवैलुमैब की सुरक्षा का मूल्यांकन करने के लिए यह अध्ययन कर रहे हैं। इस पोस्ट-मार्केटिंग अध्ययन में, आपका उपचार आपके चिकित्सक के निर्णय के अनुसार जारी रहेगा, और हम केवल आपका डेटा एकत्र करेंगे।

भागीदारी के लिए आपकी लिखित सहमति आवश्यक है। इस अध्ययन में भाग लेने का निर्णय लेने से पहले, आपको इस अध्ययन में क्या-क्या शामिल है, इसके बारे में जानकारी दी जाएगी।

इस अध्ययन का समग्र विवरण, जिसमें आपके डेटा का संग्रह, भंडारण और उपयोग, और दस्तावेजीकरण आदि शामिल है, आपके देश में एक स्वतंत्र आचार समिति द्वारा समीक्षा की गई है ताकि यह सुनिश्चित किया जा सके कि अध्ययन में शामिल रोगियों के अधिकारों, सुरक्षा और स्वास्थ्य की रक्षा की जाए।

अध्ययन में शामिल होने पर आपकी स्थिति में सुधार हो भी सकता है और नहीं भी। हालाँकि, इस अध्ययन से हमें जो जानकारी मिलेगी, वह भविष्य में इसी स्थिति से जूझ रहे अन्य रोगियों के लिए मददगार साबित हो सकती है।

1 यह अध्ययन किस बारे में है?

डूर्वालुमाब एक प्रकार की दवा है जिसे रोग-प्रतिरक्षाचिकित्सा के नाम से जाना जाता है। यह शरीर की प्रतिरक्षा प्रणाली को कैंसर कोशिकाओं को पहचानने और उन पर हमला करने में मदद करके काम करती है। कुछ कैंसर कोशिकाएं पीडी-एल1 नामक एक संकेत का उपयोग करके खुद को बचाती हैं, जो प्रतिरक्षा प्रणाली को "बंद" कर देता है। डूर्वालुमाब इस संकेत को अवरुद्ध करता है, जिससे आपकी प्रतिरक्षा प्रणाली को कैंसर कोशिकाओं को ढूंढने और नष्ट करने में मदद मिलती है।

हम यह अध्ययन इसलिए कर रहे हैं ताकि यह जान सकें कि फेफड़ों के कैंसर के एक प्रकार, हटाने योग्य एनएससीएलसी के उपचार में डूर्वालुमाब का उपयोग कितना सुरक्षित है। इस प्रकार का कैंसर तब होता है जब फेफड़ों में अनियंत्रित कोशिकाएं गुणा होकर ट्यूमर का रूप ले लेती हैं। डूर्वालुमाब और प्लैटिनम कीमोचिकित्सा के संयोजन जैसी शल्य चिकित्सा-के पहले सर्जरी से पहले दी जाती है ताकि ट्यूमर को सिकोड़ने और शरीर की प्रतिरक्षा प्रणाली को मजबूत करने में मदद मिल सके। ट्यूमर को हटाने के लिए सर्जरी किए जाने के बाद, कुछ छोटी कैंसर कोशिकाएं रह सकती हैं जो एमआरआई, सीटी या पीईटी स्कैन द्वारा पता लगाने के लिए बहुत छोटी होती हैं। ये अवशिष्ट कोशिकाएँ कभी-कभी जीवित रह सकती हैं और बाद में कैंसर के पुनरावर्तन का कारण बन सकती हैं। सर्जरी के बाद, शरीर की अवशिष्ट कैंसर कोशिकाओं से लड़ने की क्षमता को मजबूत करने और कैंसर के पुनरावर्तन के जोखिम को कम करने के लिए डूर्वालुमाब मोनोचिकित्सा दी जाती है।

इस अध्ययन का उद्देश्य यह सुनिश्चित करना है कि डूर्वालुमाब सुरक्षित है, जैसा कि पहले के अध्ययनों में दिखाया गया है, साथ ही किसी भी नए या अप्रत्याशित दुष्प्रभाव पर भी नजर रखना है। डूर्वालुमाब 2017 से बाजार में है और इसे संयुक्त राज्य अमेरिका के खाद्य एवं औषधि प्रशासन (यूएसएफडीए) द्वारा अनुमोदित किया गया है।

इस अध्ययन में लगभग 78 रोगी भाग लेंगे। इस अध्ययन की कुल अवधि डूर्वालुमाब की पहली खुराक की दिनांक से लेकर डूर्वालुमाब की अंतिम खुराक की दिनांक +90 दिन या बाद की कैंसर-रोधी चिकित्सा की पहली खुराक की दिनांक तक, सहमति वापस लेने, फॉलो-अप से बाहर होने या मृत्यु होने तक, इनमें से जो भी पहले हो, तक होगी।

2 क्या मुझे इसमें भाग लेना होगा?

आपके पास यह विकल्प है कि आप इसमें भाग लेना चाहते हैं या नहीं।

कृपया इस अध्ययन में भाग लेना चाहते/ती हैं या नहीं, यह निर्णय लेने के लिए जितना समय आवश्यक हो, लें। यह निर्णय लेते समय अपने मित्रों और परिवार के साथ बात करना सहायक हो सकता है।

यदि आप अध्ययन में शामिल होते हैं, तो आप इसे किसी भी समय छोड़ सकते/ती हैं (अधिक जानकारी के लिए “अनुभाग 14” देखें)। अध्ययन छोड़ने से आपकी देखभाल पर कोई असर नहीं पड़ेगा। अगर आप अध्ययन छोड़ना चाहते/ती हैं, तो कृपया अपने अध्ययन चिकित्सक को जल्द से जल्द सूचित करें।

कृपया शोध रोगी के रूप में अध्ययन के लिए आवश्यक समय और जिम्मेदारियों पर विचार करें जब आप इसमें भाग लेने का निर्णय ले रहे हों।

यदि आप अध्ययन में शामिल नहीं होते/ती हैं, तो भी आपकी फेफड़े का कैंसर के लिए आपको देखभाल मिलती रहेगी। आपके अध्ययन चिकित्सक या उपचार करने वाले चिकित्सक आपको अन्य संभावित दवाओं, उनके जोखिमों और लाभों के बारे में बताएंगे।

3 यदि मैं अध्ययन में शामिल हो जाऊं तो क्या होगा?

चूंकि यह एक अवलोकनात्मक अध्ययन है, इसलिए इस अध्ययन के भाग के रूप में प्रायोजक द्वारा आपको कोई दवा या अन्य उपचार प्रदान नहीं किया जाता है।

आपको नियमित रूप से चिकित्सक के पास जाना होगा और चिकित्सक द्वारा बताई गई नियमित दवाएं लेनी होंगी।

अध्ययन में दवा शामिल करने से पहले आपको कई परीक्षणों से गुजरना होगा। इसे स्क्रीनिंग कहते हैं। अगर आप स्क्रीनिंग के मानदंडों को पूरा करते/ती हैं, तो आप अध्ययन में शामिल हो सकते/ती हैं। यदि आप स्क्रीनिंग मानदंडों को पूरा नहीं करते/ती हैं, तो कारण बताए जाएंगे। आपके अध्ययन चिकित्सक या उपचार करने वाले चिकित्सक आपसे अन्य संभावित उपचारों/विकल्पों के बारे में बात करेंगे।

आपकी नियमित बायोप्सी और अवस्था जांच की जाएगी और आपके चिकित्सक द्वारा अनुमोदित दी गई जानकारी के अनुसार आपको शल्य चिकित्सा-के पहले और शल्य चिकित्सा-के बाद की चिकित्सा की चिकित्सा के रूप में डूर्वालुमाब की पेशकश की जाएगी। हम अध्ययन के दौरान आपका डेटा एकत्र करेंगे। आप डूर्वालुमाब की पहली खुराक की दिनांक से लेकर डूर्वालुमाब की अंतिम खुराक की दिनांक +90 दिन या बाद की कैंसर-रोधी चिकित्सा की पहली खुराक की दिनांक तक, सहमति वापस लेने, फॉलो-अप से बाहर होने या मृत्यु होने तक, इनमें से जो भी पहले हो, अध्ययन में शामिल रहेंगे। अध्ययन के प्रश्नों के बेहतर उत्तर प्राप्त करने के लिए अध्ययन में आपकी भागीदारी की अवधि लंबी हो सकती है।

रोगी की स्थिति के आधार पर अन्वेषक के विवेकानुसार मुलाकातों की कुल संख्या और मुलाकात का समय निर्धारित किया जाएगा।

नियमित मुलाकातों के दौरान, अध्ययन के लिए जानकारी एकत्र की जाएगी और इससे आपकी नियमित मुलाकात में कुछ अतिरिक्त समय लग सकता है।

यदि आप मुलाकात के लिए नहीं आ सकते/ती हैं, तो आपको अपने अध्ययन चिकित्सक को सूचित करना होगा।

कृपया ध्यान दें कि अध्ययन, और अध्ययन में आपकी भागीदारी, अपेक्षा से पहले रोकी जा सकती है, उदाहरण के लिए वैज्ञानिक या सुरक्षा कारणों से (अधिक जानकारी के लिए “अनुभाग 9” देखें)।

4 आवश्यक परीक्षण और प्रक्रियाएं क्या हैं?

जब आप इस अध्ययन में शामिल होंगे, तो हमें आपके मेडिकल रिकॉर्ड से आपका मेडिकल डेटा लेने की आवश्यकता होगी। मानक देखभाल संबंधी जांचों के भाग के रूप में, निम्नलिखित परीक्षणों और प्रक्रियाओं से प्राप्त डेटा को रिकॉर्ड किया जाएगा:

रोगी की जनसांख्यिकी और चिकित्सा इतिहास

आपकी जन्मतिथि, लिंग, ऊंचाई, वजन, महिला रोगियों के मामले में गर्भावस्था और स्तनपान की स्थिति, और पुरुष रोगियों के मामले में महिला साथियों की गर्भावस्था की स्थिति से संबंधित जानकारी एकत्र की जाएगी। इसके अलावा, किसी अन्य बीमारी का चिकित्सीय इतिहास और मेनिंगोकोकल विरोधी टीकाकरण की तिथि और प्रकार, जिसमें बूस्टर खुराक भी शामिल है, की जानकारी एकत्र की जाएगी। रोग का चिकित्सीय इतिहास और प्रारंभिक रोग की स्थिति (जिसमें ईजीएफआर/एएलके स्थिति शामिल है)। आपके

चिकित्सा अभिलेखों से आपकी बीमारी का इतिहास, जैसे कि रोग के चरण की जानकारी, ईसीओजी प्रदर्शन स्थिति (दैनिक जीवन में कार्य करने की आपकी क्षमता), और ईजीएफआर/एएलके स्थिति (जीन में परिवर्तन की उपस्थिति की जांच करने के लिए), यदि उपलब्ध हो, तो एकत्र की जाएगी।

साथ में ली जाने वाली दवाएँ

आपके चिकित्सा अभिलेखों से आपके द्वारा ली जा रही किसी भी दवा के बारे में जानकारी दर्ज की जाएगी, जिसमें दवा का नाम, दैनिक खुराक, सेवन का तरीका और संकेत शामिल हैं।

शारीरिक परीक्षण और महत्वपूर्ण संकेत

आपके अध्ययन चिकित्सक द्वारा किए गए किसी भी शारीरिक परीक्षण के परिणाम, या दर्ज किए गए महत्वपूर्ण संकेतों (विशेष रूप से शरीर का वजन) को नोट किया जाएगा।

ईसीजी

अध्ययन की अवधि के दौरान, विशेष रूप से बेसलाइन, सर्जरी से पहले और सर्जरी के बाद ली गई ईसीजी रीडिंग को आपके मेडिकल रिकॉर्ड से नोट किया जाएगा।

नैदानिक एवं रेडियोलॉजिकल मूल्यांकन

रोग की स्थिति या समग्र नैदानिक प्रतिक्रिया का मूल्यांकन करने के लिए किए गए सभी नैदानिक और रेडियोलॉजिकल आकलन, जैसे कि एमआरआई/सीटी/पीईटी, और आरईसीआईएसटी 1.1 आकलन, जो नैदानिक परीक्षणों में उपचार के प्रति ट्यूमर की प्रतिक्रिया का आकलन करते हैं, जब भी उपलब्ध हों, अध्ययन के लिए दर्ज किए जाएंगे।

प्रयोगशाला मूल्यांकन

निर्धारित उपचार के अनुसार इर्वालुमाब उपचार के दौरान और उपचार शुरू होने से पहले किए गए किसी भी प्रयोगशाला परीक्षण के परिणाम, जिनमें नैदानिक रसायन विज्ञान, रक्त विज्ञान, गुर्दा कार्य परीक्षण, यकृत कार्य परीक्षण, थायरॉइड स्तर, मूत्र विश्लेषण, हेपेटाइटिस बी और सी, एचआईवी, गर्भावस्था परीक्षण आदि शामिल हैं, लेकिन इन्हीं तक सीमित नहीं हैं, नोट किए जाएंगे।

एनएससीएलसी उपचार विवरण

निर्धारित उपचार के अनुसार दिए गए सभी उपचार, जिनमें सर्जरी और सर्जरी से पहले और बाद में कीमोचिकित्सा शामिल हैं, रिकॉर्ड किए जाएंगे। जिन विवरणों पर ध्यान दिया जाना चाहिए उनमें कुल

खुराक, उपचार की कुल अवधि, उपचार की निरंतरता या समाप्ति की स्थिति और उपचार बंद करने का कारण/उपचार की खुराक में बदलाव का कारण शामिल होगा।

सुरक्षा मूल्यांकन

आपके द्वारा अनुभव किए जा रहे किसी भी दुष्प्रभाव, चाहे वह कितना भी मामूली क्यों न हो, का मूल्यांकन आपके अध्ययन चिकित्सक द्वारा किया जाएगा। जब कोई दुष्प्रभाव होता है, तो निम्नलिखित बिंदुओं पर जानकारी एकत्र की जाएगी: दुष्प्रभाव क्या है, यह कब शुरू हुआ और कब समाप्त हुआ, यह कितना गंभीर है, इससे कितना कष्ट हुआ, क्या यह अध्ययन दवा से संबंधित है, दुष्प्रभाव के कारण दवा के संबंध में क्या कार्रवाई की गई, उसके बाद क्या हुआ, दुष्प्रभाव के संबंध में क्या कदम उठाए गए, और चिकित्सक की कोई टिप्पणी।

अध्ययन परीक्षणों और प्रक्रियाओं की पूरी सूची, जिसमें उनका विस्तृत कार्यक्रम भी शामिल है, "भाग III: रोगियों के लिए अतिरिक्त जानकारी" में उपलब्ध है।

5 वैकल्पिक परीक्षण और प्रक्रियाएं क्या हैं?

क्योंकि यह एक अवलोकन संबंधी अध्ययन है, इसलिए हम केवल आपके चिकित्सा रिकॉर्ड से ही डेटा एकत्र करेंगे। इसमें कोई अतिरिक्त या वैकल्पिक परीक्षण या प्रक्रिया शामिल नहीं होगी।

6 अध्ययन में शामिल होने के क्या जोखिम हैं?

यह अध्ययन केवल आपके चिकित्सक द्वारा आपको दी गई नियमित उपचार को ही दर्शाएगा। आपके लिए इसका कोई तत्काल नैदानिक लाभ नहीं है, औरपि इस अध्ययन से हमें जो जानकारी प्राप्त होगी, वह हमें यह बताने में मदद कर सकती है कि वास्तविक जीवन में फेफड़े के कैंसर के रोगियों का प्रबंधन किस प्रकार किया जाता है, और रोग और इसके लक्षणों के बारे में हमारी जानकारी बढ़ाने में मदद कर सकती है। उम्मीद है कि इससे हमें भविष्य में फेफड़े के कैंसरके रोगियों का बेहतर इलाज करने में मदद मिलेगी।

क्योंकि डूर्वालुमाब एक रोग-प्रतिरक्षाचिकित्सा है जो प्रतिरक्षा प्रणाली को कैंसर से लड़ने में मदद करती है। क्योंकि यह प्रतिरक्षा प्रणाली को सक्रिय करता है, इसलिए कभी-कभी यह प्रतिरक्षा प्रणाली को सामान्य अंगों को प्रभावित करने का कारण बन सकता है और कुछ अवांछित प्रभाव पैदा कर सकता है।

सामान्य दुष्प्रभाव

- लाल रक्त कोशिकाओं की संख्या कम होना (एनीमिया)
- मतली
- कब्ज
- थकान
- मांसपेशियों या हड्डियों में दर्द
- त्वचा पर दाने

प्रतिरक्षा संबंधी संभावित दुष्प्रभाव

डूर्वालुमाब विभिन्न अंगों में सूजन पैदा कर सकता है, जिनमें शामिल हैं:

- फेफड़े (खांसी, सांस लेने में तकलीफ)
- यकृत (त्वचा/आंखों का पीलापन, यकृत संबंधी असामान्य परीक्षण)
- आंतें (दस्त, पेट दर्द)
- हार्मोन ग्रंथियां (थायरॉइड या अधिवृक्क ग्रंथियों की समस्याएं जिनके कारण थकान, चक्कर आना या वजन में बदलाव हो सकता है)
- गुर्दे
- त्वचा

ये दुष्प्रभाव उपचार के दौरान या बाद में हो सकते हैं। यदि इनका जल्दी पता चल जाए तो अधिकतर का इलाज संभव है, लेकिन कुछ गंभीर हो सकते हैं और इनके लिए अस्पताल में भर्ती होने या उपचार रोकने की आवश्यकता पड़ सकती है। दुर्लभ मामलों में, गंभीर जटिलताएं जानलेवा भी हो सकती हैं।

अन्य उपचारों के दुष्प्रभाव

यदि आप नियमित उपचार के हिस्से के रूप में कीमोचिकित्सा, सर्जरी या विकिरण चिकित्सा प्राप्त करते हैं, तो इन उपचारों से मतली, बालों का झड़ना, संक्रमण, रक्तस्राव, दर्द, सांस लेने में तकलीफ या थकान जैसे अतिरिक्त दुष्प्रभाव हो सकते हैं। आपके चिकित्सक इन जोखिमों के बारे में अलग से जानकारी देंगे।

नियमित जांच के जोखिम

नियमित रक्त जांच से हल्का दर्द या नील पड़ सकता है। इसीजी से त्वचा में हल्की जलन हो सकती है। इन प्रक्रियाओं से कोई बड़ा खतरा होने की संभावना नहीं है। हालांकि, यह जोखिम है कि अध्ययन के दौरान आपके फेफड़ों के कैंसर की स्थिति में सुधार न हो या वह और भी बिगड़ सकती है।

यह ध्यान रखना महत्वपूर्ण है कि आपको होने वाले किसी भी दुष्प्रभाव का संबंध आपके द्वारा चुने गए उपचार से हो सकता है और यह इस अध्ययन में भाग लेने का परिणाम नहीं है। यह अध्ययन पूरी तरह से अवलोकन पर आधारित है और इसमें केवल आपके चिकित्सक द्वारा प्रदान की गई आपकी नियमित चिकित्सा संबंधी जानकारी दर्ज की जाएगी। साथ ही, चूंकि यह अध्ययन हस्तक्षेप रहित है, इसलिए इससे आपके चिकित्सक द्वारा आपके उपचार के प्रबंधन के तरीके में कोई बदलाव नहीं आएगा।

जोखिमों के बारे में अधिक जानने के लिए, "रोगियों के लिए अतिरिक्त जानकारी" में दी गई अतिरिक्त जोखिम जानकारी देखें।

7 क्या कोई अन्य बातें या जोखिम हैं जिनके बारे में मुझे जानना आवश्यक है?

विशेष चेतावनियाँ

- डूर्वालुमाब प्रतिरक्षा संबंधी दुष्प्रभाव पैदा कर सकता है जो फेफड़े, यकृत, आंतों, गुर्दे, हार्मोन ग्रंथियों, त्वचा, हृदय या तंत्रिका तंत्र जैसे अंगों को प्रभावित कर सकते हैं।
- ये प्रतिक्रियाएं उपचार के दौरान या उपचार बंद होने के बाद भी हो सकती हैं।
- कुछ दुष्प्रभाव शुरुआती उपचार न मिलने पर गंभीर हो सकते हैं।
- यदि आपको सांस लेने में कठिनाई, लगातार दस्त, त्वचा/आंखों का पीला पड़ना, अत्यधिक थकान, सीने में दर्द, भ्रम या गंभीर चकत्ते जैसे नए या बिगड़ते लक्षण महसूस हों, तो आपको तुरंत अपने चिकित्सक को सूचित करना चाहिए।

अन्य दवाइयां, खाद्य पदार्थ और पेय पदार्थ

- आपको अपने चिकित्सक को उन सभी दवाओं के बारे में बताना चाहिए जो आप ले रहे हैं, जिनमें चिकित्सक के पर्चे पर मिलने वाली दवाएं, बिना पर्चे के मिलने वाली दवाएं, हर्बल उत्पाद और सप्लीमेंट शामिल हैं।
- कुछ दवाओं (विशेष रूप से स्टेरॉयड या प्रतिरक्षा प्रणाली को प्रभावित करने वाली दवाएं) के लिए डूर्वालुमाब लेते समय चिकित्सकीय देखरेख की आवश्यकता हो सकती है।

- अपने चिकित्सक से सलाह लिए बिना कोई भी नई दवा शुरू न करें।
- खाने-पीने पर कोई विशेष प्रतिबंध नहीं है, लेकिन उपचार के दौरान आपको अपने चिकित्सक की आहार संबंधी सलाह का पालन करना चाहिए।

वाहन चलाना, मशीनरी, खेल और गतिविधियाँ

- ड्रॉलुमाब से थकान, चक्कर आना या कमजोरी हो सकती है।
- यदि आप अस्वस्थ, थके हुए या चक्कर महसूस करते हैं, तो आपको वाहन चलाने, मशीनरी चलाने या पूरी सतर्कता की आवश्यकता वाली गतिविधियों को करने से बचना चाहिए।
- खेलों या गतिविधियों पर कोई विशेष प्रतिबंध नहीं है, लेकिन आपको अपनी स्थिति और समग्र स्वास्थ्य के आधार पर अपने चिकित्सक की सलाह का पालन करना चाहिए।

गर्भावस्था, गर्भनिरोध और स्तनपान

क्योंकि अजन्मे बच्चे या शिशु पर ड्रॉलुमाब के प्रभावों के बारे में जानकारी नहीं है, इसलिए आपको (या यदि आप पुरुष हैं तो आपकी महिला साथी को) अध्ययन के दौरान गर्भवती नहीं होना चाहिए या बच्चे को स्तनपान नहीं कराना चाहिए।

अध्ययन में शामिल चिकित्सक आपसे गर्भनिरोध के स्वीकार्य तरीकों पर चर्चा कर सकते हैं।

महिला रोगियों के लिए:

यदि आप गर्भवती हो जाती हैं, तो आपको अध्ययन में शामिल चिकित्सक को तुरंत सूचित करना होगा। आपको अपने अध्ययन चिकित्सक से बात करने तक अध्ययन की दवा का सेवन तुरंत बंद करना होगा। आपसे आपके और आपके बच्चे के बारे में जानकारी देने के लिए कहा जाएगा। इसमें आपके बच्चे के स्वास्थ्य और विकास की निगरानी करने की अनुमति देने के लिए एक अलग सहमति पत्र शामिल हो सकता है।

जिन पुरुष रोगियों की पत्नियां गर्भवती हो जाती हैं:

यदि आपकी साथी गर्भवती हो जाती है, तो आपको तुरंत अध्ययन में शामिल चिकित्सक को सूचित करना होगा। आपकी साथी से एक अलग सहमति पत्र के तहत, उनके स्वास्थ्य और आपके बच्चे के स्वास्थ्य के बारे में जानकारी मांगी जाएगी।

उपवास

इस अध्ययन में भाग लेने के लिए किसी विशेष उपवास की आवश्यकता नहीं है, जब तक कि आपके इलाज करने वाले चिकित्सक द्वारा नियमित चिकित्सा परीक्षाओं या प्रक्रियाओं के लिए ऐसा करने की सलाह न दी जाए।

टीकाकरण

- कोई भी टीका लगवाने से पहले अपने चिकित्सक को सूचित करें।
- डूर्वालुमाब के साथ उपचार के दौरान और उपचार के बाद कुछ समय तक, चिकित्सक की सलाह के अनुसार, जीवित टीकों से आमतौर पर बचना चाहिए।
- यदि आपके चिकित्सक द्वारा इसकी सलाह दी जाती है तो निष्क्रिय (गैर-जीवित) टीके दिए जा सकते हैं।

रक्तदान

आपको डूर्वालुमाब के उपचार के दौरान और अंतिम खुराक के बाद कुछ समय तक रक्त या रक्त उत्पाद दान नहीं करना चाहिए, जैसा कि आपके चिकित्सक ने सलाह दी है।

8 इसमें भाग लेने के संभावित लाभ क्या हैं?

इस अध्ययन से अध्ययन प्रायोजक को प्राप्त जानकारी भविष्य में फेफड़ों के कैंसर के रोगियों के बेहतर उपचार में सहायक हो सकती है।

यह निश्चित नहीं है कि अध्ययन में भाग लेने से आपको सीधे लाभ मिलेगा। हालाँकि, आपकी भागीदारी भविष्य में अन्य रोगियों को रोगों के बारे में जानकारी बढ़ाने और चिकित्सा देखभाल में सुधार करने में मदद कर सकती है। हमें नहीं पता कि इसमें भाग लेने से आपकी स्थिति में सुधार होगा या नहीं, लेकिन हमें उम्मीद है कि ऐसा होगा।

9 यदि अध्ययन के दौरान कुछ परिवर्तन हो जाए, जैसे कि नई जानकारी मिल जाए तो क्या होगा?

अध्ययन में कुछ बदलाव हो सकते हैं जिनके कारण आप अध्ययन में भाग लेना जारी रखने के बारे में अपना विचार बदल सकते/ती हैं। अगर कोई बदलाव होता है, तो हम आपको जल्द से जल्द सूचित करेंगे।

आप किसी भी समय अध्ययन छोड़ने का विकल्प चुन सकते/ती हैं। अधिक जानकारी के लिए नीचे अनुभाग 14 देखें।

अध्ययन चिकित्सक, यदि उन्हें लगता है कि यह आपके लिए सर्वोत्तम है, तो आपको अध्ययन से बाहर करने का विकल्प भी चुन सकते/ती हैं।

अध्ययन में आपकी भागीदारी तब भी रुक जाती है जब प्रायोजक; भारत स्वास्थ्य प्राधिकारी, आचार या नियामक एजेंसियां यह निर्णय लेती हैं कि अध्ययन को रोक दिया जाना चाहिए।

10 यदि अध्ययन के दौरान मुझे कोई नुकसान या चोट पहुंचती है तो क्या होगा?

चूंकि यह एक अवलोकन संबंधी अध्ययन है, इसलिए इसमें आपके चिकित्सक द्वारा प्रदान की जाने वाली नियमित चिकित्सा देखभाल के अलावा कोई प्रयोगात्मक उपचार या प्रक्रिया शामिल नहीं है। इसलिए, अध्ययन में भाग लेने से नुकसान या चोट लगने का जोखिम बेहद कम है। आपके चिकित्सक आपकी देखभाल और उपचार को पहले की तरह जारी रखेंगे। यदि आपको कोई चिंता है, तो आप आगे की सहायता के लिए अध्ययन टीम या अपने चिकित्सक से संपर्क कर सकते हैं।

यदि कोई आपात स्थिति हो, तो जितनी जल्दी हो सके अपने अध्ययन चिकित्सक से संपर्क करें। सभी प्रासंगिक संपर्क विवरण भाग III में पाए जा सकते हैं: "[रोगियों] के लिए अतिरिक्त जानकारी"।

यदि आप इस शोध अध्ययन के दौरान बीमार हो जाते हैं या घायल हो जाते हैं, तो आपको तुरंत अपने अध्ययन चिकित्सक को बताना चाहिए।

अध्ययन दवा परीक्षण या प्रक्रियाओं के कारण होने वाली चोटों को 'अनुसंधान चोटें' कहा जाता है। आपकी सामान्य चिकित्सा देखभाल या आपके फेफड़े के कैंसर के कारण होने वाली चोटें, अनुसंधान चोटें नहीं हैं।

यदि आपके पास चिकित्सा बीमा है, तो कृपया अपनी बीमा कंपनी से जांच लें कि इस शोध अध्ययन में भाग लेने से आपकी कवरेज प्रभावित नहीं होगी।

इस फॉर्म पर हस्ताक्षर करने से आप अपने किसी भी कानूनी अधिकार को नहीं छोड़ते हैं।

11 अध्ययन में एकत्रित मेरे डेटा का क्या होगा?

ए. कौन सा डेटा एकत्र किया जाता है?

अध्ययन करने के लिए, अध्ययन स्थल को आपकी पहचान से संबंधित जानकारी एकत्र और पंजीकृत करनी होगी, जैसे कि आपकी चिकित्सीय स्थिति और चिकित्सा इतिहास (इसमें आपके चिकित्सकों से प्राप्त जानकारी / आपके चिकित्सा रिकॉर्ड में उपलब्ध जानकारी शामिल हो सकती है), आपकी जीवनशैली, आपकी जनसांख्यिकी (आयु, लिंग, जातीय और नस्लीय पृष्ठभूमि), नैदानिक रसायन विज्ञान, रक्त विज्ञान, गुर्दा कार्य परीक्षण, यकृत कार्य परीक्षण, थायरॉइड स्तर, मूत्र विश्लेषण, हेपेटाइटिस बी और सी, एचआईवी, गर्भावस्था परीक्षण आदि के साथ-साथ आप किसी अन्य बीमारी के लिए जो दवाएं ले रहे हैं, उन्हें भी नोट किया जाएगा। इसके अलावा, ईसीजी और एमआरआई/पीईटी/सीटी जैसी इमेजिंग तकनीकों से प्राप्त डेटा भी एकत्र किया जाएगा। आपको जो उपचार दिया जाएगा, उस पर आपकी प्रतिक्रिया, दुष्प्रभाव या कोई भी असुविधा जो आपको हो सकती है, वह सब भी एकत्र किया जाएगा।

बी. मेरे डेटा की क्या आवश्यकता है?

प्रायोजक को डूर्वालुमाब के उपयोग पर विपणनोत्तर सुरक्षा साक्ष्य उत्पन्न करने के लिए आपके डेटा की आवश्यकता है ताकि भारतीय स्वास्थ्य प्राधिकरण के प्रति अनुमोदन के बाद की नियामक प्रतिबद्धता को पूरा किया जा सके। इसलिए, इस अध्ययन में योजनाबद्ध तरीके से और साथ ही दवा विकास कार्यक्रम के लिए आवश्यक संबंधित अनुसंधान गतिविधियों के भीतर डेटा का उपयोग किया जाएगा ताकि अध्ययन की जा रही बीमारी और उससे जुड़ी स्वास्थ्य समस्याओं को बेहतर ढंग से समझा जा सके। इनका उपयोग वैज्ञानिक पत्रिकाओं में शोध परिणामों को प्रकाशित करने या शैक्षिक उद्देश्यों के लिए भी किया जा सकता है।

सी. मेरे डेटा तक कौन पहुंच सकता है?

केवल अध्ययन स्थल पर ही आपका नाम और संपर्क विवरण अध्ययन चिकित्सक और अध्ययन टीम को उपलब्ध होगा। प्रायोजक की ओर से कार्य करने वाले और गोपनीयता के दायित्व से बंधे गैर-

चिकित्सा कर्मियों के साथ-साथ स्वास्थ्य अधिकारियों और आचार समितियों को भी इस डेटा तक केवल यह सत्यापित करने के लिए पहुँच दी जा सकती है कि अध्ययन कानूनी और गुणवत्ता संबंधी आवश्यकताओं के अनुपालन में किया गया है। जहां अनुमति हो, वहां आपके कुछ डेटा तक दूरस्थ रूप से भी पहुँच बनाई जा सकती है।

अध्ययन स्थल आपके डेटा को प्रायोजक के साथ साझा करेगा, लेकिन ऐसा केवल तभी किया जाएगा जब उन्हें कोडित कर दिया जाएगा (जिसका अर्थ है कि आपका नाम, संपर्क विवरण या स्वास्थ्य बीमा नंबर, कोड द्वारा प्रतिस्थापित कर दिया गया है)। कोडिंग के बारे में अधिक जानकारी के लिए, इस दस्तावेज़ के अंत में भाग III में विवरण देखें: "प्रायोजक के लिए अतिरिक्त जानकारी)।

प्रायोजक दवा विकास कार्यक्रम के प्रयोजनों के लिए आपके कोडित डेटा को अपने **अनुसंधान भागीदारों और सेवा प्रदाताओं** के साथ साझा कर सकता है।

अध्ययन के उचित संचालन और सटीक परिणामों को सुनिश्चित करने और दवा के विपणन की अनुमति प्राप्त करने के लिए, प्रायोजक आपके कोडित डेटा को प्राधिकारियों और संभवतः आचार समितियों के साथ साझा करेगा। इन्हें वैज्ञानिक पत्रिकाओं के साथ भी साझा किया जा सकता है, ताकि अध्ययन के परिणामों की समीक्षा स्वतंत्र वैज्ञानिकों द्वारा की जा सके और परिणामों की सटीकता सुनिश्चित की जा सके।

इनमें से किसी भी मामले में आपकी पहचान उजागर नहीं की जाएगी।

उपर्युक्त व्यक्तियों में से कुछ आपके देश के बाहर स्थित हो सकते हैं। यदि इस अन्य देश में आपके देश के समान व्यक्तिगत डेटा सुरक्षा मानक नहीं हैं, तो आपके डेटा की गोपनीयता की रक्षा और उसे बनाए रखने के लिए उपयुक्त सुरक्षा उपाय (जैसे अनुबंध और तकनीकी सुरक्षा उपाय) अपनाए जाएंगे, जैसा कि दस्तावेज़ के अंत में भाग III में आगे वर्णित है: "रोगियों के लिए अतिरिक्त जानकारी"।

यदि कोई अन्य संगठन अध्ययन दवा के विकास या व्यावसायीकरण का कार्यभार संभालता है, तो आपका कोडित डेटा उन्हें प्रेषित किया जा सकता है। तब उन्हें आपके डेटा की सुरक्षा उसी प्रकार करनी होगी जैसा कि यहाँ वर्णित है।

डी. मेरे संपर्क विवरण तक और किसे पहुँच हो सकती है और क्यों?

आपकी जीवित स्थिति के बारे में जानकारी प्राप्त करने के लिए आपका नाम या संपर्क विवरण सेवा प्रदाताओं के साथ साझा किया जा सकता है।

सेवा प्रदाताओं को आपका नाम या संपर्क विवरण गोपनीय रखना होगा और वे प्रायोजक के साथ आपकी पहचान बताने वाली कोई भी जानकारी साझा नहीं करेंगे।

ई. मेरा कोडित डेटा कब तक रखा जाएगा?

अध्ययन स्थल और प्रायोजक, अध्ययन की समाप्ति के बाद 15 वर्षों तक सभी अध्ययन डेटा को रखने के लिए बाध्य हैं, ताकि अध्ययन स्थल और प्रायोजक के कानूनी दायित्वों का पालन किया जा सके। आप www.astrazenecapersonaldataretention.com पर जाकर जान सकते हैं कि प्रायोजक आपकी व्यक्तिगत जानकारी कैसे रखता है। इसके बाद, आपका कोडित डेटा हटा दिया जाएगा या गुमनाम कर दिया जाएगा।

अनामीकरण के बारे में अधिक जानकारी के लिए, भाग 1 अनुभाग 11जी देखें: अनाम डेटा का क्या अर्थ है?

एफ. डेटा संरक्षण कानून के तहत मेरे अधिकार क्या हैं?

आपको यह समीक्षा करने का अधिकार है कि आपका कौन सा डेटा एकत्र किया गया है और उसका उपयोग किया जा रहा है; आप इस डेटा की एक प्रतिलिपि भी मांग सकते/ती हैं, इस डेटा के उपयोग पर प्रतिबंध लगाने के लिए कह सकते/ती हैं, या गलत डेटा को ठीक करने के लिए कह सकते हैं।

अध्ययन की वैज्ञानिक अखंडता सुनिश्चित करने के लिए, आप अध्ययन समाप्त होने तक कुछ डेटा की समीक्षा नहीं कर पाएंगे या इसकी एक प्रति प्राप्त नहीं कर पाएंगे।

इन सीमित अधिकारों का प्रयोग करने के लिए, कृपया अध्ययन चिकित्सक से संपर्क करें।

जी. अनामीकृत डेटा का क्या अर्थ है?

स्वास्थ्य अधिकारियों के साथ-साथ दवा कम्पनियों का मानना है कि नैदानिक अध्ययन के आंकड़ों तक पहुंच से नैदानिक विज्ञान और चिकित्सा ज्ञान में वृद्धि होती है और यह रोगियों और सार्वजनिक स्वास्थ्य के सर्वोत्तम हित में है, बशर्ते कि रोगी की गोपनीयता सुरक्षित रहे। इसलिए, प्रायोजक अध्ययन में एकत्रित आपके डेटा का एक अनाम सेट तैयार कर सकता है और उसे आंतरिक रूप से या अन्य शोधकर्ताओं के साथ साझा कर सकता है (उदाहरण के लिए, www.vivli.org पर)। इसका अर्थ यह है कि आपके कोडित डेटा से आपका रोगी कोड और साथ ही आपकी पहचान के लिए इस्तेमाल की जा सकने वाली अन्य जानकारी जैसे कि आपकी जन्मदिनांक आदि हटा दी जाएगी।

12 इसमें भाग लेने की लागत क्या है?

इस अध्ययन में भाग लेने पर आपको अपने चिकित्सक के साथ नियमित मुलाकातों से संबंधित लागतों के अलावा कुछ भी खर्च नहीं करना पड़ेगा। इस अध्ययन में भाग लेने के लिए आपको कोई भुगतान नहीं किया जाएगा। अध्ययन में प्रयुक्त दवा और प्रयोगशाला जांचों का खर्च अध्ययन के माध्यम से वहन नहीं किया जाएगा।

13 अध्ययन के बाद अधिक जानकारी कैसे प्राप्त करें?

परीक्षण परिणाम सारांश इस अध्ययन के परिणामों का संक्षिप्त और आसानी से समझने योग्य सारांश है। इन्हें अध्ययन में शामिल अंतिम रोगी के अंतिम साइट दौरे के 1 वर्ष के भीतर www.trialssummaries.com पर अपलोड कर दिया जाएगा। आप अपनी अध्ययन रिपोर्ट के परिणामों का सारांश उपलब्ध होने पर ईमेल द्वारा सूचना प्राप्त करने के लिए www.trialssummaries.com वेबसाइट पर कभी भी पंजीकरण कर सकते हैं। या यदि आपको दस्तावेज़ की मुद्रित प्रति की आवश्यकता है, तो कृपया अपने अध्ययन चिकित्सक को सूचित करें।

अध्ययन प्रोटोकॉल और परिणामों से संबंधित तकनीकी भाषा में जानकारी <http://astrazenecaclinicaltrials> और <http://www.clinicaltrials.gov> पर पोस्ट की जाएगी। इस अध्ययन का विवरण <http://ctri.nic.in> पर भी उपलब्ध है। इन वेबसाइटों में आपके बारे में कोई जानकारी नहीं है।

14 यदि मैं अध्ययन छोड़ना चाहूँ तो क्या होगा?

अध्ययन में आपकी भागीदारी स्वैच्छिक है, अर्थात आप किसी भी समय अपनी भागीदारी रोक सकते हैं। यदि आप अध्ययन दवा लेना बंद करना चाहते/ती हैं, संशोधित मुलाकात कार्यक्रम चाहते/ती हैं या अपनी भागीदारी रोकना चाहते/ती हैं, तो आपको अध्ययन चिकित्सक को बताना चाहिए और उपलब्ध विकल्पों पर चर्चा करनी चाहिए।

यदि आप अध्ययन में भाग लेना बंद कर देते/ती हैं, तो ध्यान रखें कि यह एक "अध्ययन विच्छेदन" है, और व्यक्तिगत डेटा के प्रसंस्करण के लिए सहमति की वापसी / आपत्ति नहीं है, अध्ययन चिकित्सक आपके डेटा का संग्रह बंद कर देगा, लेकिन आपके पहले से एकत्र किए गए डेटा को रखा जाएगा और अध्ययन की वैधता की गारंटी देने और कानून द्वारा अनुमत नियामक आवश्यकताओं का अनुपालन करने के लिए उपयोग किया जाएगा। इसके बाद, अध्ययन चिकित्सक आपको आपकी भलाई की जाँच के लिए अध्ययन समाप्ति परीक्षा के लिए आमंत्रित करेंगे। यदि आप निर्धारित मुलाकात में उपस्थित नहीं होते हैं, तो अध्ययन चिकित्सक आपसे संपर्क करने का प्रयास करेंगे। अध्ययन के परिणामों के लिए यह महत्वपूर्ण है। यह अनिवार्य नहीं है, लेकिन अध्ययन के लिए यह उपयोगी होगा यदि आप अपने अध्ययन चिकित्सक को बताएं कि आप अपनी भागीदारी क्यों रोकना चाहते हैं, विशेष रूप से यदि आपने असुविधा का अनुभव किया है।

हम आपकी मूल सहमति के अनुसार आपके डेटा और एकत्रित नमूने का उपयोग जारी रखेंगे, जब तक कि आप यह न चाहें कि अध्ययन छोड़ने के बाद आपके डेटा का उपयोग न किया जाए। ऐसे मामले में, आपको अध्ययन करने वाले चिकित्सक को सूचित करना होगा, लेकिन आपके द्वारा पहले एकत्र किया गया कोडित डेटा नैदानिक नियमों के अनुसार सुरक्षित रखा जाएगा।

15 मेरे किसी भी प्रश्न का उत्तर कौन दे सकता है?

याद रखें, कोई भी सवाल बेतुका नहीं होता! बेझिझक कभी भी पूछ सकते हैं! इस अध्ययन में भाग लेने का निर्णय लेने से पहले पूरी जानकारी प्राप्त करना आपका अधिकार है। आप भाग III: "रोगियों के लिए अतिरिक्त जानकारी" में दिए गए पते पर किसी भी समय अध्ययन चिकित्सक से संपर्क कर सकते/ती हैं।

भाग II: सहमति पत्र

डी9106आर00007, डूर्वालुमाब

रिसेक्टेबल (हटाने योग्य) गैर-छोटे कोशिका वाले फेफड़े का कैंसर (एनएससीएलसी) से पीड़ित भारतीय वयस्क रोगी में डूर्वालुमाब की सुरक्षा का आकलन करने के लिए एक संभावित, अवलोकन संबंधी, बहुकेंद्रीय, विपणन-पश्चात निगरानी अध्ययन।

व्यक्तिपात्र के प्रारंभिक:			
व्यक्तिपात्र का नाम:			
जन्म दिनांक (डीडी-एमएम-वाईवाईवाई):		उम्र (साल):	
व्यक्तिपात्र का पता:			
योग्यता:			
व्यवसाय: (कृपया उपयुक्त विकल्प पर निशान लगाएं)	विद्यार्थी ☐ स्वरोजगार ☐ सेवा ☐ गृहिणी ☐ अन्य _____		
व्यक्तिपात्र की वार्षिक आय:			
नामांकित व्यक्ति/व्यक्तियों का नाम एवं पता तथा व्यक्तिपात्र से उनका संबंध:			

कृपया इस सहमति पत्र पर तभी हस्ताक्षर करें जब आपको प्रश्न पूछने का अवसर मिल चुका हो और आपके सभी प्रश्नों के संतोषजनक उत्तर प्राप्त हो चुके हों। इस पृष्ठ पर हस्ताक्षर करके, आप निम्नलिखित कथनों की पुष्टि करेंगे:

क्र.सं.	इन कथनों के प्रति अपनी सहमति की पुष्टि करने के लिए कृपया निम्नलिखित प्रत्येक कथन के सामने अपने प्रारंभिक (संक्षिप्त हस्ताक्षर या हस्ताक्षर) या अंगूठे का निशान (जैसा लागू हो) प्रदान करें।	
(i)	मैं पुष्टि करता/करती हूँ कि मैंने उपरोक्त अध्ययन के लिए दिनांक, संस्करण संख्या के अध्ययन संबंधी सूचना और सहमति प्रपत्र को पढ़ और समझ लिया है तथा मुझे प्रश्न पूछने का अवसर मिला है।	[]
(ii)	मैं समझता/समझती हूँ कि इस अध्ययन में मेरी भागीदारी स्वैच्छिक है और मैं बिना कोई कारण बताए, किसी भी समय इससे हटने के लिए स्वतंत्र हूँ, और इससे मेरे चिकित्सा अधिकारों या कानूनी अधिकारों पर कोई प्रभाव नहीं पड़ेगा।	[]
(iii)	मैं समझता/समझती हूँ कि नैदानिक परीक्षण के प्रायोजक, प्रायोजक की ओर से काम करने वाले अन्य लोग, नैतिकता समिति और नियामक प्राधिकरणों को वर्तमान अध्ययन और इससे संबंधित भविष्य में किए जाने वाले किसी भी शोध के संबंध में मेरे स्वास्थ्य रिकॉर्ड देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी, भले ही मैं परीक्षण से हट जाऊँ। मैं इस पहुँच के लिए सहमत हूँ। हालाँकि, मैं समझता/समझती हूँ कि मेरी पहचान किसी भी तीसरे पक्ष को दी गई या प्रकाशित की गई जानकारी में प्रकट नहीं की जाएगी।	[]
(iv)	मैं इस अध्ययन से प्राप्त किसी भी डेटा या परिणाम के उपयोग को प्रतिबंधित न करने के लिए सहमत हूँ, बशर्ते कि ऐसा उपयोग केवल वैज्ञानिक उद्देश्यों के लिए हो।	[]
(v)	मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूँ।	[]

हस्ताक्षरकर्ता/कानूनी रूप से स्वीकार्य प्रतिनिधि (एलएआर) के हस्ताक्षर (या अंगूठे का निशान) हस्ताक्षर की दिनांक

हस्ताक्षरकर्ता का नाम (जिस व्यक्ति या कानूनी प्रतिनिधि ने हस्ताक्षर किए हैं उसका नाम)

जहां एक व्यक्तिपात्र

सूचित सहमति देने में (उदाहरण के लिए, एक बेहोश व्यक्ति, एक नाबालिग, या गंभीर मानसिक बीमारी या विकलांगता से पीड़ित व्यक्ति।) सक्षम व्यक्ति, कानूनी रूप से स्वीकार्य प्रतिनिधि से हो सकता है (कानूनी रूप से स्वीकार्य प्रतिनिधि वह व्यक्ति होता है जो भारत के कानून के अनुसार रोगी में किसी हस्तक्षेप के लिए सहमति देने या उसे अधिकृत करने में सक्षम हो)।

व्यक्तिपात्र के साथ कानूनी रूप से स्वीकार्य प्रतिनिधि का संबंध

अन्वेषक के हस्ताक्षर

हस्ताक्षर की दिनांक

अध्ययन अन्वेषक का नाम

यदि व्यक्तिपात्र या उसका कानूनी रूप से मान्य प्रतिनिधि पढ़ने/लिखने में असमर्थ है, तो पूरी सूचित सहमति प्रक्रिया के दौरान एक निष्पक्ष गवाह उपस्थित होना चाहिए, जिसे सहमति पत्र पर अपने हस्ताक्षर करने होंगे।

निष्पक्ष गवाह वह व्यक्ति होता है जो परीक्षण से स्वतंत्र होता है, जिस पर परीक्षण से जुड़े लोगों का अनुचित प्रभाव नहीं पड़ सकता है, जो सूचित सहमति प्रक्रिया में उपस्थित होता है यदि व्यक्तिपात्र या व्यक्तिपात्र का कानूनी रूप से स्वीकार्य प्रतिनिधि पढ़ नहीं सकता है, और जो सूचित सहमति प्रपत्र और व्यक्तिपात्र को दी गई किसी भी अन्य लिखित जानकारी को पढ़ता है।

निष्पक्ष गवाह के हस्ताक्षर

हस्ताक्षर की दिनांक

निष्पक्ष गवाह का नाम

रोगी सूचना पत्र (वयस्क अध्ययन प्रतिभागी मास्टर सूचना) और विधिवत भरा हुआ सूचित सहमति प्रपत्र की प्रतिलिपि को व्यक्तिपात्र या उसके कानूनी रूप से स्वीकार्य प्रतिनिधि को सौंप दिया जाएगा।

भाग III: रोगियों के लिए अतिरिक्त जानकारी

1 सम्पर्क करने का विवरण

अध्ययन चिकित्सक	अध्ययन समन्वयक (जैसे अध्ययन के लिए नियुक्त नर्स)
फ़ोन नंबर	फ़ोन नंबर
पता	पता
ईमेल पता	ईमेल पता

ईसी सदस्य सचिव का नाम	
ईसी सदस्य सचिव का फ़ोन नंबर	

2 मुलाकातों और परीक्षण/प्रक्रियाओं की विस्तृत सूची

वर्तमान अध्ययन में कोई प्रोटोकॉल अनिवार्य नहीं है, इसलिए आपके चल रहे उपचार के अलावा आपकी कोई अलग जांच नहीं की जाएगी। हम डूर्वालुमाब की पहली खुराक से लेकर डूर्वालुमाब की अंतिम खुराक की दिनांक + 90 दिन या बाद की कैंसर-रोधी चिकित्सा की पहली खुराक की दिनांक तक, सहमति वापस लेने, फॉलो-अप में कमी या मृत्यु, इनमें से जो भी पहले हो, तक आपके स्वास्थ्य के बारे में जानकारी एकत्र करेंगे। अध्ययन के दौरान, हम आपके द्वारा अनुभव किए जाने वाले किसी भी दुष्प्रभाव को रिकॉर्ड करेंगे, जैसे कि थकान, मांसपेशियों और हड्डियों में दर्द, कब्ज, भूख में कमी, मतली, परिधीय शोफ, मूत्र पथ में संक्रमण, या कोई भी अज्ञात दुष्प्रभाव। चिकित्सक रोगी की स्थिति के आधार पर परामर्श के लिए मुलाकातों की संख्या और समय तय करेंगे। अध्ययन की शुरुआत में

और पूरे अध्ययन के दौरान रोगी की आयु, रोग की स्थिति, परीक्षण परिणाम, डूर्वालुमाब की खुराक और अन्य उपचारों जैसी जानकारी एकत्र की जाएगी।

3 विस्तृत अध्ययन परीक्षण और प्रक्रिया अनुसूचियां

यहां बताया गया है कि आपको वहां क्या देखने को मिलेगा।

आधारभूत/स्क्रीनिंग

प्रारंभिक चरण में, अध्ययन के लिए आपकी पात्रता का आकलन करने के लिए आपकी प्रारंभिक प्रक्रियाएं की जाएंगी। इसमें सूचित सहमति प्रपत्र पर हस्ताक्षर करना, समावेशन/बहिष्करण मानदंडों का सत्यापन करना और जनसांख्यिकीय जानकारी, चिकित्सा इतिहास और आपके द्वारा ली जा रही दवाओं के बारे में विवरण दर्ज करना शामिल है। रोगी की शारीरिक जांच, महत्वपूर्ण संकेतों की जांच, ईसीओजी प्रदर्शन स्थिति मूल्यांकन और आधारभूत नैदानिक और रेडियोलॉजिकल इमेजिंग की जाएगी। प्रारंभिक ट्यूमर माप को आर ईसीआईएसटी 1.1 दिशानिर्देशों के अनुसार प्रलेखित किया जाएगा, जो उपचार की प्रतिक्रिया के आकलन के लिए नियमों का एक मानकीकृत सेट प्रदान करते हैं, और आवश्यक प्रयोगशाला मूल्यांकन आयोजित किए जाएंगे।

नियोएडजुवेंट चिकित्सा अवधि

नियमित मूल्यांकन में साथ में ली जा रही दवाओं का रिकॉर्ड रखना, शारीरिक परीक्षण रिकॉर्ड करना और महत्वपूर्ण संकेतों की जांच करना शामिल होगा। उपचार की प्रतिक्रिया पर नज़र रखने के लिए नैदानिक और रेडियोलॉजिकल मूल्यांकन किए जाएंगे, और प्रयोगशाला मूल्यांकन चिकित्सा से संबंधित परिवर्तनों को ट्रैक करने में मदद करेंगे। किसी भी प्रतिकूल घटना (एई) या गंभीर प्रतिकूल घटना (एसएई) को सावधानीपूर्वक प्रलेखित किया जाएगा।

सर्जरी से पूर्व का चरण

सर्जरी की तैयारी के दौरान, आवश्यकता पड़ने पर पात्रता मानदंडों की दोबारा जांच की जा सकती है। साथ में ली जाने वाली दवाओं और नैदानिक/रेडियोलॉजिकल आकलन, जिनमें आर ईसीआईएसटी 1.1 मूल्यांकन भी शामिल हैं, के अद्यतन रिकॉर्ड दर्ज किए जाएंगे। शल्यक्रिया पूर्व चरण में यह सुनिश्चित करने पर ध्यान केंद्रित किया जाएगा कि रोगी शल्यक्रिया के लिए सर्वोत्तम रूप से तैयार हो। इस चरण के दौरान एई और एसएई की सुरक्षा निगरानी जारी रहेगी।

शल्यक्रिया चरण

सर्जरी चरण में ट्यूमर को हटाने के लिए वास्तविक शल्यक्रिया की जाती है। इस दौरान, आवश्यक शल्यक्रियाकालीन दवाओं का विवरण दर्ज किया जाएगा। सुरक्षा निगरानी का मुख्य उद्देश्य शल्यक्रिया से संबंधित एई या एसएई की पहचान करना होगा।

सर्जरी के बाद का चरण

सर्जरी के बाद, रोगियों की स्वास्थ्य निगरानी की जाएगी ताकि उनकी स्वास्थ्य लाभ और सर्जिकल परिणामों का आकलन किया जा सके। इसमें साथ में ली जा रही दवाओं को रिकॉर्ड करना, शारीरिक परीक्षण करना और महत्वपूर्ण संकेतों की जांच करना शामिल है। नैदानिक और रेडियोलॉजिकल आकलन शल्य चिकित्सा की सफलता और किसी भी अवशिष्ट बीमारी का मूल्यांकन करेंगे, जबकि आरईसीआईएसटी 1.1 मूल्यांकन और प्रयोगशाला परीक्षण आगे की जानकारी प्रदान करेंगे। इस चरण के दौरान एई और एसएई की निगरानी करना प्राथमिकता बनी रहेगी।

डूवालुमाब मोनोचिकित्सा अवधि

सहायक चिकित्सा अवधि का उद्देश्य रोग की पुनरावृत्ति के जोखिम को कम करना है। रोगियों को नियमित मूल्यांकन के साथ उपचार मिलता रहेगा, जिसमें साथ में ली जा रही दवाओं पर अपडेट, शारीरिक परीक्षण, नैदानिक और रेडियोलॉजिकल आकलन, आरईसीआईएसटी 1.1 ट्यूमर मूल्यांकन और प्रयोगशाला निगरानी शामिल हैं। किसी भी एई और एसएई का विस्तृत दस्तावेजीकरण करते हुए सुरक्षा निगरानी अत्यंत महत्वपूर्ण बनी हुई है।

अनुवर्ती निगरानी अवधि

अनुवर्ती अवधि के दौरान, रोगियों की दीर्घकालिक निगरानी की जाएगी ताकि किसी भी प्रकार की पुनरावृत्ति या विलंबित जटिलताओं का पता लगाया जा सके। नैदानिक और रेडियोलॉजिकल आकलन, साथ ही आरईसीआईएसटी 1.1 मूल्यांकन जारी रहेंगे। साथ में दी जाने वाली दवाओं के बारे में अपडेट और एई /एसएई की रिपोर्टिंग भी इस चरण के दौरान उपचार की अंतिम खुराक के 90 दिन बाद तक या किसी अन्य उपचार के शुरू होने के पहले दिन तक, सहमति वापस लेने, फॉलो-अप में कमी या मृत्यु होने तक, जो भी पहले हो, की जाएगी।

प्रत्येक मुलाकात के दौरान क्या उम्मीद करनी है, इसका विवरण देने वाली तालिका:

डेटा संग्रह और प्रविष्टि	आधारभूत/स्क्रीनिंग	नियोएडजुवेंट चिकित्सा अवधि	सर्जरी से पहले	सर्जरी	सर्जरी के बाद	सहायक चिकित्सा अवधि	अनुवर्ती कार्रवाई अवधि
सूचित सहमति	X						
स्क्रीनिंग	X		X				
गर्भावस्था परीक्षण ^ए	X						
रोगी की जनसांख्यिकी और चिकित्सा इतिहास	X				X		
रोग का चिकित्सीय इतिहास और प्रारंभिक रोग स्थिति (जिसमें ईजीएफआर/एएलके स्थिति शामिल है)	X						
आप जो दवा ले रहे हैं।	X	X	X	X	X	X	X
शारीरिक परीक्षण और महत्वपूर्ण संकेत	X	X				X	X
ईसीओजी प्रदर्शन स्थिति	X						X
नैदानिक और रेडियोलॉजिकल मूल्यांकन	X	X	X		X	X	X
आरईसीआईएसटी 1.1 मूल्यांकन	X		X		X	X	X
ईसीजी	जैसा कि चिकित्सकीय रूप से संकेत दिया गया है						
प्रयोगशाला मूल्यांकन	X	X				X	X
एनएससीएलसी उपचार संबंधी विवरण		X				X	X
प्रतिकूल प्रतिकूल प्रभाव आई और एसआई की रिपोर्टिंग	X	X	X	X	X	X	X

ए केवल प्रजनन क्षमता वाली महिलाएं

4 जोखिमों, दुष्प्रभावों और असुविधाओं की सूची

चूंकि यह एक अवलोकन संबंधी अध्ययन है, इसलिए इस अध्ययन में भाग लेने से सीधे तौर पर जुड़े कोई दुष्प्रभाव या जोखिम नहीं हैं।

डूर्वालुमाब एक प्रतिरक्षा चिकित्सा है जो प्रतिरक्षा प्रणाली को कैंसर से लड़ने में मदद करती है। चूंकि यह प्रतिरक्षा प्रणाली को सक्रिय करती है, इसलिए कभी-कभी यह प्रतिरक्षा प्रणाली के सामान्य अंगों को भी प्रभावित कर सकती है।

सामान्य दुष्प्रभाव

- लाल रक्त कोशिकाओं की संख्या में कमी (रक्ताल्पता)
- मतली
- कब्ज
- थकान
- मांसपेशियों या हड्डियों में दर्द
- त्वचा पर लाल चकत्ते

प्रतिरक्षा संबंधी संभावित दुष्प्रभाव

डूर्वालुमाब विभिन्न अंगों में सूजन पैदा कर सकता है, जिनमें शामिल हैं:

- फेफड़े (खांसी, सांस लेने में तकलीफ)
- यकृत (त्वचा/आंखों का पीला पड़ना, यकृत संबंधी असामान्य परीक्षण)
- आंतें (दस्त, पेट दर्द)
- हार्मोन ग्रंथियां (थायराइड या एड्रिनल ग्रंथियों की समस्याएं जिनके कारण थकान, चक्कर आना या वजन में बदलाव हो सकता है)
- गुर्दे
- त्वचा

ये दुष्प्रभाव उपचार के दौरान या बाद में हो सकते हैं। यदि इनका जल्दी पता चल जाए तो अधिकतर का इलाज संभव है, लेकिन कुछ गंभीर हो सकते हैं और इनके लिए अस्पताल में भर्ती होने या उपचार रोकने की आवश्यकता पड़ सकती है। दुर्लभ मामलों में, गंभीर जटिलताएं जानलेवा भी हो सकती हैं।

अन्य उपचारों के दुष्प्रभाव

यदि आप नियमित उपचार के हिस्से के रूप में कीमोचिकित्सा, सर्जरी या विकिरण चिकित्सा प्राप्त करते हैं, तो इन उपचारों से मतली, बालों का झड़ना, संक्रमण, रक्तस्राव, दर्द, सांस लेने में तकलीफ या थकान जैसे अतिरिक्त दुष्प्रभाव हो सकते हैं। आपके चिकित्सक इन जोखिमों के बारे में अलग से जानकारी देंगे।

नियमित जांचों के जोखिम

नियमित रक्त जांच से हल्का दर्द या नील पड़ सकता है। इसीजी से त्वचा में हल्की जलन हो सकती है। इन प्रक्रियाओं से कोई बड़ा जोखिम होने की संभावना नहीं है।

5 एकत्रित की गई व्यक्तिगत जानकारी की पूरी सूची

भाग I खंड 11क में वर्णित सभी जानकारी अध्ययन के दौरान एकत्रित की जाएगी।

6 शब्दकोष

आपका कोडित डेटा	अध्ययन स्थल पर आपके नाम और संपर्क विवरण सहित एकत्रित सभी डेटा को एक कोड द्वारा प्रतिस्थापित कर दिया गया है। यह कार्य अध्ययन चिकित्सक द्वारा किया जाता है जो आपकी सुरक्षा और गोपनीयता सुनिश्चित करने के लिए आपके नाम/संपर्क विवरण और कोड के बीच संबंध बनाए रखता है। यह अध्ययन कार्य चिकित्सक द्वारा किया गया है जो आपकी सुरक्षा और सुरक्षा सुनिश्चित करने के लिए आपका नाम/संपर्क विवरण और कोड के बीच संबंध बनाए रखता है।
प्रायोजक विवरण	प्रायोजक: एस्ट्राजेनेका फार्मा इंडिया लिमिटेड। प्रायोजक के पास नैदानिक अध्ययन की समग्र जिम्मेदारी होती है।

अध्ययन स्थल विवरण	वह स्थान जहां नैदानिक अध्ययन हो रहा है और जहां आपको नियोजित मुलाकातों के लिए जाना होगा।
स्वास्थ्य अधिकारी	वे प्राधिकारी जो अध्ययन की निगरानी करते हैं, जो दवा के व्यावसायीकरण को मंजूरी देते हैं या जो आपके देश में या अन्य देशों में प्रतिकूल घटनाओं की रिपोर्टिंग प्राप्त करते हैं।
अनुसंधान भागीदार	कोई भी संगठन जो औषधि विकास कार्यक्रम या भविष्य के अनुसंधान के लिए प्रायोजक के साथ सहयोग करता है।
सेवा प्रदाताओं	कोई भी संगठन जो प्रायोजक के साथ अनुबंध द्वारा बंधा हुआ है, जो प्रायोजक के सख्त निर्देशों के तहत उसकी ओर से गतिविधियों का संचालन कर सकता है। इसमें औरकथित "अनुबंधित अनुसंधान संगठन" (सीआरओ) और आईटी कंपनियां शामिल हो सकती हैं जो नैदानिक डेटा होस्ट करती हैं या नई प्रणालियों और सेवाओं को विकसित करने सहित आईटी सेवाएं प्रदान करती हैं।

सुरक्षा	अध्ययन के दौरान और उसके बाद कोडित डेटा की सुरक्षा के लिए उचित सुरक्षा उपाय लागू किए जाएंगे और इसमें निम्नलिखित शामिल हो सकते हैं: कोडित डेटा तक पहुंच गोपनीयता दायित्वों के अधीन विशिष्ट व्यक्तियों तक सीमित होगी (जिसमें व्यक्तियों की पुनः पहचान करने/नैदानिक डेटा को डिकोड करने का प्रयास न करने का दायित्व भी शामिल है)। कोडित डेटा को डेटा परिवर्तन, हानि और अनधिकृत पहुंच से बचने के लिए सुरक्षा उपायों के साथ संरक्षित किया जाएगा और आगे भी पहचान-रहित करने वाली तकनीकों को लागू किया जा सकता है। प्रत्येक वैज्ञानिक अनुसंधान से जुड़े गोपनीयता जोखिमों (यदि कोई हों) की पहचान करने और उन्हें कम करने के लिए डेटा संरक्षण प्रभाव मूल्यांकन (डीपीआईए) लागू किया जाएगा। जब लागू कानून द्वारा आवश्यक हो, तो वैज्ञानिक अनुसंधान आचार समितियों के अनुमोदन के अधीन होता है। कोडित डेटा को प्रत्यक्ष विपणन उद्देश्यों या अन्य उद्देश्यों के लिए साझा नहीं किया जाएगा जो कानूनी कर्तव्य नहीं हैं या लागू डेटा संरक्षण कानून के अनुसार वैज्ञानिक अनुसंधान नहीं माने जाते हैं। विशेष रूप से, इसका उपयोग भविष्य में आपके लिए उपलब्ध सेवाओं, जैसे कि बीमा, के बारे में निर्णय लेने के लिए नहीं किया जाएगा।
सुरक्षा उपाय: अन्य देशों में मेरा डेटा कैसे सुरक्षित है?	आपके डेटा का प्रसंस्करण अध्ययन स्थल पर शुरू होता है। फिर आपके डेटा को सत्यापन और परिणामों की गणना के लिए कई डेटा विशेषज्ञों को हस्तांतरित किया जाएगा। आपके डेटा को कोडित करने के अलावा, आपका डेटा उच्च मानक तकनीकी सुरक्षा साधनों जैसे कि मजबूत पहुंच नियंत्रण और एन्क्रिप्शन द्वारा भी सुरक्षित है।

	प्रायोजक समूह के भीतर, आपका कोडित डेटा बाध्यकारी कॉर्पोरेट नियमों (बीसीआर) द्वारा सुरक्षित है। प्रायोजकों के बीसीआर के बारे में अधिक जानकारी आप यहाँ पा सकते हैं: www.astrazenecabindingcorporaterules.com आप अपने अध्ययन चिकित्सक से पूछकर अधिक जानकारी के साथ-साथ इन उपायों की एक प्रति भी प्राप्त कर सकते हैं।
प्रतिबंधित अधिकार	कृपया ध्यान दें कि जीडीपीआर और यूके गोपनीयता कानून द्वारा प्रदत्त डेटा को नष्ट करवाने का अधिकार (अर्थात, भूल जाने का अधिकार) ऐसे अध्ययनों पर लागू नहीं होता है।
वैज्ञानिक अनुसंधान	वैज्ञानिक अनुसंधान में तकनीकी विकास और प्रदर्शन, मौलिक अनुसंधान, अनुप्रयुक्त अनुसंधान और निजी तौर पर वित्तपोषित अनुसंधान के साथ-साथ सार्वजनिक स्वास्थ्य के क्षेत्र में सार्वजनिक हित में किए गए अध्ययन शामिल हैं। इसका अर्थ यह है कि हम डेटा का उपयोग बीमारियों के इलाज के लिए नई दवाएं, चिकित्सा उपकरण, नैदानिक उत्पाद, उपकरण और/या अन्य उपचार बनाने के बारे में अपनी समझ को बढ़ाने के लिए कर सकते हैं। हम इस डेटा का उपयोग भविष्य के नैदानिक अध्ययनों, सेवाओं और दवाओं के डिजाइन और निष्पादन में सुधार करने, परिणाम अनुसंधान गतिविधियों के लिए और मूल्य निर्धारण और प्रतिपूर्ति गतिविधियों में सहायता के लिए भी कर सकते हैं।

वैज्ञानिक डेटाबेस में जमा करें	अधिक प्रभावशाली अनुसंधान करने के लिए, शोधकर्ताओं के लिए डेटा को एक या अधिक वैज्ञानिक डेटाबेस में रखकर साझा करना सहायक होता है। इसके बाद शोधकर्ता कई शोध परियोजनाओं से एकत्रित आंकड़ों का अध्ययन कर सकते हैं और स्वास्थ्य एवं रोग के बारे में और भी अधिक जानकारी प्राप्त कर सकते हैं। अनुमोदित वैज्ञानिक अनुसंधान परियोजना वाले शोधकर्ता आपके कोडित डेटा के साथ-साथ कई अन्य लोगों के डेटा को भी देख और उपयोग कर सकते हैं। आपका नाम और अन्य जानकारी जिससे आपकी सीधे पहचान हो सकती है (जैसे पता या सामाजिक सुरक्षा संख्या) कभी भी ऐसे वैज्ञानिक डेटाबेस में नहीं डाली जाएगी। शोधकर्ताओं का हमेशा यह कर्तव्य होगा कि वे आपकी गोपनीयता की रक्षा करें और आपकी जानकारी को गोपनीय रखें।
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CORE STUDY ICD IN ENGLISH VERSION NO. 1.0 DATED
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2026

অধ্যয়ন সংক্রান্ত তথ্য এবং অবহিত সম্মতি ফর্ম

অধ্যয়ন কোড:	D9106R00007	সাইট নং:	
স্পনসর:	অ্যাস্ট্রাজেনেকা ফার্মা ইন্ডিয়া লিমিটেড	পরীক্ষাধীন ব্যক্তির আইডি:	
প্রধান তদন্তকারী:			
অধ্যয়নের শিরোনাম:	অপ্রোপচারযোগ্য নন-স্মল সেল ফুসফুস ক্যান্সারে (এনএসসিএলসি) আক্রান্ত ভারতীয় প্রাপ্তবয়স্ক রোগীদের ক্ষেত্রে ডুরভালুম্যাব-এর নিরাপত্তা মূল্যায়নের লক্ষ্যে একটি সম্ভাব্য, পর্যবেক্ষণমূলক, বহু-কেন্দ্রিক ও বাজারকরণ-পরবর্তী নজরদারি অধ্যয়ন		

এই নথিতে [3]টি অংশ রয়েছে:

অংশ I: ক্লিনিক্যাল অধ্যয়নে অংশগ্রহণের সিদ্ধান্ত নেওয়ার জন্য প্রয়োজনীয় "অধ্যয়ন সংক্রান্ত তথ্য",

অংশ II: আপনার "সম্মতি ফর্ম" যা আপনি কী বিষয়ে সম্মত হচ্ছেন তার সারসংক্ষেপ প্রদান করে,

অংশ III: "রোগীদের জন্য অতিরিক্ত তথ্য" বিভাগে সম্পূর্ণ তথ্য, যার মধ্যে একটি শব্দকোষ বা গ্লসারি অন্তর্ভুক্ত রয়েছে।

অংশ I: অধ্যয়ন সংক্রান্ত তথ্য

D9106R00007, ডুরভালুম্যাব-এর বাজারকরণ-পরবর্তী নিরাপত্তা বিষয়ক অধ্যয়ন

অপ্রোপচারযোগ্য ফুসফুসের ক্যান্সারে আক্রান্ত ভারতীয় প্রাপ্তবয়স্কদের ক্ষেত্রে ডুরভালুম্যাব-এর নিরাপত্তা মূল্যায়নের জন্য একটি পর্যবেক্ষণমূলক অধ্যয়ন

প্রিয় মহোদয়া/মহোদয়,

আপনাকে এই অধ্যয়নে অংশগ্রহণের আমন্ত্রণ জানানো হচ্ছে, কারণ সম্প্রতি আপনার অস্ত্রোপচারযোগ্য (অস্ত্রোপচারের মাধ্যমে অপসারণযোগ্য) নন-স্মল সেল লাং ক্যান্সার (এনএসসিএলসি) নামক এক ধরনের ফুসফুসের ক্যান্সার ধরা পড়েছে। আপনি প্রস্তাবিত চিকিৎসা পদ্ধতিটি গ্রহণ করেছেন যার মধ্যে অন্তর্ভুক্ত আছে অস্ত্রোপচারের পূর্ববর্তী চিকিৎসা হিসেবে কেমোথেরাপির সাথে ডুরভালুম্যাব-এর সম্মিলিত প্রয়োগ এবং পরবর্তীতে অস্ত্রোপচারের পর কেবল ডুরভালুম্যাব-এর মোনোথেরাপি। এই চিকিৎসাটি এমনভাবে সাজানো হয়েছে, যাতে এটি টিউমারের আকার ছোট করতে এবং ক্যান্সার পুনরায় ফিরে আসার ঝুঁকি কমাতে সহায়তা করে।

আমরা অস্ত্রোপচারযোগ্য এনএসসিএলসি-তে আক্রান্ত রোগীদের ক্ষেত্রে ডুরভালুম্যাব-এর নিরাপত্তা মূল্যায়নের উদ্দেশ্যে এই অধ্যয়নটি পরিচালনা করছি। বাজারকরণ-পরবর্তী এই অধ্যয়নে, আপনার চিকিৎসা আপনার চিকিৎসকের সিদ্ধান্ত অনুযায়ীই চলতে থাকবে এবং আমরা কেবল আপনার ডেটা সংগ্রহ করবো। এটিতে অংশগ্রহণের জন্য আপনার লিখিত সম্মতির প্রয়োজন হবে। আপনি এই অধ্যয়নে অংশগ্রহণ করবেন কিনা সেই বিষয়ে সিদ্ধান্ত নেওয়ার পূর্বে, অধ্যয়নটির বিস্তারিত বিষয়বস্তু সম্পর্কে আপনাকে ব্যাখ্যা প্রদান করা হবে।

এই অধ্যয়নের সামগ্রিক বিবরণ, যার মধ্যে অন্তর্ভুক্ত রয়েছে আপনার ডেটা ও নথিপত্র সংগ্রহ, সংরক্ষণ এবং ব্যবহার ইত্যাদি, যা আপনার দেশে একটি স্বাধীন নৈতিকতা কমিটি কর্তৃক পর্যালোচনা করা হয়েছে এবং এর উদ্দেশ্য হল অধ্যয়নে অংশগ্রহণকারী রোগীদের অধিকার, নিরাপত্তা এবং কল্যাণ নিশ্চিত করা।

আপনি যদি এই অধ্যয়নে অংশগ্রহণ করেন, তবে আপনার অবস্থার উন্নতি হতেও পারে, আবার নাও হতে পারে। তবে, এই অধ্যয়ন থেকে আমরা যে তথ্য পাবো, তা ভবিষ্যতে একই সমস্যায় আক্রান্ত অন্যান্য রোগীদের সাহায্য করতে পারে।

1 এই অধ্যয়নটি কী সংক্রান্ত?

ডুরভালুম্যাব হল এক ধরণের ওষুধ, যা ইমিউনোথেরাপি হিসেবে পরিচিত। এটি আপনার শরীরের রোগ প্রতিরোধ ব্যবস্থাকে ক্যান্সার কোষগুলি শনাক্ত করতে এবং সেগুলির ওপর আক্রমণ চালাতে সহায়তা করার মাধ্যমে কাজ করে। কিছু ক্যান্সার কোষ 'PD-L1' নামক একটি সংকেত ব্যবহার করে নিজেদের রক্ষা করে, যা রোগ প্রতিরোধ ব্যবস্থাকে কার্যত "নিষ্ক্রিয়" করে দেয়। ডুরভালুম্যাব এই সংকেতটিকে অবরুদ্ধ করে দেয়, যার ফলে আপনার রোগ প্রতিরোধ ব্যবস্থা ক্যান্সার কোষগুলিকে খুঁজে বের করতে এবং ধ্বংস করতে সক্ষম হয়।

আমরা এই অধ্যয়নটি পরিচালনা করছি মূলত এটি জানার জন্য যে, ফুসফুসের এক ধরণের ক্যান্সার যা অপসারণযোগ্য এনএসসিএলসি নামে পরিচিত, সেটির চিকিৎসায় ডুরভালুম্যাব কতটা নিরাপদ। এই ধরণের ক্যান্সার তখন দেখা দেয়, যখন ফুসফুসের অভ্যন্তরে কোষগুলি অনিয়ন্ত্রিতভাবে বংশবৃদ্ধি করে এবং একটি টিউমার গঠন করে। অস্ত্রোপচারের পূর্বে প্রাক-অস্ত্রোপচার চিকিৎসা হিসেবে ডুরভালুম্যাব ও প্লাটিনাম কেমোথেরাপির সম্মিলিত প্রয়োগ প্রদান করা হয়, যার উদ্দেশ্য হল টিউমারটিকে সংকুচিত করতে সহায়তা করা এবং শরীরের নিজস্ব রোগ প্রতিরোধ ক্ষমতাকে জোরদার করা। টিউমারটি অপসারণের জন্য অস্ত্রোপচার সম্পন্ন হওয়ার পরেও, কিছু অতি ক্ষুদ্র ক্যান্সার কোষ শরীরে অবশিষ্ট থেকে যেতে পারে, যা এমআরআই, সিটি কিংবা পিইটি স্ক্যানের মাধ্যমে শনাক্ত করা সম্ভব হয় না। এই অবশিষ্ট কোষগুলি কখনও কখনও বেঁচে থাকে এবং পরবর্তীতে ক্যান্সারের পুনরাবির্ভাব ঘটতে পারে। অস্ত্রোপচারের পরবর্তী পর্যায়ে, শরীরে অবশিষ্ট থাকা ক্যান্সার কোষগুলির বিরুদ্ধে লড়াই করার ক্ষমতাকে শক্তিশালী করতে এবং ক্যান্সারের পুনরায় ফিরে আসার ঝুঁকি কমাতে ডুরভালুম্যাব মনোথেরাপি প্রদান করা হয়।

এই অধ্যয়নের লক্ষ্য হল পূর্ববর্তী গবেষণাসমূহে যেমনটি দেখা গেছে, সেই অনুযায়ী ডুরভালুম্যাব যে নিরাপদ, তা নিশ্চিত করা, তার পাশাপাশি কোনো নতুন বা অপ্রত্যাশিত পার্শ্বপ্রতিক্রিয়া দেখা দেয় কিনা, সেদিকেও নজর রাখা। ডুরভালুম্যাব 2017 সাল থেকে বাজারে প্রচলিত রয়েছে এবং এটি যুক্তরাষ্ট্রের খাদ্য ও ওষুধ প্রশাসন (ইউএসএফডিএ) কর্তৃক অনুমোদিত।

এই অধ্যয়নে প্রায় 78 জন রোগী অংশগ্রহণ করবেন। অধ্যয়নের মোট সময়কাল ডুরভালুম্যাব-এর প্রথম মাত্রা গ্রহণের তারিখ থেকে শুরু করে ডুরভালুম্যাব শেষ ডোজ গ্রহণের তারিখের পরবর্তী 90 দিন, অথবা পরবর্তী ক্যান্সার-বিরোধী চিকিৎসা শুরু করার তারিখ, কিংবা সম্মতি প্রত্যাহার, ফলো-আপ থেকে বিচ্ছিন্ন হয়ে যাওয়া, অথবা মৃত্যু, এগুলোর মধ্যে যেটি আগে ঘটবে, সেই তারিখ পর্যন্ত হবে।

2 আমাকে কি অংশগ্রহণ করতে হবে?

আপনি অংশগ্রহণ করবেন কিনা তা আপনার কাছে বেছে নেওয়ার সুযোগ আছে।

এই গবেষণায় অংশগ্রহণ করবেন কিনা তা সিদ্ধান্ত নেওয়ার জন্য অনুগ্রহ করে যতটা সময় প্রয়োজন ততোটা নিন। এই সিদ্ধান্ত নেওয়ার সময় আপনার বন্ধু-বান্ধব এবং পরিবারের সাথে কথা বলা সহায়ক হতে পারে।

আপনি যদি অধ্যয়নে যোগদান করেন, তাহলে আপনি যেকোনো সময় এটি ছেড়ে যেতে পারেন (আরও বিস্তারিত জানার জন্য "অনুচ্ছেদ 14" দেখুন)। অধ্যয়নটি ছেড়ে চলে গেলে সেটি আপনার পরিচর্যা ওপর কোনো প্রভাব ফেলবে না। আপনি যদি অধ্যয়ন ছেড়ে যেতে চান, তাহলে যত তাড়াতাড়ি সম্ভব আপনার অধ্যয়ন ডাক্তারকে সেটি জানান।

গবেষণায় অংশগ্রহণ করার সিদ্ধান্ত নেওয়ার সময়, অনুগ্রহ করে একজন গবেষণায় অংশগ্রহণকারী রোগী হিসেবে অধ্যয়নের জন্য প্রয়োজনীয় সময়ের প্রতিশ্রুতি এবং দায়িত্বসমূহ বিবেচনা করবেন।

আপনি যদি এই অধ্যয়নে অংশগ্রহণ না করেন, তবুও আপনার ফুসফুসের ক্যান্সারের চিকিৎসা অব্যাহত থাকবে। আপনার অধ্যয়ন চিকিৎসক অথবা আপনার চিকিৎসাকারী ডাক্তার আপনার সাথে অন্যান্য সম্ভাব্য ওষুধ, সেগুলির ঝুঁকি এবং উপকারিতা সম্পর্কে আলোচনা করবেন।

3 আমি যদি এই অধ্যয়নে অংশগ্রহণ করি, তাহলে কী হবে?

যেহেতু এটি একটি পর্যবেক্ষণমূলক অধ্যয়ন, তাই এই অধ্যয়নের অংশ হিসেবে স্পনসর কর্তৃক আপনাকে কোনো ওষুধ বা অন্য কোনো চিকিৎসা প্রদান করা হবে না।

আপনাকে আপনার নিয়মিত চিকিৎসকের অ্যাপয়েন্টমেন্টগুলি চালিয়ে যেতে হবে এবং চিকিৎসক যেভাবে নির্দেশ দিয়েছেন, সে অনুযায়ী আপনার নিয়মিত ওষুধ সেবন করতে হবে।

অধ্যয়ন ওষুধটি সেবন শুরু করার আগে আপনার বেশ কয়েকটি পরীক্ষা করা হবে। এই প্রক্রিয়াটিকে স্ক্রিনিং বলা হয়। আপনি যদি স্ক্রিনিংয়ের শর্তাবলি পূরণ করেন, তবে আপনি এই অধ্যয়নে অংশগ্রহণ করতে পারবেন। আর যদি আপনি শর্তাবলি পূরণ করতে না পারেন, তাহলে তার কারণগুলি আপনাকে ব্যাখ্যা করে জানানো হবে। আপনার অধ্যয়নের চিকিৎসক অথবা আপনার চিকিৎসাকারী ডাক্তার আপনার সাথে চিকিৎসার অন্যান্য সম্ভাব্য উপায় বা বিকল্পগুলি নিয়ে আলোচনা করবেন।

আপনার নিয়মিত বায়োপসি এবং রোগের পর্যায় নির্ণয়ের পরীক্ষা-নিরীক্ষা করা হবে; এছাড়া আপনার চিকিৎসকের অনুমোদিত নির্দেশিকা অনুযায়ী, অস্ত্রোপচারের আগে ও পরে চিকিৎসা হিসেবে আপনাকে ডুরভালুম্যাব প্রদান করা হবে। এই অধ্যয়নের পুরো সময়কাল জুড়ে আমরা আপনার ডেটা সংগ্রহ করব। এই অধ্যয়নে আপনার অংশগ্রহণ শুরু হবে ডুরভালুম্যাব-এর প্রথম ডোজ গ্রহণের দিন থেকে এবং তা অব্যাহত থাকবে, যা ডুরভালুম্যাব-এর শেষ ডোজ গ্রহণের পরবর্তী 90 দিন পর্যন্ত, অথবা পরবর্তী কোনো ক্যানসার-প্রতিরোধ চিকিৎসা শুরু করার দিন পর্যন্ত, কিংবা আপনার সম্মতি প্রত্যাহার, পর্যবেক্ষণের বাইরে চলে যাওয়া বা মৃত্যু, এগুলির মধ্যে যেটি আগে ঘটবে, সেই দিন পর্যন্ত। অধ্যয়নের প্রশ্নগুলির অধিকতর সঠিক উত্তর পাওয়ার স্বার্থে, এই অধ্যয়ন আপনার অংশগ্রহণের মেয়াদ দীর্ঘায়িত করার প্রয়োজন হতে পারে।

রোগীর অবস্থার ওপর ভিত্তি করে, ভিজিটের মোট সংখ্যা এবং ভিজিটের সময় তদন্তকারীর বিবেচনামতো নির্ধারিত হবে।

নিয়মিত ভিজিটের সময় এই অধ্যয়নের উদ্দেশ্যে তথ্য সংগ্রহ করা হবে এবং এর ফলে আপনার নিয়মিত ভিজিটে কিছুটা অতিরিক্ত সময় লাগতে পারে।

আপনি যদি ভিজিটে আসতে না পারেন, তাহলে আপনাকে অবশ্যই আপনার অধ্যয়ন চিকিৎসককে তা জানাতে হবে।

অনুগ্রহ করে মনে রাখবেন যে, এই অধ্যয়নটি এবং এতে আপনার অংশগ্রহণ, প্রত্যাশার চেয়ে আগেই বন্ধ হয়ে যেতে পারে; উদাহরণস্বরূপ, বৈজ্ঞানিক বা নিরাপত্তা-সংক্রান্ত কারণে (বিস্তারিত তথ্যের জন্য “অনুচ্ছেদ 9” দেখুন)।

4 প্রয়োজনীয় পরীক্ষা ও প্রক্রিয়াগুলি কী কী?

আপনি যখন এই অধ্যয়নে অংশগ্রহণ করবেন, তখন আপনার চিকিৎসার নথিপত্র থেকে আমাদের কিছু চিকিৎসা-সংক্রান্ত ডেটা সংগ্রহ করতে হবে। চিকিৎসার মানদণ্ড অনুযায়ী পরিচালিত নিয়মিত পরীক্ষার অংশ হিসেবে, নিচের পরীক্ষা ও প্রক্রিয়াগুলি থেকে প্রাপ্ত ডেটা নথিভুক্ত করা হবে:

রোগীর জনমিতি ও চিকিৎসার ইতিহাস

আপনার জন্ম তারিখ, লিঙ্গ, উচ্চতা, ওজন এবং মহিলা রোগীদের ক্ষেত্রে গর্ভাবস্থা ও স্তন্যপান করানোর বিষয়টি, আর পুরুষ রোগীদের ক্ষেত্রে তাদের নারী সঙ্গীর গর্ভাবস্থার অবস্থা, এই তথ্যগুলো সংগ্রহ করা হবে। এছাড়া, অন্য কোনো রোগের চিকিৎসার ইতিহাস এবং মেনিনোকোকাল-প্রতিরোধী টিকার তারিখ ও ধরন, যার মধ্যে বুস্টার ডোজসমূহ অন্তর্ভুক্ত রয়েছে, সেই সকল তথ্যও সংগ্রহ করা হবে। রোগের চিকিৎসা ইতিহাস এবং রোগের প্রাথমিক অবস্থা (ইজিএফআর/এএলকে-এর অবস্থা সহ)। আপনার রোগের ইতিহাস যেমন রোগের পর্যায় বা স্টেজিং সংক্রান্ত তথ্য, ইসিওজি পারফর্মেন্স স্ট্যাটাস (দৈনন্দিন জীবনে আপনার কার্যক্ষমতা), এবং ইজিএফআর/এএলকে-এর অবস্থা (জিনে কোনো পরিবর্তন বা মিউটেশনের উপস্থিতি যাচাইয়ের জন্য) এবং যদি আপনার এই সংক্রান্ত চিকিৎসা নথিপত্রে উপলব্ধ থাকে, তবে তা সেখান থেকে সংগ্রহ করা হবে।

সহগামী ওষুধ

আপনার গ্রহণ করা যেকোনো চলমান ওষুধের তথ্য আপনার চিকিৎসার নথিপত্র থেকে লিপিবদ্ধ করা হবে, যার অন্তর্ভুক্ত থাকবে ওষুধের নাম, দৈনিক ডোজ, প্রয়োগের পদ্ধতি এবং ব্যবহারের নির্দেশিকা।

শারীরিক পরীক্ষা ও গুরুত্বপূর্ণ লক্ষণসমূহ

আপনার অধ্যয়ন চিকিৎসক কর্তৃক পরিচালিত শারীরিক পরীক্ষার যেকোনো ফলাফল, অথবা রেকর্ডকৃত গুরুত্বপূর্ণ শারীরিক সূচকসমূহ (বিশেষ করে শরীরের ওজন) লিপিবদ্ধ করা হবে।

ইসিজি

অধ্যয়ন চলাকালীন সময়ে, বিশেষ করে প্রারম্ভিক পর্যায়ে, অস্ত্রোপচারের পূর্বে এবং পরে, সংগৃহীত ইসিজি-এর রিডিং আপনার চিকিৎসার নথিপত্র থেকে লিপিবদ্ধ করা হবে।

ক্লিনিক্যাল এবং রেডিওলজিক্যাল মূল্যায়ন

রোগের অবস্থা বা সামগ্রিক ক্লিনিক্যাল প্রতিক্রিয়া মূল্যায়নের উদ্দেশ্যে সম্পাদিত সমস্ত ক্লিনিক্যাল এবং রেডিওলজিক্যাল পরীক্ষা যেমন এমআরআই, সিটি বা পিইটি এবং রিসিস্ট 1.1 যা ক্লিনিক্যাল ট্রায়ালে চিকিৎসার প্রতি টিউমারের প্রতিক্রিয়া মূল্যায়ন করে, যখনই উপলব্ধ হয়, যা অধ্যয়নের জন্য লিপিবদ্ধ করা হবে।

ল্যাবরেটরি মূল্যায়ন

নির্ধারিত চিকিৎসা পদ্ধতি অনুযায়ী, প্রাথমিক পর্যায়ে এবং ডুরভালুম্যাব চিকিৎসা চলাকালীন সময়ে সম্পাদিত যেকোনো ল্যাবরেটরি পরীক্ষার ফলাফল লিপিবদ্ধ করা হবে, এর অন্তর্ভুক্ত বিষয়গুলির মধ্যে রয়েছে তবে এর মধ্যেই সীমাবদ্ধ নয়—ক্লিনিক্যাল কেমিস্ট্রি, হেমাটোলজি, কিডনি কার্যকারিতা পরীক্ষা, লিভার কার্যকারিতা পরীক্ষা, থাইরয়েড হরমোনের মাত্রা, মূত্র পরীক্ষা, হেপাটাইটিস বি ও সি, এইচআইভি, গর্ভাবস্থা পরীক্ষা ইত্যাদি।

এনএসএলসি চিকিৎসার বিস্তারিত বিবরণ

নির্ধারিত চিকিৎসা পরিকল্পনা অনুযায়ী প্রদত্ত সমস্ত চিকিৎসা যার অন্তর্ভুক্ত রয়েছে অস্ত্রোপচার এবং অস্ত্রোপচারের আগে ও পরে প্রদত্ত কেমোথেরাপি, সেগুলি সম্পর্কে বিস্তারিত বিবরণ লিপিবদ্ধ করা হবে। লিপিবদ্ধ করা বিষয়গুলির মধ্যে থাকবে মোট ওষুধের ডোজ, চিকিৎসার মোট সময়কাল, চিকিৎসার বর্তমান অবস্থা (চলমান নাকি স্থগিত), এবং চিকিৎসা স্থগিত করার কারণ কিংবা ওষুধের ডোজ পরিবর্তনের কারণ।

নিরাপত্তা মূল্যায়ন

আপনি যে কোনো পার্শ্বপ্রতিক্রিয়া অনুভব করছেন তা যত সামান্যই হোক না কেন, সেটা আপনার অধ্যয়ন ডাক্তারের দ্বারা মূল্যায়ন করা হবে। যখন কোনো পার্শ্বপ্রতিক্রিয়া দেখা দেয়, তখন নিম্নলিখিত বিষয়গুলি সম্পর্কিত তথ্য সংগ্রহ করা হবে: পার্শ্বপ্রতিক্রিয়াটি ঠিক কী, এটি কখন শুরু হয়ে কখন শেষ হয়েছে, এটি কতটা গুরুতর, এটি আপনার কাছে কতটা কষ্টদায়ক মনে হয়েছে, এটি গবেষণার ওষুধটির সাথে সম্পর্কিত কি না, এই পার্শ্বপ্রতিক্রিয়ার কারণে ওষুধটির বিষয়ে কী পদক্ষেপ নেওয়া হয়েছে, পরবর্তীতে কী ঘটেছে, পার্শ্বপ্রতিক্রিয়াটি মোকাবিলায় অন্য কী কী ব্যবস্থা গ্রহণ করা হয়েছে এবং চিকিৎসকের কোনো মন্তব্য।

অধ্যয়ন সংক্রান্ত পরীক্ষা ও প্রক্রিয়ার সম্পূর্ণ তালিকা, তাদের বিস্তারিত সময়সূচি সহ, “অংশ III: রোগীদের জন্য অতিরিক্ত তথ্য”-তে পাওয়া যাবে।

5. ঐচ্ছিক পরীক্ষা ও পদ্ধতিগুলি কী কী?

যেহেতু এটি একটি পর্যবেক্ষণমূলক অধ্যয়ন, তাই আমরা শুধুমাত্র আপনার চিকিৎসার নথিপত্র থেকে তথ্য সংগ্রহ করব। এতে কোনো অতিরিক্ত বা ঐচ্ছিক পরীক্ষা-নিরীক্ষা কিংবা পদ্ধতি অন্তর্ভুক্ত থাকবে না।

6. অধ্যয়নটিতে অংশগ্রহণের ঝুঁকিগুলি কী কী?

এই অধ্যয়নটি শুধুমাত্র আপনার চিকিৎসক আপনাকে যে নিয়মিত চিকিৎসা প্রদান করেন, সেটাই অন্তর্ভুক্ত করা হবে। এর ফলে আপনি তাৎক্ষণিকভাবে কোনো প্রত্যক্ষ চিকিৎসাগত সুবিধা পাবেন না। তবে, এই অধ্যয়ন থেকে আমরা যে তথ্য পাবো, তা আমাদের বাস্তব চিকিৎসাসাফ্রে ফুসফুসের ক্যান্সারে আক্রান্ত রোগীদের কীভাবে চিকিৎসা ও ব্যবস্থাপনা করা হয়, সেটি বর্ণনা করতে এবং এই রোগ ও এর লক্ষণ সম্পর্কে আমাদের জ্ঞান বৃদ্ধি করতে সহায়তা করতে পারে। আশা করা যায়, ভবিষ্যতে ফুসফুসের ক্যান্সারে আক্রান্ত রোগীদের আরও ভালোভাবে চিকিৎসা প্রদান করতে এটি আমাদের সহায়তা করবে।

যেহেতু ডুরভালুম্যাব হল একটি ইমিউনোথেরাপি যা রোগ প্রতিরোধ ক্ষমতাকে ক্যান্সারের বিরুদ্ধে লড়াই করতে সাহায্য করে। যেহেতু এটি রোগ প্রতিরোধ ক্ষমতাকে সক্রিয় করে, তাই এটি কখনও কখনও রোগ প্রতিরোধ ক্ষমতার কারণে স্বাভাবিক অঙ্গগুলিকে প্রভাবিত করতে পারে এবং কিছু অবস্থিত প্রভাব ফেলতে পারে।

সাধারণ পার্শ্ব প্রতিক্রিয়া

- কম লোহিত রক্তকণিকার সংখ্যা (রক্তাঙ্গতা)
- বমি বমি ভাব
- কোষ্ঠকাঠিন্য
- ক্লান্তি
- পেশি বা হাড়ের ব্যথা
- স্বকের ব্যাশ

রোগ প্রতিরোধ ব্যবস্থা-সম্পর্কিত সম্ভাব্য পার্শ্বপ্রতিক্রিয়া

ডুরভালুম্যাব শরীরের বিভিন্ন অঙ্গে প্রদাহ সৃষ্টি করতে পারে, যার মধ্যে অন্তর্ভুক্ত রয়েছে:

- ফুসফুস (কাশি, শ্বাসকষ্ট)
- লিভার (স্বক/চোখ হলুদ হয়ে যাওয়া, লিভারের পরীক্ষার অস্বাভাবিক ফলাফল)
- অন্ত্র (ডায়রিয়া, পেটে ব্যথা)
- হরমোন গ্রন্থি (থাইরয়েড বা অ্যাড্রেনাল গ্রন্থির সমস্যা, যা ক্লান্তি, মাথা ঘোরা বা ওজনের পরিবর্তনের কারণ হয়)
- কিডনি
- স্বক

এই পার্শ্বপ্রতিক্রিয়াগুলি চিকিৎসার সময় বা পরে ঘটতে পারে। অধিকাংশ পার্শ্বপ্রতিক্রিয়াই প্রাথমিক পর্যায়ে শনাক্ত করা গেলে চিকিৎসাযোগ্য; তবে কিছু ক্ষেত্রে এগুলি গুরুতর হতে পারে এবং এর জন্য হাসপাতালে ভর্তি হওয়া কিংবা চিকিৎসা বন্ধ করার প্রয়োজন হতে পারে। কদাচিৎ, গুরুতর জটিলতাগুলি প্রাণঘাতীও হতে পারে।

অন্যান্য চিকিৎসার পার্শ্বপ্রতিক্রিয়া

আপনার নিয়মিত চিকিৎসার অংশ হিসেবে আপনি যদি কেমোথেরাপি, অস্ত্রোপচার অথবা রেডিয়েশন থেরাপি গ্রহণ করেন, তবে এই চিকিৎসাগুলির ফলে বমি বমি ভাব, চুল পড়া, সংক্রমণ, রক্তপাত, ব্যথা, শ্বাসকষ্ট বা অবসাদের মতো অতিরিক্ত পার্শ্বপ্রতিক্রিয়া দেখা দিতে পারে। আপনার চিকিৎসক আপনাকে আলাদাভাবে এই ঝুঁকিগুলি সম্পর্কে বিস্তারিত বুঝিয়ে বলবেন।

নিয়মিত পরীক্ষার ঝুঁকি

রুটিন রক্ত পরীক্ষার ফলে সামান্য ব্যথা বা কালশিটে দাগ দেখা দিতে পারে। ইসিজি-এর কারণে স্বক সামান্য অস্বস্তি বা জ্বালা হতে পারে। এই প্রক্রিয়াগুলির কারণে কোনো বড় ঝুঁকির আশঙ্কা নেই। একটি ঝুঁকি থেকেই যায় যে এই অধ্যয়নকালীন সময়ে আপনার ফুসফুসের ক্যান্সার হয়তো ভালো হবে না অথবা সেটি আরও খারাপের দিকেও যেতে পারে।

এটি উল্লেখ করা জরুরি যে, আপনি যদি কোনো পার্শ্বপ্রতিক্রিয়া অনুভব করেন, তবে তা সম্ভবত আপনার বেছে নেওয়া চিকিৎসার সাথে সম্পর্কিত এবং এই অধ্যয়নে অংশগ্রহণের কারণে নয়। এই অধ্যয়নটি সম্পূর্ণভাবে পর্যবেক্ষণমূলক এবং এতে কেবল আপনার চিকিৎসকের সরবরাহকৃত নিয়মিত চিকিৎসা সংক্রান্ত তথ্য লিপিবদ্ধ করা হয়। তাছাড়া, যেহেতু এই অধ্যয়নটি কোনো প্রকার হস্তক্ষেপমূলক নয়, তাই এটি আপনার চিকিৎসার ব্যবস্থাপনায় চিকিৎসকের গৃহীত পদ্ধতির কোনো পরিবর্তন ঘটাবে না।
যাঁকি সম্পর্কে আরও জানতে, “রোগীদের জন্য অতিরিক্ত তথ্য” অংশে প্রদত্ত অতিরিক্ত যাঁকির তথ্যাবলি দেখুন।

7. আর কি কোনো বিষয় বা যাঁকি আছে, যা সম্পর্কে আমার জানা প্রয়োজন?

বিশেষ সতর্কবার্তা

- ডুরভালুম্যাব রোগ প্রতিরোধ ব্যবস্থা-সম্পর্কিত এমন কিছু পার্শ্বপ্রতিক্রিয়া সৃষ্টি করতে পারে, যা ফুসফুস, লিভার, অস্ত্র, কিডনি, হরমোন গ্রন্থি, হৃক, হার্ট অথবা স্নায়ুতন্ত্রের মতো অঙ্গগুলিকে প্রভাবিত করতে পারে।
- এই প্রতিক্রিয়াগুলো চিকিৎসার চলাকালীন কিংবা চিকিৎসা বন্ধ করার পরেও ঘটতে পারে।
- কিছু পার্শ্বপ্রতিক্রিয়ার যদি দ্রুত চিকিৎসা করা না হয়, তবে তা গুরুতর হয়ে উঠতে পারে।
- যদি আপনার শ্বাসকষ্ট, দীর্ঘস্থায়ী ডায়রিয়া, হৃক বা চোখের হলদে ভাব, তীব্র ক্লান্তি, বৃকে ব্যথা, বিভ্রান্তি অথবা তীব্র স্নায়ুতন্ত্রের মতো নতুন কোনো উপসর্গ দেখা দেয় কিংবা বিদ্যমান উপসর্গগুলির অবনতি ঘটে, তবে অবিলম্বে আপনার চিকিৎসককে সেটি জানান।

অন্যান্য ওষুধ, খাবার ও পানীয়

- আপনি যেসব ওষুধ সেবন করছেন, যার মধ্যে প্রেসক্রিপশনের ওষুধ, ওভার-দ্যা-কাউন্টার ওষুধ, ভেষজ পণ্য এবং স্যাপ্লিমেন্ট অন্তর্ভুক্ত রয়েছে, সেগুলি সম্পর্কে আপনার ডাক্তারকে জানানো উচিত।
- আপনি যখন ডুরভালুম্যাব গ্রহণ করছেন, তখন কিছু ওষুধের (বিশেষ করে স্টেরয়েড বা যেসব ওষুধ রোগ প্রতিরোধ ব্যবস্থাকে প্রভাবিত করে) ক্ষেত্রে চিকিৎসকের তত্ত্বাবধানের প্রয়োজন হতে পারে।
- আপনার ডাক্তারের সাথে আলোচনা না করে কোনো নতুন ওষুধ সেবন করা শুরু করবেন না।
- খাবার বা পানীয়ের ক্ষেত্রে সুনির্দিষ্ট কোনো বিধিনিষেধ নেই; তবে চিকিৎসা চলাকালীন আপনার চিকিৎসকের দেওয়া খাদ্যাভ্যাস সংক্রান্ত পরামর্শ মেনে চলা উচিত।

গাড়ি চালানো, মেশিন পরিচালনা করা, খেলাধুলা এবং কার্যকলাপ করা

- ডুরভালুম্যাব ক্লান্তি, মাথা ঘোরা বা দুর্বলতা সৃষ্টি করতে পারে।
- আপনি যদি অসুস্থ, ক্লান্ত কিংবা মাথা ঘোরা অনুভব করেন, তবে গাড়ি চালানো, মেশিন পরিচালনা করা অথবা পূর্ণ সতর্কতার প্রয়োজন এমন কোনো কাজ করা থেকে বিরত থাকা উচিত।
- খেলাধুলা বা কার্যকলাপের ওপর সুনির্দিষ্ট কোনো বিধিনিষেধ নেই; তবে আপনার শারীরিক অবস্থা এবং সামগ্রিক স্বাস্থ্যের ওপর ভিত্তি করে ডাক্তারের পরামর্শ মেনে চলা উচিত।

গর্ভাবস্থা, গর্ভনিরোধ এবং স্তন্যপান

যেহেতু অনাগত শিশু বা নবজাতকের ওপর (অথবা আপনি পুরুষ হলে আপনার নারী সঙ্গীর ওপর) ডুরভালুম্যাব-এর প্রভাব সম্পর্কে কিছু জানা নেই, তাই এই অধ্যয়নকালীন সময়ে আপনি গর্ভধারণ কিংবা শিশুকে স্তন্যপান করাতে পারবেন না।

অধ্যয়ন ডাক্তার আপনার সাথে গ্রহণযোগ্য জন্মনিয়ন্ত্রণ পদ্ধতিগুলি নিয়ে আলোচনা করতে পারেন।

মহিলা রোগীদের জন্য:

আপনি যদি গর্ভবতী হন, তবে আপনাকে অবিলম্বে দোঁহায়ন ডাক্তারকে তা জানাতে হবে। আপনার চিকিৎসকের সাথে কথা না বলা পর্যন্ত আপনাকে অবিলম্বে অধ্যয়ন ওষুধ সেবন করা বন্ধ করতে হবে। আপনার এবং আপনার শিশু সম্পর্কে তথ্য প্রদান করার জন্য আপনাকে অনুরোধ জানানো হবে। এর অংশ হিসেবে, আপনার শিশুর স্বাস্থ্য ও বিকাশ পর্যবেক্ষণ করার অনুমতি প্রদানের জন্য আপনাকে হয়তো আলাদাভাবে সম্মতি জানাতে হতে পারে।

যেসব পুরুষ রোগীর সঙ্গিনী গর্ভবতী হন, তাঁদের জন্য:

যদি আপনার সঙ্গিনী গর্ভবতী হন, তবে আপনাকে অবিলম্বে অধ্যয়ন ডাক্তারকে তা জানাতে হবে। একটি পৃথক সম্মতির ভিত্তিতে, আপনার সঙ্গিনীকে তার নিজের স্বাস্থ্য এবং আপনাদের সন্তানের স্বাস্থ্য সম্পর্কিত তথ্য প্রদান করার জন্য অনুরোধ জানানো হবে।

উপবাস করা

এই অধ্যয়নে অংশগ্রহণের জন্য নির্দিষ্ট কোনো উপবাসের প্রয়োজন নেই, যদি না আপনার চিকিৎসাকারী ডাক্তার রুটিন চিকিৎসা পরীক্ষা বা প্রক্রিয়ার জন্য এর পরামর্শ দিয়ে থাকেন।

টিকাদান

- কোনো টিকা নেওয়ার আগে আপনার ডাক্তারকে জানান।
- ভুরভালুম্যাব দ্বারা চিকিৎসার সময় এবং চিকিৎসার পরবর্তী একটি নির্দিষ্ট সময় পর্যন্ত, আপনার চিকিৎসকের পরামর্শ অনুযায়ী, সাধারণত লাইভ টিকা গ্রহণ করা থেকে বিরত থাকা উচিত।
- আপনার চিকিৎসকের পরামর্শ অনুযায়ী নিষ্ক্রিয় (নন-লাইভ) টিকা দেওয়া যেতে পারে।

রক্তদান

চিকিৎসাকালীন সময়ে এবং ভুরভালুম্যাব-এর শেষ ডোজ গ্রহণের পরবর্তী নির্দিষ্ট সময় পর্যন্ত, যেমনটি আপনার চিকিৎসক পরামর্শ দিয়েছেন সেই অনুযায়ী আপনার রক্ত বা রক্তের উপাদান দান করা উচিত নয়।

8. অংশগ্রহণের সম্ভাব্য সুবিধাগুলি কী কী?

এই অধ্যয়ন থেকে অধ্যয়ন স্পন্সর যে তথ্য পাবেন, তা ভবিষ্যতে ফুসফুসের ক্যান্সারে আক্রান্ত রোগীদের আরও ভালোভাবে চিকিৎসায় সহায়তা করতে পারে।

এই অধ্যয়নে অংশগ্রহণের ফলে আপনি সরাসরি উপকৃত হবেন এমন কোনো নিশ্চয়তা নেই। তবে, আপনার এই অংশগ্রহণ ভবিষ্যতে রোগ সম্পর্কে আমাদের জ্ঞান বৃদ্ধি এবং চিকিৎসাসেবার মান উন্নয়নের মাধ্যমে অন্যান্য রোগীদের উপকারে আসতে পারে। এটিতে অংশ নেওয়া আপনার শারীরিক অবস্থার উন্নতি ঘটাবে কিনা তা আমাদের জানা নেই, তবে আমরা আশা করি যে, তা ঘটবে।

9. আমি অধ্যয়নে অংশগ্রহণরত অবস্থায় যদি কোনো পরিবর্তন ঘটে, যেমন, যদি নতুন কোনো তথ্য পাওয়া যায়, তাহলে কী হবে?

অধ্যয়নে এমন কিছু পরিবর্তন ঘটতে পারে, যার ফলে অধ্যয়নে অংশগ্রহণ চালিয়ে যাওয়া নিয়ে আপনার মত পরিবর্তন হতে পারে। যদি কোনো পরিবর্তন ঘটে, তবে আমরা যত দ্রুত সম্ভব আপনাকে তা জানিয়ে দেব।

আপনি যেকোনো সময় এই অধ্যয়নটি ত্যাগ করার সিদ্ধান্ত নিতে পারেন। বিস্তারিত তথ্যের জন্য, নিচে 14 নম্বর অনুচ্ছেদটি দেখুন।

অধ্যয়ন ডাক্তার যদি মনে করেন যে এটি আপনার জন্য সর্বোত্তম, তবে তিনি আপনাকে অধ্যয়নটি থেকে সরিয়ে নেওয়ার সিদ্ধান্তও নিতে পারেন।

যখন স্পন্সর, ভারতীয় স্বাস্থ্য কর্তৃপক্ষ কিংবা নৈতিক বা নিয়ন্ত্রণকারী সংস্থাগুলি সিদ্ধান্ত নেয় যে অধ্যয়নটি অবশ্যই বন্ধ করতে হবে, তখন অধ্যয়নে আপনার অংশগ্রহণও সমাপ্ত হয়।

10. অধ্যয়নে আমি যদি ক্ষতিগ্রস্ত বা আহত হই, তাহলে কী হবে?

যেহেতু এটি একটি পর্যবেক্ষণমূলক অধ্যয়ন, তাই এতে আপনার ডাক্তারের প্রদানকৃত নিয়মিত চিকিৎসার বাইরে কোনো পরীক্ষামূলক চিকিৎসা বা প্রক্রিয়া অন্তর্ভুক্ত নেই। সুতরাং, এই অধ্যয়নে অংশগ্রহণের ফলে কোনো ক্ষতি বা আঘাতের ঝুঁকি অত্যন্ত নগণ্য। আপনার চিকিৎসক যথারীতি প্রয়োজনীয় সেবা প্রদান এবং আপনার চিকিৎসার ব্যবস্থাপনা অব্যাহত রাখবেন। আপনার যদি কোনো উদ্বেগ থাকে, তবে পরবর্তী সহায়তার জন্য আপনি অধ্যয়ন দলের সাথে অথবা আপনার চিকিৎসকের সাথে যোগাযোগ করতে পারেন।

যদি কোনো জ্বরুরি পরিস্থিতি দেখা দেয়, তাহলে যত দ্রুত সম্ভব আপনার অধ্যয়ন ডাক্তারকে কল করুন। যোগাযোগের সমস্ত প্রাসঙ্গিক তথ্য অংশে III: “রোগীদের জন্য অতিরিক্ত তথ্য”-তে পাওয়া যাবে।

আপনি যদি এই গবেষণা অধ্যয়নে অংশগ্রহণরত অবস্থায় অসুস্থ হয়ে পড়েন অথবা আঘাতপ্রাপ্ত হন, তবে আপনাকে অবশ্যই অবিলম্বে আপনার অধ্যয়ন ডাক্তারকে জানাতে হবে।

অধ্যয়নের ওষুধ, পরীক্ষা বা বিভিন্ন পদ্ধতির কারণে যেসব আঘাত বা ক্ষতি হয়, সেগুলিকে ‘গবেষণাজনিত আঘাত’ বলা হয়। আপনার স্বাভাবিক চিকিৎসা সেবা কিংবা আপনার ফুসফুসের ক্যান্সারের কারণে সৃষ্ট কোনো আঘাত গবেষণাজনিত আঘাত হিসেবে গণ্য হবে না।

আপনার যদি চিকিৎসা বীমা থাকে, তাহলে অনুগ্রহ করে আপনার বীমা কোম্পানির সাথে যোগাযোগ করে নিশ্চিত হয়ে নিন যে, এই গবেষণা অধ্যয়নে অংশগ্রহণ আপনার বীমা কভারেজকে প্রভাবিত করবে না।

এই ফর্ম স্বাক্ষর করার মাধ্যমে আপনি আপনার কোনো সম্ভাব্য আইনি অধিকার পরিত্যাগ করছেন না।

11. অধ্যয়ন থেকে সংগৃহীত আমার ডেটার কী হবে?

a. কোন ডেটা সংগ্রহ করা হয়?

অধ্যয়ন পরিচালনা করার জন্য, অধ্যয়ন সাইটটিকে আপনার পরিচয় সম্পর্কিত তথ্য সংগ্রহ এবং নিবন্ধন করতে হবে, যেমন আপনার চিকিৎসা অবস্থা এবং চিকিৎসা ইতিহাস (এতে আপনার চিকিৎসকদের কাছ থেকে তথ্য / আপনার চিকিৎসা রেকর্ডে উপলব্ধ তথ্য অন্তর্ভুক্ত থাকতে পারে), আপনার জীবনধারা, আপনার জনতত্ত্ব (বয়স, লিঙ্গ, জাতিগত এবং বর্ণগত পটভূমি), ক্লিনিক্যাল কেমিস্ট্রি, হেমাটোলজি, কিডনি ফাংশন পরীক্ষা, লিভার ফাংশন পরীক্ষা, থাইরয়েডের মাত্রা, প্রস্রাব পরীক্ষার ফলাফল, হেপাটাইটিস বি এবং সি, এইচআইভি, গর্ভাবস্থা পরীক্ষা ইত্যাদি। অন্য কোনো রোগের জন্য আপনি যে ওষুধ খাচ্ছেন তার সাথে এটিও নোট করা হবে। এছাড়াও, ইসিজি এবং এমআরআই/পিইটি/সিটি-র মতো ইমেজিং কৌশল থেকে তৈরি ডেটা সংগ্রহ করা হবে। আপনি যে চিকিৎসা পাবেন, তার সাথে চিকিৎসার প্রতি আপনার প্রতিক্রিয়া এবং পার্শ্ব প্রতিক্রিয়া বা আপনার যে কোনো অস্বস্তি হতে পারে তা সংগ্রহ করা হবে।

b. আমার ডেটা কী কাজে প্রয়োজন?

ভারতীয় স্বাস্থ্য কর্তৃপক্ষের নিকট অনুমোদনোত্তর নিয়ন্ত্রণমূলক প্রতিশ্রুতি পালনের লক্ষ্যে, ডুরভালুম্যাব-এর ব্যবহার সম্পর্কিত অনুমোদনোত্তর নিরাপত্তা সংক্রান্ত প্রমাণাদি সংগ্রহের জন্য স্পন্সরের আপনার তথ্যের প্রয়োজন। তাই, এই অধ্যয়নে যেমনটি পরিকল্পিত হয়েছে, ঠিক সেভাবেই আপনার এই তথ্য ব্যবহৃত হবে; পাশাপাশি, সংশ্লিষ্ট রোগ এবং এর সাথে যুক্ত স্বাস্থ্য সমস্যাগুলি সম্পর্কে আরও ভালোভাবে

বোঝার উদ্দেশ্যে ওষুধ উন্নয়ন কর্মসূচির আওতাধীন প্রয়োজনীয় অন্যান্য গবেষণামূলক কর্মকাণ্ডও এই ডেটা ব্যবহৃত হতে পারে। এছাড়া, বৈজ্ঞানিক জার্নালে গবেষণার ফলাফল প্রকাশ কিংবা শিক্ষামূলক উদ্দেশ্যেও এটি ব্যবহৃত হতে পারে।

C. কে আমার ডেটা অ্যাক্সেস করতে পারে?

শুধুমাত্র অধ্যয়ন কেন্দ্রে, আপনার নাম এবং যোগাযোগের বিবরণ অধ্যয়নকারী ডাক্তার এবং অধ্যয়ন পরিচালনাকারী অধ্যয়ন দলের কাছে অ্যাক্সেসযোগ্য হবে। স্পনসরের পক্ষে কাজ করা এবং গোপনীয়তার দায়িত্ব পালনকারী অ-চিকিৎসা কর্মীদের পাশাপাশি স্বাস্থ্য কর্তৃপক্ষ এবং নীতিশাস্ত্র কমিটিগুলিকেও এই ডেটাতে অ্যাক্সেস দেওয়া যেতে পারে শুধুমাত্র এটি যাচাই করার জন্য যে অধ্যয়নটি আইনি এবং মানসম্মত প্রয়োজনীয়তা মেনে পরিচালিত হচ্ছে। আপনার কিছু ডেটা দূরবর্তীভাবে অ্যাক্সেস করা যেতে পারে, যেখানে অনুমতি দেওয়া হয়েছে।

অধ্যয়ন সাইটটি আপনার ডেটা স্পনসরের সাথে শেয়ার করবে, তবে তা কেবল তখনই করা হবে যখন সেগুলি কোডবদ্ধ করা হয়ে যাবে (এর অর্থ হল আপনার নাম, যোগাযোগের বিবরণ কিংবা স্বাস্থ্য বীমা নম্বর, এগুলির পরিবর্তে একটি কোড ব্যবহার করা হবে)। কোডবদ্ধকরণ সম্পর্কিত আরও তথ্যের জন্য, এই নথির শেষে অংশ III-এ “রোগীদের জন্য অতিরিক্ত তথ্য”—শিরোনামের বিস্তারিত বিবরণ দেখুন।

স্পনসর ওষুধ উন্নয়ন কর্মসূচির উদ্দেশ্যে তার গবেষণা সহযোগী এবং সেবা প্রদানকারীদের সাথে আপনার কোডবদ্ধ ডেটা শেয়ার করতে পারেন।

এই অধ্যয়নটির সূচী পরিচালনা ও ফলাফলের নির্ভুলতা নিশ্চিত করতে এবং ওষুধটির বাজারজাতকরণের অনুমতি লাভের উদ্দেশ্যে, স্পনসর আপনার কোডবদ্ধ ডেটা সংশ্লিষ্ট কর্তৃপক্ষ এবং সম্ভবত নৈতিকতা কমিটির সাথে শেয়ার করবেন। এছাড়া, অধ্যয়নের ফলাফলসমূহ স্বাধীন বিজ্ঞানীদের দ্বারা পর্যালোচিত হওয়ার সুযোগ করে দিতে এবং ফলাফলের নির্ভুলতা নিশ্চিত করতে, এই সেগুলি বৈজ্ঞানিক জার্নালগুলির সাথেও শেয়ার করা হতে পারে।

এই কোনো ক্ষেত্রেই আপনার পরিচয় প্রকাশ করা হবে না।

উপরে উল্লিখিত ব্যক্তিদের কেউ কেউ আপনার দেশের বাইরে অবস্থান করতে পারেন। যদি সেই অন্য দেশে আপনার দেশের সমতুল্য ব্যক্তিগত ডেটা সুরক্ষার মানদণ্ড বিদ্যমান না থাকে, তবে আপনার তথ্যের গোপনীয়তা রক্ষা ও বজায় রাখার লক্ষ্যে যথাযথ সুরক্ষাব্যবস্থা (যেমন—চুক্তি এবং টেকনিক্যাল নিরাপত্তা ব্যবস্থা) গ্রহণ করা হবে; এ বিষয়ে এই নথির শেষে অংশ III “রোগীদের জন্য অতিরিক্ত তথ্য” তে আরও বিস্তারিত বর্ণনা দেওয়া হয়েছে।

যদি অন্য কোনো সংস্থা অধ্যয়ন ওষুধটির উন্নয়ন বা বাণিজ্যিকীকরণের দায়িত্ব গ্রহণ করে, তবে আপনার কোডবদ্ধ ডেটা তাদের কাছে হস্তান্তর করা হতে পারে। সেক্ষেত্রে, এখানে যেভাবে বর্ণনা করা হয়েছে, ঠিক একইভাবে তাদেরও আপনার তথ্য সুরক্ষা করতে হবে।

d. আর কারা আমার যোগাযোগের তথ্যের অ্যাক্সেস পেতে পারে এবং কেন?

আপনার বেঁচে থাকার অবস্থা সম্পর্কিত তথ্য সংগ্রহের উদ্দেশ্যে, আপনার নাম বা যোগাযোগের বিবরণ পরিষেবা প্রদানকারীদের সাথে শেয়ার করা হতে পারে।

পরিষেবা প্রদানকারীদের অবশ্যই আপনার নাম বা যোগাযোগের বিবরণ গোপন রাখতে হবে এবং এমন কোনো তথ্য তারা স্পনসরের সাথে শেয়ার করবে না, যা সরাসরি আপনাকে শনাক্ত করতে পারে।

e. আমার কোডবদ্ধ ডেটা কতদিন সংরক্ষণ করা হবে?

অধ্যয়ন সাইট এবং স্পনসর তাদের আইনি বাধ্যবাধকতা পালনার্থে, অধ্যয়ন সমাপ্ত হওয়ার পর 15 বছর পর্যন্ত অধ্যয়নের সমস্ত তথ্য সংরক্ষণ করতে বাধ্য। স্পনসর কীভাবে ব্যক্তিগত তথ্য সংরক্ষণ করে, সে সম্পর্কে আপনি www.astrazenecapersonaldataretention.com ঠিকানায় আরও বিস্তারিত জানতে পারবেন। এরপর আপনার কোডবদ্ধ ডেটা মুছে ফেলা হবে অথবা বেনামীকরণ করা হবে।

বেনামীকরণ সম্পর্কে আরও বিস্তারিত জানতে, অংশ 1 অনুচ্ছেদ 11g দেখুন: “বেনামী ডেটা বলতে কী বোঝায়?”

f. ডেটা সুরক্ষা আইনের অধীনে আমার অধিকারগুলি কী কী?

আপনার কোন ডেটা সংগ্রহ করা হয়েছে এবং ব্যবহার করা হচ্ছে তা পর্যালোচনা করার অধিকার আপনার আছে; আপনি এই ডেটার একটি কপিও চাইতে পারেন, এই ডেটা ব্যবহার সীমাবদ্ধ করার জন্য অনুরোধ করতে পারেন, অথবা ভুল ডেটা সংশোধনের জন্য অনুরোধ করতে পারেন।

অধ্যয়নের বৈজ্ঞানিক অখণ্ডতা নিশ্চিত করার জন্য, অধ্যয়ন শেষ না হওয়া পর্যন্ত আপনি কিছু ডেটা পর্যালোচনা করতে পারবেন না বা এর কোনো কপি পেতে পারবেন না।

এই সীমাবদ্ধ অধিকারগুলি প্রয়োগ করতে, অনুগ্রহ করে অধ্যয়ন ডাক্তারের সাথে যোগাযোগ করুন।

g. বেনামী ডেটা বলতে কী বোঝায়?

স্বাস্থ্য কর্তৃপক্ষ এবং ওষুধ কোম্পানিগুলি উভয়েই মনে করেন যে, ক্লিনিক্যাল অধ্যয়নের ডেটার অ্যাক্সেস ক্লিনিক্যাল বিজ্ঞান ও চিকিৎসা জ্ঞানের অগ্রগতি ঘটায় এবং রোগী ও জনস্বাস্থ্যের সর্বোত্তম স্বার্থ নিশ্চিত করে, তবে শর্ত থাকে যে, রোগীর গোপনীয়তা অবশ্যই সুরক্ষিত থাকতে হবে। অতএব, স্পনসর আপনার অধ্যয়নে সংগৃহীত ডেটার একটি বেনামী সেট অভ্যন্তরীণভাবে বা অন্যান্য গবেষকদের সাথে তৈরি এবং ভাগ করে নিতে পারে (যেমন, www.vivli.org)। এর মানে হলো, আপনার কোডবদ্ধ ডেটা থেকে আপনার রোগীর কোড এবং সেইসাথে এমন অন্য যেকোনো তথ্য যা আপনাকে শনাক্ত করতে যুক্তিসঙ্গতভাবে ব্যবহার করা যেতে পারে, যেমন আপনার জন্ম তারিখ, মুছে ফেলা হবে।

12. অংশগ্রহণের খরচ কত?

এই অধ্যয়নে অংশগ্রহণ করলে আপনার ডাক্তারের সাথে আপনার নিয়মিত অ্যাপয়েন্টমেন্টের খরচের চেয়ে বেশি কিছু খরচ হবে না। এই অধ্যয়নে অংশগ্রহণের জন্য আপনাকে কোনো টাকা দেওয়া হবে হবে না। অধ্যয়নের ওষুধ এবং ল্যাব তদন্তের খরচ অধ্যয়নের মাধ্যমে বহন করা হবে না।

13. অধ্যয়নের পরে আরও কীভাবে জানা যাবে?

ট্রায়াল রেজাল্ট সারাংশ হল এই অধ্যয়নের ফলাফলের একটি সংক্ষিপ্ত এবং সহজে বোধগম্য সারাংশ। শেষ অধ্যয়নের রোগীদের শেষ সাইট ভিজিটের 1 বছরের মধ্যে এগুলি www.trialssummaries.com-এ যোগ করা হবে। আপনার অধ্যয়নের ট্রায়াল রেজাল্ট সারাংশ উপলব্ধ হয়েছে কিনা সেই ব্যাপারে জানতে ইমেলের মাধ্যমে অবহিত হওয়ার জন্য আপনি যেকোনো সময় www.trialssummaries.com ওয়েবসাইটে সাইন আপ করতে পারেন। অথবা আপনার যদি নথির একটি মুদ্রিত কপির প্রয়োজন হয় তাহলে অনুগ্রহ করে আপনার অধ্যয়ন ডাক্তারকে জানান।

অধ্যয়ন প্রোটোকল এবং ফলাফল সম্পর্কিত টেকনিক্যাল ভাষায় তথ্য <http://astrazenecaclinicaltrials> এবং <http://www.clinicaltrials.gov> ওয়েবসাইটে পোস্ট করা হবে। এই অধ্যয়নের বিবরণ <http://ctri.nic.in> ওয়েবসাইটেও পাওয়া যাবে। এই ওয়েবসাইটগুলিতে আপনার সম্পর্কে কোনো তথ্য থাকে না।

14. আমি যদি অধ্যয়নটি ছেড়ে দিতে চাই তাহলে কী হবে?

অধ্যয়নে আপনার অংশগ্রহণ স্বেচ্ছামূলক, যার অর্থ আপনি যেকোনো সময় আপনার অংশগ্রহণ বন্ধ করতে পারেন। আপনি যদি অধ্যয়নের ওষুধ সেবন করা বন্ধ করতে চান, একটি পরিবর্তিত ডিজিটের সময়সূচী নির্ধারণ করতে চান অথবা আপনি যদি আপনার অংশগ্রহণ বন্ধ করতে চান, তাহলে আপনার অধ্যয়ন ডাক্তারকে জানানো উচিত এবং উপলব্ধ বিকল্পগুলি নিয়ে আলোচনা করা উচিত।

আপনি যদি এই অধ্যয়নে অংশগ্রহণ করা বন্ধ করেন, তবে অনুগ্রহ করে জেনে রাখুন যে এটি কেবল "গবেষণায় অংশগ্রহণ প্রত্যাহার" হিসেবে গণ্য করা হবে, ব্যক্তিগত তথ্য প্রক্রিয়াকরণের বিষয়ে প্রদত্ত সম্মতি প্রত্যাহার বা তার প্রতি আপত্তি হিসেবে নয়। অধ্যয়ন ডাক্তার আপনার ডেটা সংগ্রহ করা বন্ধ করে দেবেন তবে, অধ্যয়নের ফলাফল ও নির্ভরযোগ্যতা নিশ্চিত করার স্বার্থে এবং আইন দ্বারা অনুমোদিত সীমার মধ্যে থেকে বিভিন্ন বিধিগত ও নিয়ন্ত্রণমূলক শর্তাবলি মেনে চলার উদ্দেশ্যে, আপনার ইতিপূর্বে সংগৃহীত তথ্যসমূহ সংরক্ষণ ও ব্যবহার করা হবে। এরপর অধ্যয়ন ডাক্তার আপনার শারীরিক অবস্থা যাচাই করার জন্য আপনাকে অধ্যয়ন শেষের পরীক্ষার জন্য আমন্ত্রণ জানাবেন। নির্ধারিত কোনো ডিজিটের দিন আপনি উপস্থিত না হলে, অধ্যয়ন ডাক্তার আপনার সাথে যোগাযোগের চেষ্টা করবেন। অধ্যয়নের ফলাফলের স্বার্থে এটি অত্যন্ত গুরুত্বপূর্ণ। অধ্যয়নে আপনার অংশগ্রহণ কেন বন্ধ করতে চাইছেন, বিশেষ করে আপনি যদি কোনো শারীরিক অস্বস্তি বা সমস্যার সম্মুখীন হয়ে থাকেন তাহলে সে বিষয়ে অধ্যয়ন ডাক্তারকে ব্যাখ্যা করা বাধ্যতামূলক নয়, তবে এটি অধ্যয়নের জন্য সহায়ক হবে।

আমরা আপনার তথ্য এবং সংগৃহীত নমুনাগুলি সেইভাবেই ব্যবহার করা চালিয়ে যাব, যেভাবে ব্যবহারের জন্য আপনি প্রাথমিকভাবে সম্মতি দিয়েছিলেন, যদি না আপনি চান যে আপনি অধ্যয়ন ছেড়ে দেওয়ার পরে আপনার ডেটা ব্যবহার না করা হোক। সেক্ষেত্রে আপনাকে অবশ্যই অধ্যয়ন ডাক্তারকে বিষয়টি অবহিত করতে হবে, তবে ক্লিনিক্যাল প্রবিধান অনুযায়ী আপনার পূর্বে সংগৃহীত ও কোডবদ্ধ ডেটা সংরক্ষণ করা হবে।

15. আমার যেকোনো প্রশ্নের উত্তর কে দিতে পারবে?

মনে রাখবেন, কোনো প্রশ্নই অর্থহীন নয়! যেকোনো সময়ে নির্দিধায় প্রশ্ন করুন! এই অধ্যয়নে অংশগ্রহণ করার সিদ্ধান্ত নেওয়ার আগে সম্পূর্ণ তথ্য সম্পর্কে অবগত হওয়া আপনার অধিকার। আপনি যেকোনো সময়ে অধ্যয়ন ডাক্তারের সাথে যোগাযোগ করতে পারেন; যোগাযোগের ঠিকানাটি অংশে III “রোগীদের জন্য অতিরিক্ত তথ্য” তে উল্লেখ করা আছে।

অংশ II সম্মতি ফর্ম

D9106R00007, ডুরভালুম্যাব

অন্ত্রোপচারযোগ্য নন-স্কল সেল ফুসফুস ক্যান্সারে (এনএসসিএলসি) আক্রান্ত ভারতীয় প্রাপ্তবয়স্ক রোগীদের ক্ষেত্রে ডুরভালুম্যাব-এর নিরাপত্তা মূল্যায়নের লক্ষ্যে একটি সম্ভাব্য, পর্যবেক্ষণমূলক, বহু-কেন্দ্রিক ও বাজারকরণ-পরবর্তী নজরদারি অধ্যয়ন

পরীক্ষাধীন ব্যক্তির নামের আদ্যক্ষর:	
পরীক্ষাধীন ব্যক্তির নাম:	

জন্ম তারিখ (দিন-মাস-বছর):		বয়স (বছর):	
পরীক্ষাধীন ব্যক্তির ঠিকানা:			
যোগ্যতা:			
পেশা: (অনুগ্রহ করে উপর্যুক্ত ঘরে টিক চিহ্ন দিন)	শিক্ষার্থী ☐ স্ব-নিযুক্ত ☐ সার্ভিস ☐ গৃহিণী ☐ অন্যান্য _____		
পরীক্ষাধীন ব্যক্তির বার্ষিক আয়:			
নমিনি(দের) নাম ও ঠিকানা এবং পরীক্ষাধীন ব্যক্তির সাথে তার/তাদের সম্পর্ক:			

অনুগ্রহ করে এই সম্মতিপত্রে কেবল তখনই স্বাক্ষর করবেন, যখন আপনি প্রশ্ন করার সুযোগ পাবেন এবং আপনার সমস্ত প্রশ্নের সন্তোষজনক উত্তর লাভ করবেন। এই পৃষ্ঠায় স্বাক্ষর করার মাধ্যমে, আপনি নিম্নলিখিত বিবৃতিগুলি নিশ্চিত করবেন:

অবহিত সম্মতি ফর্ম

ক্র.নং.	এই বিবৃতিগুলিতে আপনার সম্মতি নিশ্চিত করার লক্ষ্যে, অনুগ্রহ করে নিচের প্রতিটি বিবৃতির পাশে আপনার নামের আদ্যক্ষর (সংক্ষিপ্ত স্বাক্ষর বা স্বাক্ষর) অথবা বৃদ্ধাঙ্গুলের ছাপ (প্রযোজ্য ক্ষেত্রে) প্রদান করুন।	
(i)	আমি নিশ্চিত করছি যে, উপরোক্ত গবেষণার জন্য নির্ধারিত তারিখের, সংস্করণ সংখ্যা বিশিষ্ট অধ্যয়ন সংক্রান্ত তথ্য ও অবহিত সম্মতিপত্র আমি পড়েছি ও বুঝেছি এবং আমার প্রশ্ন করার সুযোগ ছিল।	[]
(ii)	আমি বুঝি যে, এই অধ্যয়নে আমার অংশগ্রহণ সম্পূর্ণ ঐচ্ছিক এবং আমি যেকোনো সময় কোনো কারণ ছাড়াই এটি থেকে সরে আসতে পারি এবং এতে আমার চিকিৎসা পরিষেবা বা আইনি অধিকারের ওপর কোনো প্রভাব পড়বে না।	[]
(iii)	আমি বুঝি যে, এই ক্লিনিক্যাল ট্রায়ালের স্পন্সর, স্পন্সরের পক্ষে কর্মরত অন্যান্য ব্যক্তি, নৈতিকতা কমিটি এবং নিয়ন্ত্রক কর্তৃপক্ষ, কারো পক্ষেই আমার স্বাস্থ্য সংক্রান্ত নথিপত্র যাচাই করার জন্য	[]

	আমার অনুমতির প্রয়োজন হবে না; তা বর্তমান গবেষণার ক্ষেত্রেই হোক কিংবা এর সাথে সম্পর্কিত ভবিষ্যতে পরিচালিত হতে পারে এমন যেকোনো গবেষণার ক্ষেত্রেই হোক, এমনকি আমি যদি এই ট্রায়াল থেকে নিজেকে প্রত্যাহারও করে নিই, তবুও। আমি এই নথিপত্র যাচাইয়ের বিষয়ে সম্মতি প্রদান করছি। তবে, আমি এও অবগত আছি যে, তৃতীয় কোনো পক্ষের নিকট প্রকাশিত বা প্রচারকৃত কোনো তথ্যের মাধ্যমেই আমার প্রকৃত পরিচয় প্রকাশ করা হবে না।	
(iv)	আমি সম্মত হচ্ছি যে, এই অধ্যয়ন থেকে প্রাপ্ত কোনো ডেটা বা ফলাফলের ব্যবহারের ওপর আমি কোনো বিধিনিষেধ আরোপ করব না, তবে শর্ত থাকে যে, এই ব্যবহার কেবল বৈজ্ঞানিক উদ্দেশ্যেই হতে হবে।	[]
(v)	আমি উপরোক্ত অধ্যয়নে অংশগ্রহণ করতে সম্মত।	[]

পরীক্ষাধীন ব্যক্তির / আইনগতভাবে স্বীকৃত প্রতিনিধির (এলএআর) স্বাক্ষর (অথবা বৃদ্ধাঙ্গুলির ছাপ) ও স্বাক্ষরের তারিখ

স্বাক্ষরকারীর নাম (পরীক্ষাধীন ব্যক্তির বা এলএআর-এর নাম, যিনি স্বাক্ষর করেছেন)

যে ক্ষেত্রে একজন পরীক্ষাধীন ব্যক্তি অবহিত সম্মতি প্রদান করতে অক্ষম হন (যেমন: কোনো অচেতন ব্যক্তি, অপ্রাপ্তবয়স্ক ব্যক্তি, কিংবা গুরুতর মানসিক অসুস্থতা বা প্রতিবন্ধকতায় আক্রান্ত ব্যক্তি), সেক্ষেত্রে উক্ত সম্মতি একজন আইনগতভাবে স্বীকৃত প্রতিনিধির নিকট থেকে গ্রহণ করা যেতে পারে (আইনগতভাবে স্বীকৃত প্রতিনিধি হলেন এমন একজন ব্যক্তি, যিনি ভারতের প্রচলিত আইন(সমূহ) অনুযায়ী রোগীর ক্ষেত্রে কোনো হস্তক্ষেপের বিষয়ে সম্মতি প্রদান করতে কিংবা তার অনুমোদন দিতে সক্ষম)।

আইনগতভাবে স্বীকৃত প্রতিনিধির সাথে পরীক্ষাধীন ব্যক্তির সম্পর্ক

তদন্তকারীর স্বাক্ষর

স্বাক্ষরের তারিখ

অধ্যয়ন তদন্তকারীর নাম

যদি পরীক্ষাধীন ব্যক্তি বা তার আইনগতভাবে স্বীকৃত প্রতিনিধি পড়তে বা লিখতে অক্ষম হন, তবে অবহিত সম্মতির সম্পূর্ণ প্রক্রিয়া চলাকালীন একজন নিরপেক্ষ সাক্ষীর উপস্থিতি থাকা আবশ্যিক, উক্ত সাক্ষীকে অবশ্যই সম্মতি ফর্ম স্বাক্ষর করতে হবে।

একজন নিরপেক্ষ সাক্ষী হলেন এমন একজন ব্যক্তি, যিনি ট্রায়াল থেকে সম্পূর্ণ স্বাধীন, যিনি ট্রায়ালের সাথে সংশ্লিষ্ট ব্যক্তিদের দ্বারা কোনোভাবেই অন্যায়ভাবে প্রভাবিত হতে পারেন না, যিনি যদি অধ্যয়নের অধীনে থাকা পরীক্ষাধীন ব্যক্তি বা তার আইনগতভাবে স্বীকৃত প্রতিনিধি পড়তে অক্ষম হন, তাহলে অবহিত সম্মতি প্রদানের প্রক্রিয়ায় উপস্থিতি থাকেন এবং যিনি উক্ত অবহিত সম্মতি ফর্মসহ অধ্যয়নের অধীনে থাকা পরীক্ষাধীন ব্যক্তিকে সরবরাহকৃত অন্য যেকোনো লিখিত তথ্য পড়ে শোনান।

নিরপেক্ষ সাক্ষীর স্বাক্ষর

স্বাক্ষরের তারিখ

নিরপেক্ষ সাক্ষীর নাম

রোগী তথ্যপত্রের (প্রাপ্তবয়স্ক অধ্যয়ন অংশগ্রহণকারীর মূল তথ্য) একটি কপি এবং যথাযথভাবে পূরণকৃত ‘অবহিত সম্মতি ফর্ম’ সংশ্লিষ্ট অংশগ্রহণকারী অথবা তার আইনগতভাবে স্বীকৃত প্রতিনিধির নিকট হস্তান্তর করতে হবে।

অংশ III: রোগীদের জন্য অতিরিক্ত তথ্য

1. যোগাযোগের বিবরণ

অধ্যয়ন ডাক্তার	অধ্যয়ন সমন্বয়কারী (যেমন: অধ্যয়নের জন্য নিযুক্ত নার্স)
ফোন নম্বর	ফোন নম্বর
ঠিকানা	ঠিকানা
ইমেল ঠিকানা	ইমেল ঠিকানা

ইসি সদস্য সচিবের নাম	
ইসি সদস্য সচিবের ফোন নম্বর	

2. ভিজিট এবং পরীক্ষা/প্রক্রিয়ার বিস্তারিত তালিকা

বর্তমান অধ্যয়ন প্রোটোকল-সংক্রান্ত কোনো বাধ্যতামূলক নির্দেশ নেই; তাই, আপনি বর্তমানে যে চিকিৎসা গ্রহণ করছেন, তা ছাড়া আপনার ওপর আলাদা কোনো পরীক্ষা চালানো হবে না। আমরা ডুরভালুম্যাব এর প্রথম ডোজ গ্রহণের দিন থেকে শুরু করে ডুরভালুম্যাব এর শেষ ডোজ গ্রহণের পরবর্তী *90 দিন পর্যন্ত, অথবা পরবর্তী কোনো ক্যানসার-প্রতিরোধী চিকিৎসা শুরু করার দিন পর্যন্ত, অথবা আপনার সম্মতি প্রত্যাহার, ফলো-আপ থেকে বিচ্ছিন্ন হয়ে যাওয়া, অথবা মৃত্যু, এগুলির মধ্যে যেটি আগে ঘটবে, সেই সময়কাল পর্যন্ত আপনার স্বাস্থ্যের তথ্যাবলি সংগ্রহ করব। এই অধ্যয়নের সময়কালে, আপনার মধ্যে দেখা দিতে পারে এমন যেকোনো পার্শ্বপ্রতিক্রিয়া যেমন: ক্লান্তি, পেশি ও হাড়ের ব্যথা, কোষ্ঠকাঠিন্য, ক্ষুধা হ্রাস, বমি বমি ভাব, হাত-পা ফুলে যাওয়া (পেরিফেরাল ইডেমা), মূত্রনালীর সংক্রমণ অথবা অন্য কোনো অজানা পার্শ্বপ্রতিক্রিয়া আমরা লিপিবদ্ধ করবো। কতবার এবং কখন চিকিৎসকের কাছে আসতে হবে, তা রোগীর শারীরিক অবস্থার ওপর ভিত্তি করে চিকিৎসকের বিবেচনামতো নির্ধারিত হবে। রোগীর বয়স, রোগের বর্তমান অবস্থা, বিভিন্ন পরীক্ষার ফলাফল, ডুরভালুম্যাব-এর মাত্রা এবং অন্যান্য চিকিৎসা সংক্রান্ত তথ্য অধ্যয়নের শুরুতে এবং পুরো অধ্যয়নকাল জুড়ে সংগ্রহ করা হবে।

3. বিস্তারিত অধ্যয়ন পরীক্ষা ও কার্যপ্রণালীর সময়সূচি

এখানে কী আশা করা যায় তার রূপরেখা দেওয়া হল

প্রাথমিক মূল্যায়ন / স্ক্রিনিং

প্রাথমিক মূল্যায়নে, এই অধ্যয়নে অংশগ্রহণের জন্য আপনার উপযুক্ততা যাচাইয়ের উদ্দেশ্যে প্রয়োজনীয় প্রাথমিক প্রক্রিয়াগুলি সম্পন্ন করা হবে। এর অন্তর্ভুক্ত বিষয়গুলির মধ্যে রয়েছে—অবহিত সম্মতি ফর্ম স্বাক্ষর করা, অন্তর্ভুক্তকরণ/ বহিষ্কার সংক্রান্ত মানদণ্ডগুলি যাচাই করা, আপনার জনতত্ত্ব তথ্য, চিকিৎসার ইতিহাস এবং বর্তমানে সেবনকৃত ওষুধ সংক্রান্ত বিস্তারিত বিবরণ লিপিবদ্ধ করা এবং রোগীর শারীরিক পরীক্ষা, গুরুত্বপূর্ণ লক্ষণগুলি বা গুরুত্বপূর্ণ শারীরিক সূচকগুলির যাচাই করা, ইসিওজি পারফর্মেন্স স্ট্যাটাস মূল্যায়ন এবং প্রাথমিক পর্যায়ের ক্লিনিক্যাল ও রেডিওলজিক্যাল ইমেজিং সম্পন্ন করা। টিউমারের প্রাথমিক পরিমাপগুলো রেসিস্ট 1.1 নির্দেশিকা অনুযায়ী নথিভুক্ত করা হবে যা চিকিৎসার প্রতি রোগীর সাড়াকে মূল্যায়নের জন্য একটি প্রমিত বা মানসম্মত নিয়মাবলি প্রদান করে এবং পাশাপাশি প্রয়োজনীয় ল্যাবরেটরি মূল্যায়নগুলিও সম্পন্ন করা হবে।

নিওঅ্যাডজুভেন্ট চিকিৎসার সময়কাল

নিয়মিত মূল্যায়নের অন্তর্ভুক্ত থাকবে সহগামী ওষুধের তথ্য লিপিবদ্ধকরণ, শারীরিক পরীক্ষা এবং গুরুত্বপূর্ণ লক্ষণগুলির যাচাইকরণ। চিকিৎসার প্রতি রোগীর সাড়াকে পর্যবেক্ষণ করার লক্ষ্যে ক্লিনিক্যাল ও রেডিওলজিক্যাল মূল্যায়ন সম্পাদন করা হবে, সেই সাথে চিকিৎসার সাথে সম্পর্কিত পরিবর্তনসমূহ নজরে রাখতে ল্যাবরেটরি মূল্যায়ন সহায়তা করবে। যেকোনো ধরনের বিরূপ ঘটনা (এইএ) কিংবা গুরুতর বিরূপ ঘটনা (এসএএ) সবকিছুই অত্যন্ত সতর্কতার সাথে নথিভুক্ত করা হবে।

অস্ত্রোপচারের পূর্ববর্তী সময়কাল

অস্ত্রোপচারের প্রস্তুতির অংশ হিসেবে, প্রয়োজনে রোগীর যোগ্যতার মাপকাঠিগুলি পুনরায় যাচাই করা হতে পারে। রোগীর বর্তমানে সেবনকৃত সহগামী ওষুধসমূহ এবং রেসিস্ট 1.1 মূল্যায়নসহ বিভিন্ন ক্লিনিক্যাল ও রেডিওলজিক্যাল পরীক্ষার আপ টু ডেট তথ্য নথিভুক্ত করা হবে। অস্ত্রোপচার-পূর্ববর্তী এই পর্যায়ে রোগীর অস্ত্রোপচারের জন্য সর্বোত্তম প্রস্তুতি নিশ্চিত করার ওপর বিশেষ গুরুত্ব দেওয়া হবে। এই পুরো সময়কাল জুড়ে বিরূপ ঘটনা (এই) এবং গুরুতর বিরূপ ঘটনাগুলোর (এসএএই) নিরাপত্তা পর্যবেক্ষণ অব্যাহত থাকবে।

অস্ত্রোপচার সময়কাল

অস্ত্রোপচারের পর্যায়ে টিউমার অপসারণের জন্য প্রকৃত অস্ত্রোপচারের হস্তক্ষেপ জড়িত। এই সময়ের মধ্যে, প্রয়োজনীয় পেরিওপারেটিভ ওষুধগুলি নথিভুক্ত করা হবে। নিরাপত্তা পর্যবেক্ষণ অস্ত্রোপচার-সম্পর্কিত এই-গুলি বা এসএই-গুলি সনাক্তকরণের উপর দৃষ্টি নিবদ্ধ করবে।

অস্ত্রোপচার-পরবর্তী সময়কাল

অস্ত্রোপচারের পর, রোগীদের আরোগ্য এবং অস্ত্রোপচারের ফলাফল মূল্যায়নের জন্য স্বাস্থ্য পর্যবেক্ষণ করা হবে। এর মধ্যে রয়েছে সহগামী ওষুধ রেকর্ড করা, শারীরিক পরীক্ষা পরিচালনা করা এবং গুরুত্বপূর্ণ লক্ষণগুলি পরীক্ষা করা। ক্লিনিক্যাল এবং রেডিওলজিক্যাল মূল্যায়ন অস্ত্রোপচারের সাফল্য এবং অবশিষ্ট রোগের মূল্যায়ন করবে, যখন রেসিস্ট 1.1 মূল্যায়ন এবং পরীক্ষাগার পরীক্ষা আরও অন্তর্দৃষ্টি প্রদান করবে। এই পর্যায়ে এই-গুলি এবং এসএই-গুলি এর জন্য পর্যবেক্ষণ একটি অগ্রাধিকার হিসাবে থাকে।

ডুরভালুম্যাব মনোথেরাপি পর্যায়

সহায়ক চিকিৎসা চলাকালীন সময়ের মূল লক্ষ্য হল রোগের পুনরাবৃত্তির ঝুঁকি হ্রাস করা। রোগীরা নিয়মিত মূল্যায়নের মাধ্যমে চিকিৎসা গ্রহণ অব্যাহত রাখবেন, এই মূল্যায়নের অন্তর্ভুক্ত থাকবে সহগামী ওষুধ সংক্রান্ত আপডেট করা তথ্য, শারীরিক পরীক্ষা, ক্লিনিক্যাল ও রেডিওলজিক্যাল মূল্যায়ন, রেসিস্ট 1.1 প্রক্রিয়া অনুযায়ী টিউমার মূল্যায়ন এবং ল্যাবরেটরি পর্যবেক্ষণ। রোগীর নিরাপত্তা পর্যবেক্ষণ অত্যন্ত গুরুত্বপূর্ণ একটি বিষয়, এবং এই প্রক্রিয়ায় যেকোনো ধরনের এই-গুলি বা এসএই-গুলি বিস্তারিত নথিপত্র সংরক্ষণ করা হবে।

ফলো-আপ পর্যায়

ফলো-আপ পর্যায়ে, রোগের পুনরাবৃত্তি বা পরবর্তীকালে উদ্ভূত কোনো জটিলতা শনাক্ত করার লক্ষ্যে রোগীদের দীর্ঘমেয়াদী পর্যবেক্ষণে রাখা হবে। এই সময়ে ক্লিনিক্যাল ও রেডিওলজিক্যাল মূল্যায়ন এবং সেই সাথে রেসিস্ট 1.1 ভিত্তিক পর্যালোচনা কার্যক্রম অব্যাহত থাকবে। এছাড়া, এই পুরো পর্যায় জুড়ে চিকিৎসার সর্বশেষ ডোজ গ্রহণের 90 দিন পর পর্যন্ত অথবা অন্য কোনো নতুন চিকিৎসা শুরুর প্রথম দিন পর্যন্ত (যেটি আগে ঘটবে), রোগীর সেবনকৃত অন্যান্য ওষুধের আপডেট করা তথ্য সংগ্রহ এবং যেকোনো ধরনের এই-গুলি বা এসএই-গুলি-এর প্রতিবেদন তৈরির কাজও সম্পন্ন করা হবে, তবে রোগীর সম্মতি প্রত্যাহার, পর্যবেক্ষণের আওতা থেকে বিচ্ছিন্ন হয়ে যাওয়া, অথবা মৃত্যু, এসব ঘটনার মধ্যে যেটি আগে ঘটবে, সেই সময় পর্যন্তই এই কার্যক্রম চলবে।

প্রতিটি ভিজিটে কী প্রত্যাশা করা উচিত, তার বিবরণ সম্বলিত সারণি:

ডেটা সংগ্রহ ও সন্নিবেশ	প্রাথমিক মূল্যায়ন / স্ক্রিনিং	নিওঅ্যাডজুভেন্ট চিকিৎসার সময়কাল	অস্ত্রোপচারের পূর্বে	অস্ত্রোপচার	অস্ত্রোপচার-পরবর্তী	সহায়ক চিকিৎসা সময়কাল	ফলো-আপ সময়কাল
অবহিত সম্মতি	X						
স্ক্রিনিং	X		X				
গর্ভাবস্থা পরীক্ষা ^a	X						
রোগীর জনতত্ত্ব ও চিকিৎসার ইতিহাস	X				X		
রোগের চিকিৎসা ইতিহাস ও রোগের প্রাথমিক অবস্থা (ইজিএফআর/এএলকে অবস্থা সহ)	X						
আপনি যে ওষুধ খাচ্ছেন	X	X	X	X	X	X	X
শারীরিক পরীক্ষা ও গুরুত্বপূর্ণ লক্ষণসমূহ	X	X				X	X
ইসিওজি কর্মক্ষমতা অবস্থা	X						X
ক্লিনিক্যাল ও রেডিওলজিক্যাল মূল্যায়ন	X	X	X		X	X	X
রেসিস্ট 1.1 মূল্যায়ন	X		X		X	X	X
ইসিজি		ক্লিনিক্যাল নির্দেশিত অনুযায়ী					
ল্যাবরেটরি মূল্যায়ন	X	X				X	X
এনএসসিএলসি চিকিৎসার বিস্তারিত বিবরণ		X				X	X
এই এবং এসএই প্রতিবেদন	X	X	X	X	X	X	X

^a শুধুমাত্র সন্তান ধারণের সম্ভাবনা সম্পন্ন মহিলারা

4. ঝুঁকি, পার্শ্বপ্রতিক্রিয়া এবং অস্বস্তিসমূহের পূর্ণাঙ্গ তালিকা

যেহেতু এটি একটি পর্যবেক্ষণমূলক অধ্যয়ন, তাই এই অধ্যয়নে অংশগ্রহণের সাথে সরাসরি যুক্ত কোনো পার্শ্বপ্রতিক্রিয়া বা ঝুঁকি নেই।

দুরভ্যাস্য হ'ল এক ধরনের ইমিউনোথেরাপি, যা রোগ প্রতিরোধ ব্যবস্থাকে ক্যান্সারের বিরুদ্ধে লড়াই করতে সহায়তা করে। যেহেতু এটি রোগ প্রতিরোধ ব্যবস্থাকে সক্রিয় করে তোলে, তাই এটি মাঝে মাঝে রোগ প্রতিরোধ ব্যবস্থাকে শরীরের স্বাভাবিক অঙ্গপ্রত্যঙ্গগুলির ওপর প্রভাব ফেলতে পারে।

সাধারণ পার্শ্বপ্রতিক্রিয়া

- কম লোহিত রক্তকণিকার সংখ্যা (অ্যানিমিয়া)
- বমি বমি ভাব
- কোষ্ঠকাঠিন্য
- ক্লান্তি
- পেশি বা হাড়ের ব্যথা
- স্বকের র‍্যাশ

রোগ প্রতিরোধ ব্যবস্থা-সম্পর্কিত সম্ভাব্য পার্শ্বপ্রতিক্রিয়া

দুরভ্যাস্য শরীরের বিভিন্ন অঙ্গে প্রদাহ সৃষ্টি করতে পারে, যার মধ্যে অন্তর্ভুক্ত রয়েছে:

- ফুসফুস (কাশি, শ্বাসকষ্ট)
- লিভার (স্বক/চোখ হলুদ হয়ে যাওয়া, অ্যাবনরমাল লিভার পরীক্ষা)
- অস্ত্র (ডায়রিয়া, পেটে ব্যথা)
- হরমোন গ্রন্থি (থাইরয়েড বা অ্যাড্রেনাল গ্রন্থির সমস্যা, যা ক্লান্তি, মাথা ঘোরা বা ওজনের পরিবর্তনের কারণ হয়)
- কিডনি
- স্বক

চিকিৎসাকালীন বা চিকিৎসার পরবর্তী এই পার্শ্বপ্রতিক্রিয়াগুলি দেখা দিতে পারে। অধিকাংশ পার্শ্বপ্রতিক্রিয়াই প্রাথমিক পর্যায়ে শনাক্ত করা গেলে চিকিৎসায়োগ্য; তবে কিছু ক্ষেত্রে এগুলি গুরুতর হতে পারে এবং এর জন্য হাসপাতালে ভর্তি হওয়া কিংবা চিকিৎসা বন্ধ করার প্রয়োজন হতে পারে। কদাচিৎ, গুরুতর জটিলতাসমূহ প্রাণঘাতীও হতে পারে।

অন্যান্য চিকিৎসার পার্শ্বপ্রতিক্রিয়া

আপনার নিয়মিত চিকিৎসার অংশ হিসেবে আপনি যদি কেমোথেরাপি, অস্ত্রোপচার কিংবা রেডিয়েশন থেরাপি গ্রহণ করেন, তবে এই চিকিৎসাসমূহের ফলে বমি বমি ভাব, চুল পড়া, সংক্রমণ, রক্তপাত, ব্যথা, শ্বাসকষ্ট বা অবসাদের মতো অতিরিক্ত পার্শ্বপ্রতিক্রিয়া দেখা দিতে পারে। আপনার চিকিৎসক আপনাকে আলাদাভাবে এই ঝুঁকিগুলি সম্পর্কে বিস্তারিত বুঝিয়ে বলবেন।

নিয়মিত পরীক্ষার ঝুঁকি

রুটিন রক্ত পরীক্ষার ফলে সামান্য ব্যথা বা কালশিটে দাগ হতে পারে। ইসিজি-এর কারণে স্বক সামান্য অস্বস্তি বা জ্বালা হতে পারে। এই প্রক্রিয়াগুলি থেকে কোনো বড় ধরনের ঝুঁকির আশঙ্কা নেই।

5. সংগৃহীত ব্যক্তিগত ডেটার পূর্ণাঙ্গ তালিকা

অংশ I অনুচ্ছেদ 11a-তে বর্ণিত সমস্ত তথ্য এই অধ্যয়নকালে সংগ্রহ করা হবে।

6. শব্দকোষ

আপনার কোডবদ্ধ ডেটা	অধ্যয়ন সাইটে সংগৃহীত আপনার সমস্ত ডেটা যার মধ্যে আপনার নাম ও যোগাযোগের বিবরণ অন্তর্ভুক্ত রয়েছে, একটি কোড দ্বারা প্রতিস্থাপিত করা হয়েছে। এই কাজটি আপনার নিরাপত্তা ও গোপনীয়তা নিশ্চিত করার লক্ষ্যে আপনার অধ্যয়ন ডাক্তার দ্বারা সম্পন্ন করা হয়েছে, যিনি আপনার নাম/যোগাযোগের বিবরণ এবং এই কোডের মধ্যকার সংযোগটি নিজের কাছে সংরক্ষণ করেন। প্রযোজ্য আইন দ্বারা অনুমোদিত না হলে এবং আপনার অধ্যয়ন ডাক্তার আপনার নাম বা যোগাযোগের বিবরণ প্রদান না করলে, কোডবদ্ধ তথ্যের মাধ্যমে আপনাকে শনাক্ত করা সম্ভব নয়।
স্পন্সরের বিবরণ	স্পন্সর: অ্যাস্ট্রাজেনেকা ফার্মা ইন্ডিয়া লিমিটেড ক্লিনিক্যাল অধ্যয়নের সামগ্রিক দায়িত্ব হল স্পন্সরের।
অধ্যয়ন সাইটের বিবরণ	ক্লিনিক্যাল অধ্যয়ন যেখানে হচ্ছে এবং যেখানে আপনাকে পরিকল্পিত ভিজিটের জন্য যেতে হবে।
স্বাস্থ্য কর্তৃপক্ষ	যারা অধ্যয়নের তত্ত্বাবধান করেন, যারা ওষুধের বাণিজ্যিকীকরণ অনুমোদন করেন অথবা যারা প্রতিকূল ঘটনাগুলির প্রতিবেদন পান, তা আপনার দেশে হোক বা অন্য দেশে।
গবেষণা অংশীদার	ওষুধ উন্নয়ন কর্মসূচিতে বা ভবিষ্যতের গবেষণার জন্য স্পন্সরের সাথে সহযোগিতা করে এমন যেকোনো সংস্থা।
পরিষেবা প্রদানকারী	চুক্তির মাধ্যমে স্পন্সরের সাথে আবদ্ধ যেকোনো সংস্থা, যা স্পন্সরের কঠোর নির্দেশাবলীর অধীনে তার পক্ষে কার্যক্রম পরিচালনা করতে পারে। এর মধ্যে অন্যান্য গবেষক অন্তর্ভুক্ত থাকতে পারে, যার মধ্যে রয়েছে তথাকথিত "চুক্তিবদ্ধ গবেষণা সংস্থা" (সিআরও) এবং আইটি কোম্পানি যারা ক্লিনিক্যাল ডেটা হোস্ট করে বা নতুন সিস্টেম এবং পরিষেবা বিকাশ সহ আইটি পরিষেবা প্রদান করে।

সুরক্ষা ব্যবস্থা	অধ্যয়নকালীন ও পরবর্তী সময়ে কোডবদ্ধ ডেটা সুরক্ষার লক্ষ্যে যথাযথ সুরক্ষাব্যবস্থা বাস্তবায়ন করা হবে, যার অন্তর্ভুক্ত থাকতে পারে: — কোডবদ্ধ ডেটা অ্যাক্সেস করার সুযোগ কেবল নির্দিষ্ট কিছু ব্যক্তির মধ্যেই সীমাবদ্ধ থাকবে, যারা গোপনীয়তা রক্ষার বাধ্যবাধকতার অধীন (যার অন্তর্ভুক্ত হল ব্যক্তিদের পুনরায় শনাক্ত করার বা ক্লিনিক্যাল তথ্য ডিকোড করার কোনো প্রচেষ্টা না চালানোর বাধ্যবাধকতা)। — কোডবদ্ধ ডেটা সুরক্ষা ব্যবস্থার মাধ্যমে সুরক্ষিত করা হবে যাতে ডেটা পরিবর্তন, ক্ষতি এবং অননুমোদিত অ্যাক্সেস এড়ানো যায় এবং আরও শনাক্তকরণ কৌশল প্রয়োগ করা যেতে পারে। — প্রতিটি বৈজ্ঞানিক গবেষণার সাথে সম্পর্কিত গোপনীয়তার ঝুঁকি, যদি থাকে, সনাক্ত এবং প্রশমনের জন্য একটি ডেটা সুরক্ষা প্রভাব মূল্যায়ন (ডিপিআইএ) প্রয়োগ করা হবে। — প্রযোজ্য আইন অনুসারে যখন প্রয়োজন হয়, তখন বৈজ্ঞানিক গবেষণা নৈতিকতা কমিটির অনুমোদন সাপেক্ষে। — কোডবদ্ধ ডেটা সরাসরি বিপণনের উদ্দেশ্যে বা অন্যান্য উদ্দেশ্যে ভাগ করা হবে না যা আইনি কর্তব্য নয় বা প্রযোজ্য ডেটা সুরক্ষা আইন অনুসারে বৈজ্ঞানিক গবেষণা হিসাবে বিবেচিত হয় না। বিশেষ করে, এটি ভবিষ্যতে আপনার জন্য উপলব্ধ পরিষেবা, যেমন বীমা সম্পর্কে সিদ্ধান্ত নেওয়ার জন্য ব্যবহার করা হবে না।
নিরাপত্তা ব্যবস্থা: অন্যান্য দেশে আমার ডেটা কীভাবে সুরক্ষিত থাকে?	আপনার ডেটা প্রক্রিয়াকরণ অধ্যয়ন সাইট থেকে শুরু হয়। এরপর আপনার ডেটা যাচাই করার জন্য এবং ফলাফল গণনা করার জন্য বেশ কয়েকটি ডেটা বিশেষজ্ঞের কাছে স্থানান্তরিত করা হবে। আপনার ডেটা কোডবদ্ধ করার পাশাপাশি, আপনার ডেটা শক্তিশালী অ্যাক্সেস নিয়ন্ত্রণ এবং এনক্রিপশনের মতো উচ্চমানের প্রযুক্তিগত সুরক্ষা উপায় দ্বারাও সুরক্ষিত। স্পন্সর গ্রুপের মধ্যে, আপনার কোডবদ্ধ ডেটা বাইন্ডিং কর্পোরেট রুলস (বিসিআর) দ্বারা সুরক্ষিত। আপনি স্পন্সরের বিসিআর সম্পর্কে আরও তথ্য এখানে পেতে পারেন: www.astrazenecabindingcorporaterules.com আপনার অধ্যয়ন ডাক্তারের সাথে জিজ্ঞাসা করে আপনি আরও তথ্যের পাশাপাশি এই ব্যবস্থাগুলির একটি কপি পেতে পারেন।
সীমাবদ্ধ অধিকার	অনুগ্রহ করে মনে রাখবেন যে জিডিপিআর এবং যুক্তরাজ্য গোপনীয়তা আইন দ্বারা প্রদত্ত ডেটা বাতিল করার অধিকার (অর্থ্যাৎ, মুছে ফেলার অধিকার) এই ধরনের গবেষণার ক্ষেত্রে প্রযোজ্য নয়।

বৈজ্ঞানিক গবেষণা	বৈজ্ঞানিক গবেষণায় প্রযুক্তিগত উন্নয়ন এবং প্রদর্শন, মৌলিক গবেষণা, প্রয়োগিক গবেষণা এবং বেসরকারি অর্থায়নে পরিচালিত গবেষণার পাশাপাশি জনস্বাস্থ্যের ক্ষেত্রে জনস্বার্থে পরিচালিত গবেষণা অন্তর্ভুক্ত রয়েছে। এর অর্থ হল, রোগের চিকিৎসার জন্য নতুন ওষুধ, চিকিৎসা যন্ত্র, ডায়াগনস্টিক পণ্য, সরঞ্জাম এবং/অথবা অন্যান্য থেরাপি কীভাবে তৈরি করা যায় সে সম্পর্কে আমাদের ধারণা উন্নত করতে আমরা এই তথ্য ব্যবহার করতে পারি। আমরা ভবিষ্যতের ক্লিনিক্যাল অধ্যয়ন, পরিষেবা এবং ওষুধের পরিকল্পনা এবং বাস্তবায়ন উন্নত করতে, ফলাফল গবেষণা কার্যক্রমের জন্য এবং মূল্য নির্ধারণ এবং প্রতিদান কার্যক্রমে সহায়তা করার জন্যও এই তথ্য ব্যবহার করতে পারি।
বৈজ্ঞানিক ডেটাবেসে জমা করা	আরও শক্তিশালী গবেষণার জন্য, গবেষকদের জন্য এক বা একাধিক বৈজ্ঞানিক ডেটাবেসে তথ্য স্থাপন করে তথ্য ভাগ করে নেওয়া সহায়ক। গবেষকরা এরপর বেশ কয়েকটি গবেষণা প্রকল্প থেকে সম্মিলিত তথ্য অধ্যয়ন করতে পারেন এবং স্বাস্থ্য এবং রোগ সম্পর্কে আরও জানতে পারেন। অনুমোদিত বৈজ্ঞানিক গবেষণা প্রকল্পের গবেষকরা আপনার কোডবদ্ধ ডেটা, এবং অন্যান্য অনেক মানুষের ডেটা দেখতে এবং ব্যবহার করতে সক্ষম হতে পারেন। আপনার নাম এবং অন্যান্য তথ্য যা আপনাকে সরাসরি শনাক্ত করতে পারে (যেমন ঠিকানা বা সামাজিক নিরাপত্তা নম্বর) কখনই এই ধরনের বৈজ্ঞানিক ডেটাবেসে রাখা হবে না। গবেষকদের সর্বদা আপনার গোপনীয়তা রক্ষা করার এবং আপনার তথ্য গোপন রাখার দায়িত্ব থাকবে।

Translated from Bengali to English Version 1.0 Dated 16
Mar 2026

STUDY INFORMATION AND INFORMED CONSENT FORM

Code of Study:	D9106R00007	Site No:	
Sponsor:	AstraZeneca Pharma India Limited	Subject Id:	
Principal Investigator:			
Title of the Study:	A prospective, observational, multicenter, post marketing surveillance study to assess safety of Durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC)		

There are [3] parts to this document:

Part I: the “**Study Information**” essential to your decision to take part in the clinical study,

Part II: your “**Consent Form**” which summarises what you may agree to,

Part III: supplementary information in the “Additional information for patients” Section, which includes a glossary.

PART I: STUDY INFORMATION

D9106R00007, Durvalumab Post Marketing Safety Study

Observational Study to Assess the Safety of Durvalumab in Indian Adults with Removable Lung Cancer

Dear Madam/Sir,

You are invited to take part in this study because you have recently been diagnosed with a type of lung cancer called resectable (removable) non-small cell lung cancer (NSCLC). You have accepted the recommended treatment approach, which includes durvalumab in combination with chemotherapy as pre-operative therapy, followed by durvalumab monotherapy after surgery. This treatment is designed to help shrink the tumour and reduce the risk of cancer from returning.

We are conducting this study to evaluate the safety of durvalumab in patients with resectable NSCLC. In this post-marketing study, your treatment will continue as decided by your doctor, and we will only collect your data. Participation requires your written consent. You will be provided an explanation regarding what the study involves prior to you decide whether you want to take part in this study.

The overall description of this study, which includes the collection, storage, and use of your data and documentation, etc. has been reviewed in your country by an independent Ethics Committee to ensure that the rights, safety, and well-being of study patients are protected.

If you join the study your condition may or may not improve. Although, the information we get from this study might help other patients with the same condition in the future.

1 What is this study about?

Durvalumab is a type of medicine known as immunotherapy. It works by helping your body's immune system recognize and attack cancer cells. Some cancer cells protect themselves by using a signal called PD-L1 which "switch off" the immune system. Durvalumab blocks this signal, helping your immune system find and destroy the cancer cells.

We are doing this study to learn more regarding how safe durvalumab is when used for the treatment of removable NSCLC, a type of lung cancer. This type of cancer occurs when uncontrolled cells multiply in your lungs and form a tumour. Pre-operative therapy, like the combination of durvalumab and platinum chemotherapy, is provided prior to surgery to help shrink the tumour and enhance the body's defence. After surgery is done to remove a tumour, some small cancer cells that are too small to be detected by MRI, CT, or PET scans may remain. To return, later these residual cells can sometimes survive and cause the cancer. After surgery, durvalumab monotherapy is provided to strengthen the body's ability to fight against residual cancer cells and to reduce the risk of cancer from coming back.

The aim of the study is to make sure that durvalumab is safe, as shown in earlier studies, while also looking out for any new or unexpected side effects. Durvalumab has been in the market since 2017 and is approved by the United States Food and Drug Administration (USFDA).

In this study regarding 78 patients will take part. The total duration of the study will be from the date of the first dose of durvalumab until the date of the last dose of durvalumab +90 days or the date of the first dose of subsequent anti-cancer therapy, until withdrawal of consent, lost to follow-up, or death, whichever is earlier.

2 Do I have to take part?

To take part, you have a choice whether or not you would like to.

To take part in this study, kindly take as much time as you need to decide whether or not you would like to. It may be helpful to talk with your friends and family as you make this decision.

If you join the study, you can leave it at any time (see "section 14" for more details). Leaving will not affect your care. Kindly let your study doctor know as soon as possible if you choose to leave the study.

Kindly consider the study time commitments and responsibilities as a research patient when you are deciding to take part.

You will continue to receive care for your lung cancer if you don't join the study. Your study doctor or treating physician will talk to you regarding other possible drugs, their risks, and benefits.

3 What will happen if I join the study?

Because this is an observational study, no medications or other treatments are provided to you by the Sponsor as part of this study.

By your doctor, you will be needed to continue with your routine doctor's appointments and to take your regular medication as prescribed.

Prior to you join the study drug you will undergo a series of tests. This is called screening. You may enter the study. If you meet the screening criteria. If you don't meet the screening criteria, the reasons will be explained. Your study doctor or treating physician will talk to you regarding other possible treatments/options.

You will undergo routine biopsies and staging investigations and will be offered durvalumab as pre-operative and post-operative therapy in accordance with the approved prescribing information by your doctor. We will collect your data throughout the study. You will be in the study from the date of the first dose of durvalumab until the date of the last dose of durvalumab +90 days or the date of the first dose of subsequent anti-cancer therapy, until the withdrawal of consent, lost to follow-up or death, whichever is earlier. Your participation in the study may need to be longer to get better answers to the study questions.

The total number of visits and the visit time will be determined at the discretion of the investigator based on the patient's condition.

During the routine visits, information will be collected for the study, and this might add some extra time to your routine visit.

You must tell your study doctor if you cannot come to a visit.

Kindly note that the study, and your participation in the study, may be stopped earlier than expected, for example for scientific or safety reasons (see "Section 9" for more details).

4 What are the needed tests and procedures?

While you are on the study, we will need to take your medical data from your records. As part of the standard of care examinations, the data from the below mentioned tests and process will be recorded:

Patient Demographics & Medical History

Your date of birth, gender, height, weight, presence of pregnancy and breastfeeding in case of female patients, and pregnancy status of female partners in case of male patients will be collected. Also, medical history of any other disease and date and type of anti-meningococcal vaccination, which includes boosters, will be collected. Disease medical history & baseline disease status (which includes EGFR/ALK status). Your disease history, like staging

information, ECOG performance status (your ability to function in daily life), and EGFR/ALK status (to check for the presence of change in the gene), if available, will be collected from your medical records.

Concomitant Medications

Information regarding any ongoing medications you have been taking will be noted from your medical records, which includes drug name, daily dose, route, and indication.

Physical examination and Vital signs

Any results of physical examinations performed, or vital signs (especially body weight) recorded by your study doctor will be noted.

ECG

ECG readings taken over the duration of the study, especially at baseline, pre-surgery, and post-surgery, will be noted from your medical records.

Clinical & Radiological Assessments

All clinical and radiological assessments, like MRI/CT/PET, performed to evaluate the disease status or overall clinical response, and RECIST 1.1 assessments, which assess the response of the tumour to treatment in clinical trials, whenever available, will be recorded for the study.

Laboratory assessments

Results of any laboratory tests performed at baseline and during durvalumab treatment as per prescribed treatment, which includes but not limited to clinical chemistry, haematology, kidney function test, liver function test, thyroid levels, urinalysis, Hepatitis B and C, HIV, pregnancy tests, etc., will be noted.

NSCLC Treatment details

All treatments provided in line with the prescribed treatment, which includes surgery and chemotherapy prior to and after surgery, will be recorded. Details to be noted will include the total dose, total duration of treatment, ongoing or discontinuation status of treatment, and reason for discontinuation of treatment/ reason for changing the dose of treatment.

Safety assessment

The occurrence of any side effect you might be experiencing, although small it may be, will be evaluated by your study doctor. When a side effect occurs, information on the below mentioned items will be collected: what the side effect is, when it started and ended, how serious it is, how bad it felt, whether it is associated with the study drug, what is done regarding the drug because

of the side effect, what happened afterwards, what steps were taken regarding the side effect, and any comments from the doctor.

The complete list of study tests and procedures, which includes their detailed schedule is available in the “Part III: Additional information for patients”.

5. What are the optional tests and procedures?

Since this is an observational study, we will only collect data from your medical records. There will be no additional or optional tests or process.

6. What are the risks of joining the study?

By your doctor this study will only capture the routine medical treatment provided to you. There is no immediate clinical benefit for you. Although, the information we get from this study may help us to describe how lung cancer patients are managed in real-life practice and to increase our knowledge regarding the disease and its symptoms. This will hopefully help us to better treat patients with lung cancer in the future.

Since Durvalumab is an immunotherapy that helps the immune system fight cancer. Since it activates the immune system, it may sometimes cause the immune system to affect normal organs and may cause some unwanted effects.

Common Side Effects

- Low red blood cell count (anaemia)
- Nausea
- Constipation
- Tiredness
- Muscle or bone pain
- Skin rash

Possible Immune-Related Side Effects

Durvalumab may cause inflammation in various organs, which includes:

- Lungs (cough, shortness of breath)
- Liver (yellowing of skin/eyes, abnormal liver tests)
- Intestines (diarrhea, stomach pain)
- Hormone glands (thyroid or adrenal problems causing fatigue, dizziness, or weight changes)
- Kidneys
- Skin

During or after treatment, these side effects may occur. Most can be treated if detected early, but some may be serious and require hospitalization or stopping treatment. Rarely, severe complications may be life-threatening.

Side Effects of Other Treatments

If you receive chemotherapy, surgery, or radiation therapy as part of routine care, these treatments may cause additional side effects like nausea, hair loss, infections, bleeding, pain, breathing problems, or fatigue. Your doctor will explain these risks separately.

Risks of Routine Tests

Routine blood tests may cause mild pain or bruising. ECG may cause mild skin irritation. No major risks are expected from these procedures. There is a risk that your lung cancer will not get better or even get worse during the study.

It's important to note that any side effects you experience may be associated with the treatment you have chosen and are not a result of participating in this study. This study is purely observational and involves only recording your routine medical data provided by your doctor. Also, since the study is non-interventional, it will not change how your doctor manages your treatment.

To read more regarding risks, turn to the additional risk information provided in the “Additional information for patients”.

7. Are there any other considerations or risks I need to know about?

Special Warnings

- Durvalumab may cause immune-related side effects that can affect organs like the lungs, liver, intestines, kidneys, hormone glands, skin, heart, or nervous system.
- These reactions can occur during treatment or even after treatment has stopped.
- Some side effects may become serious if not treated early.
- You should inform your doctor immediately if you experience new or worsening symptoms like breathing difficulty, persistent diarrhea, yellowing of the skin/eyes, severe fatigue, chest pain, confusion, or severe rash.

Other Medicines, Food, and Drinks

- You should inform your doctor regarding all medicines you are taking, which includes prescription drugs, over-the-counter medicines, herbal products, and supplements.
- Some medicines (especially steroids or medicines that affect the immune system) may need medical supervision while you are receiving durvalumab.

- Do not start any new medicine without discussing it with your doctor.
- There are no specific food or drink restrictions, but you should follow your doctor's dietary advice during treatment.

Driving, Machinery, Sports, and Activities

- Durvalumab may cause tiredness, dizziness, or weakness.
- If you feel unwell, tired, or dizzy, you should avoid driving, operating machinery, or performing activities requiring full alertness.
- There are no specific restrictions on sports or activities, but you should follow your doctor's advice based on your condition and overall health.

Pregnancy, contraception, and breast-feeding

Because the effects of durvalumab on an unborn child or infant are not known you (or your female partner if you are a male) must not get pregnant or breastfeed a child during the study.

The study doctor can discuss acceptable birth control methods with you.

For female patients:

If you become pregnant, you must tell the study doctor straight away. You will have to stop taking the study drug immediately until you have spoken to your study doctor. You will be asked to provide information regarding you and your baby. This may involve a separate consent to allow us to monitor your baby's health and development.

For male patients whose partners become pregnant:

If your partner becomes pregnant, you must tell the study doctor immediately. Your partner will be asked, under a separate consent, to provide information regarding their health and your baby's health.

Fasting

No specific fasting is needed for participation in this study unless advised by your treating doctor for routine medical tests or procedures.

Vaccinations

- Inform your doctor prior to receiving any vaccine.
- Live vaccines should generally be avoided during treatment with durvalumab and for a period after treatment, as advised by your doctor.
- Inactivated (non-live) vaccines may be provided if recommended by your doctor.

Blood Donation

You should not donate blood or blood products during treatment and for a period after the last dose of durvalumab, as advised by your doctor.

8. What are the possible benefits of taking part?

The information the study Sponsor receives from this study may help to better treat patients with lung cancer in the future.

It is not certain that you will directly benefit from the participation in the study. Your participation may, although, help other patients in the future by improving the knowledge of disease and improving medical care. We do not know if taking part will help your condition, but we hope that it will.

9. What happens if something changes while I am in the study, e.g. if new information is found?

Changes may happen in the study that could make you change your mind regarding continuing to take part in the study. If something changes, we will tell you as soon as possible.

You can choose to leave the study at any time. For more details, see section 14 below.

The study doctor can also choose to take you out of the study if they believe that it is best for you.

Your participation in the study also stops when the Sponsor, Indian health authorities, the ethics or regulatory agencies decide that the study must be stopped.

10. What happens if I am harmed or injured during the study?

Since this is an observational study, it does not involve any experimental treatments or procedures beyond the routine medical care provided by your doctor. Hence, the risk of harm or injury from participating in the study is extremely low. Your doctor will continue to provide the necessary care and manage your treatment as usual. If you have any concerns, you can contact the study team or your doctor for further assistance.

If there is an emergency, call your study doctor as soon as you can. All relevant contact details can be found in part III: “Additional information for patients”.

If you become ill or are injured while you are in this research study, you must tell your study doctor straight away.

Injuries that have been caused by the study drug, tests, or procedures are called ‘research injuries’. Injuries caused by your usual medical care or your lung cancer are not research injuries.

If you have medical insurance, kindly check with your insurance company that taking part in this research study will not affect your coverage.

By signing this form, you do not provide up any legal right you may have.

11. What will happen to my data gathered in the study?

a. Which data are collected?

To conduct the study, the Study site will have to collect and register information regarding your identity, like your medical condition and medical history (this may include information from your physicians / available in your medical records), your lifestyle, your demographics (age, gender, ethnic and racial background), clinical chemistry, haematology, kidney function test, liver function test, thyroid levels, urinalysis, Hepatitis B&C, HIV, pregnancy tests etc will be noted along with the medicines you are taking for any other disease. Also, ECG and data generated from the imaging techniques like MRI/PET/CT will be collected. The treatment you will receive, along with your response to the treatment and side effects or any discomfort you may have, will be collected.

b. What is my data needed for?

Your data is needed for the Sponsor to generate post-marketing safety evidence on the use of durvalumab to fulfil the post-approval regulatory commitment to the Indian Health Authority. Hence, the data will be used as planned in this study as well as within related research activities necessary for the drug development programme in to better understand the studied disease and associated health problems. They may further be used to publish research results in scientific journals or use them for educational objectives.

c. Who can access my data?

Only at the study site, your name and contact details will be accessible to the study doctor and the study team to conduct the study. Non-medical personnel acting on behalf of the Sponsor and being bound by a duty of confidentiality as well as Health authorities and Ethics Committees may also be provided access to this data only to verify that the study is carried out in compliance with legal and quality requirements. Some of your data may be accessed remotely, where allowed.

The study site will share your data with the Sponsor but only after they have been coded (which means that your name, contact details or health insurance number, have been replaced by a code.

For more information regarding coding, see details at the end of this document in part III: “Additional information for patients”.

The Sponsor may share your coded data with its Research partners and Service providers for the objectives of the drug development programme.

In order to ensure proper conduct and accurate results of the study and to get permission to market the drug, the Sponsor will share your coded data with authorities and possibly with Ethics Committees. By independent scientists, and to ensure the accuracy of results, they may also be shared with scientific journals so the study results can be reviewed.

In none of these cases your identity will be revealed.

Some of the above-mentioned persons may be located outside your country. If this other country does not have equivalent personal data protection standards as your country, appropriate Safeguards (like contracts and technical Security measures) will be adopted to protect and maintain the confidentiality of your data as further described at the end of the document in part III: “Additional information for patients ”.

In case another organisation takes over development or commercialisation of the study drug, your coded data may be transmitted to them. They will then have to protect your data in the same way as described herein.

d. Who else may have access to my contact information and why?

Your name or contact details may be shared with service providers to collect information on your survival status.

The service providers must keep your name or contact details private and will NOT share any information that can directly identify you with the Sponsor.

e. How long will my coded data be kept?

The study site and the Sponsor are obliged to keep all study data for 15 years after the end of the study, to comply with study sites and Sponsor’s legal obligations. You can find out more regarding how the sponsor keeps personal information at www.astrazenecapersonaldataretention.com. Your coded data will then be deleted or anonymised.

For more details regarding anonymizing, see part 1 section 11g: What does anonymised data mean?”.

f. What are my rights under data protection law?

You have the right to review which of your data is collected and being used; you can also ask for a copy of this data, ask for restriction of use of this data, or ask to have incorrect data rectified.

To ensure the scientific integrity of the study, you will not be able to review some of the data or receive a copy of it until the study ends.

Kindly contact preferably the study doctor to exercise these restricted rights.

g. What does anonymised data mean?

Health authorities as well as pharmaceutical companies believe that access to clinical studies data advances clinical science and medical knowledge and is in the best interest of patients and public health, provided that patient privacy is protected. Hence, the Sponsor may generate and share internally or with other researchers an anonymised set of your data collected in the study (e.g., on www.vivli.org). This means your coded data will be stripped of your Patient code as well as of any other information that could reasonably be used to identify you, like your date of birth.

12. What are the costs of taking part?

Participating in this study will not cost you anything more than the costs associated with your routine appointments with your doctor. In this study you will not be paid for being there. The cost of the study drug and lab investigations will not be covered through the study.

13. How to find out more after the study?

Trial Result Summaries are a short and easy to understand summary of the results of this study. These will be added to www.trialssummaries.com within 1 year of the last study patients last site visit. You can visit www.trialssummaries.com website anytime to sign up to be notified via email when the trial results summary of your study is available. Or kindly let your study doctor know if you need a printed copy of the document.

Information in technical language associated with study protocol and the results will be posted on <http://astrazenecaclinicaltrials> and <http://www.clinicaltrials.gov>. A description of this study is also available on <http://ctri.nic.in>. These websites do not contain any information regarding you.

14. What will happen if I want to quit the study?

Your participation in the study is voluntary which means you can stop your participation at any time. If you want to stop taking the study drug, want to have a modified visit schedule or if you want to stop your participation, you should tell the study doctor and discuss available options.

If you stop participating in the study be aware that this is a “study discontinuation”, and not a withdrawal of / objection to consent for processing personal data, the study doctor will stop the collection of your data, but your previously collected data will be kept and used to guarantee the validity of the study and to comply with regulatory requirements, as allowed by law. The study doctor will then invite you to have an end of study examination to check your wellbeing. If you don’t show up at a planned visit, the study doctor will try to reach you. For study results, this is important. It is not mandatory but would be helpful for the study if you explain to your study doctor why you want to stop your participation, in particular if you have experienced discomforts.

We will continue to use your data and collected samples as originally consented, unless you would like your data not to be used after you quit the study. In such a case, you must inform the study doctor, but your coded data previously collected will be kept as needed by clinical regulations.

15. Who can answer any questions I may have?

Remember, there are no silly questions! Feel free to ask at ANY TIME! It is your right to be fully informed prior to deciding to take part in this study. You can contact the study doctor at any time at the address indicated in part III: “Additional information for patients”.

PART II: CONSENT FORM

D9106R00007, Durvalumab

A prospective, observational, multicenter, post marketing surveillance study to assess the safety of Durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC)

Initial of the Subject:			
Name of the Subject:			
Date of Birth (dd-mm-yyyy):		Age (years):	
Subject’s Address:			

Qualification:	
Occupation: (Kindly tick as appropriate)	Student ☐ Self-Employed ☐ Service ☐ Housewife ☐ Others_____
Subject's Annual Income:	
Name and address of the nominee(s) and his/her relation to the Subject:	

Kindly sign this consent form only after you have had a chance to ask questions and have received acceptable answers to all of your questions. By signing this page, you will be confirming the below mentioned statements:

Sl. No	Kindly provide your initials (short signature or signature) or thumb impression (as applicable) against each one of the below mentioned statements to confirm your consent to these statements.	
(i)	I confirm that I have read and understood the Study Information and Informed Consent Form dated, Version Number for the above study and have had the opportunity to ask questions.	[]
(ii)	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[]
(iii)	I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee, and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be performed in relation to it, even if I withdraw from the trial. I agree to this access. Although, I understand that my identity will not be revealed in any information released to third parties or published.	[]

(iv)	I agree not to restrict the use of any data or results that arise from this study, provided such a use is only for scientific objective(s)	[]
(v)	I agree to take part in the above study.	[]

INFORMED CONSENT FORM

Signature (Or Thumb impression) of the Date of Signature subject/Legally Acceptable Representative (LAR)

Name of the Signatory (Name of the subject or LAR who has signed)

Where a subject is not able to provide informed consent (e.g., an unconscious person or a minor or those suffering from severe mental illness or disability), the same may be obtained from a legally acceptable representative (a legally acceptable representative is a person who is able to provide consent for or authorise an intervention in the patient as provided by the law(s) of India).

Relationship of legally acceptable representative to subject

Investigator's Signature

Date of Signature

Name of the Study Investigator

If the Subject or his/her legally acceptable representative is not able to read/write - an impartial witness should be present during the entire informed consent process who must append his/her signatures to the consent form.

Impartial witness is a person who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally

acceptable representative cannot read, and who reads the informed consent form, and any other written information supplied to the subject.

Impartial Witness Signature

Signature Date

Impartial Witness Name

Copy of the Patient Information Sheet (Adult Study Participant Master Information) and duly filled Informed Consent Form shall be handed over to the subject or his/her legally acceptable representative.

PART III: ADDITIONAL INFORMATION FOR PATIENTS

1. Contact details

Study doctor	Study Coordinator (e.g. nurse appointed to the study)
Phone No.	Phone No.
Address	Address
Email address	Email address

Name of EC Member Secretary	
Phone No. of EC Member Secretary	

2. Detailed list of visits and Test/Procedures

There is no protocol mandate in the present study, so you will not have any separate investigation apart from the treatment you are undergoing. We will collect information regarding your health from the first dose of durvalumab until the date of the last dose of durvalumab + 90 days or the date of the first dose of subsequent anti-cancer therapy, until

withdrawal of consent, loss to follow-up, or death, whichever is earlier. During the study, we will record any side-effects you may have, like fatigue, musculoskeletal pain, constipation, decreased appetite, nausea, peripheral oedema, urinary tract infection, or any unknown side effects. The number and timing of visits will depend on the doctor's judgment based on the patient's condition. Information like the patient's age, disease status, test results, durvalumab doses, and other treatments will be collected at the start and throughout the study.

3. Detailed Study Tests and Procedures Schedules

Here is the outline of what to expect at

Baseline/Screening

At the baseline, you will undergo the initial procedures to assess your eligibility for the study. This includes signing the informed consent form, verifying inclusion/exclusion criteria, and recording details regarding demographics, medical history, and the medicines you are taking will be recorded, and the patient will have a physical examination, vital sign checks, ECOG performance status assessment, and baseline clinical and radiological imaging. Initial tumour measurements will be documented as per RECIST 1.1 guidelines, which provide a standardized set of rules for response assessment of the treatment, and necessary laboratory assessments will be performed.

Neoadjuvant Therapy Period

Regular assessments will include recording concomitant medications, recording physical examinations, and vital sign checks. Clinical and radiological assessments will be performed to monitor treatment response, and laboratory assessments will help track therapy-related changes. Any adverse events (AEs) or serious adverse events (SAEs) will be carefully documented.

Pre-Surgery Phase

In preparation for surgery, eligibility criteria may be rechecked if necessary. Updated records of concomitant medications and clinical/radiological assessments, which includes RECIST 1.1 evaluations, will be recorded. The pre-surgery phase will focus on ensuring the patient is optimally prepared for the surgical procedure. Safety monitoring for AEs and SAEs continues during this phase.

Surgery Phase

The surgery phase involves the actual surgical intervention to remove the tumour. During this time, any necessary perioperative medications will be documented. Safety monitoring will focus on identifying surgery-related AEs or SAEs.

Post-Surgery Phase

Post-surgery, patients will undergo health monitoring to assess recovery and surgical outcomes. This includes recording concomitant medications, conducting physical examinations, and

performing vital sign checks. During this phase clinical and radiological assessments will evaluate the surgical success and any residual disease, while RECIST 1.1 evaluations and laboratory tests will provide further insights. Monitoring for AEs and SAEs remains a priority.

Durvalumab monotherapy Period

The adjuvant therapy period focuses on reducing the risk of disease recurrence. Patients will continue to receive treatment with regular evaluations, which includes updates on concomitant medications, physical examinations, clinical and radiological assessments, RECIST 1.1 tumour evaluations, and laboratory monitoring. Safety monitoring remains critical, with detailed documentation of any AEs or SAEs.

Follow-Up Period

In the follow-up period, patients will be monitored long-term to detect any recurrence or late complications. Clinical and radiological assessments, along with RECIST 1.1 evaluations, will continue. Concomitant medication updates and AE/SAE reporting will also be done throughout this phase till 90 days after the last dose of the treatment or the first day of the start of another treatment, until the withdrawal of consent, loss to follow-up, or death, whichever is earlier.

The table describing what to expect at each visit:

Data Collection and Entry	Baseline/ Screening	Neoadjuvant therapy period	Pre- Surgery	Surgery	Post- Surgery	Adjuvant therapy period	Follow-up period
Informed Consent	X						
Screening	X		X				
Pregnancy test ^a	X						
Patient Demographics and Medical History	X				X		
Disease medical history & Baseline disease status (which includes EGFR/ALK status)	X						
Medicine you are taking.	X	X	X	X	X	X	X
Physical examination and Vital signs	X	X				X	X
ECOG Performance Status	X						X
Clinical & Radiological Assessments	X	X	X		X	X	X
RECIST 1.1 assessment	X		X		X	X	X
ECG	As clinically indicated						
Laboratory assessments	X	X				X	X
NSCLC Treatment details		X				X	X
AE and SAE Reporting	X	X	X	X	X	X	X

^a Women of childbearing potential only

4. Complete List of Risks, Side Effects, and Discomforts

Since this is an observational study, there are no side effects or risks directly associated with participation in this study.

Durvalumab is an immunotherapy that helps the immune system fight cancer. Because it activates the immune system, it may sometimes cause the immune system to affect normal organs.

Common Side Effects

- Low red blood cell count (anemia)
- Nausea
- Constipation
- Tiredness
- Muscle or bone pain
- Skin rash

Possible Immune-Related Side Effects

Durvalumab may cause inflammation in various organs, which includes:

- Lungs (cough, shortness of breath)
- Liver (yellowing of skin/eyes, abnormal liver tests)
- Intestines (diarrhea, stomach pain)
- Hormone glands (thyroid or adrenal problems causing fatigue, dizziness, or weight changes)
- Kidneys
- Skin

These side effects may occur during or after treatment. Most can be treated if detected early, but some may be serious and require hospitalization or stopping treatment. Rarely, severe complications may be life-threatening.

Side Effects of Other Treatments

If you receive chemotherapy, surgery, or radiation therapy as part of routine care, these treatments may cause additional side effects like nausea, hair loss, infections, bleeding, pain, breathing problems, or fatigue. Your doctor will explain these risks separately.

Risks of Routine Tests

Routine blood tests may cause mild pain or bruising. ECG may cause mild skin irritation. No major risks are expected from these procedures.

5. Complete List of Personal Data collected

All data, as described in Part I Section11a, will be collected during the study.

6. Glossary

Your coded data	All your data collected at the study site, with your name and contact details, have been replaced by a code. This is done by the study doctor who keeps the link between your name/ contact details and the code to ensure your safety and confidentiality. Coded information cannot identify you unless your study doctor provides your name or contact details, where allowed by applicable law.
Sponsor details	Sponsor: AstraZeneca Pharma India Ltd. The sponsor has the overall responsibility for a clinical study.
Details of Study site	The place where the clinical study is taking place and where you will have to go for the planned visits.
Health authorities	Authorities who supervise the study, who approve the commercialisation of the drug or who receive the adverse events reporting, whether in your country or in other countries.
Research partners	Any organisation which collaborates with the sponsor within the drug development programme or for future research.
Service providers	Any organisation bound to the sponsor by a contract, which may conduct activities on behalf of the sponsor under its strict instructions. This may include other researchers which includes so- called “contracted research organisations” (CROs) and IT companies hosting clinical data or providing IT services which includes developing new systems and services.

Safeguards	Appropriate safeguards will be implemented to protect coded data during and after the study and may include that: – Access to the coded data will be limited to specific individuals subject to confidentiality obligations (which includes the obligation to not attempt to re-identify individuals/decode the clinical data). – The coded data will be protected with security measures to avoid data alteration, loss and unauthorised accesses and further de-identification techniques may be applied. – A data protection impact assessment (DPIA) will apply to identify and mitigate privacy risks, if any, associated with each scientific research. – When needed by applicable law, scientific research is subject to the approval of Ethics Committees. – The coded data will not be shared for direct marketing objectives or other objectives that are not legal duties or are not considered scientific research as per the applicable data protection legislation. In particular, it will not be used to make decisions regarding future services available to you, like insurance.
Security measures: How is my data protected in other countries?	The processing of your data starts at the study site. Your data will then be transferred to several data experts to be verified and for results to be calculated. In addition to having your data coded, your data is also protected by high standard technical security means like strong access control and encryption. Within the sponsor group, your coded data are protected by Binding Corporate Rules (BCR). You can find more information regarding the Sponsors BCRs here: www.astrazenecabindingcorporaterules.com. You may obtain further information as well as a copy of these measures by asking your study doctor.
Restricted rights	Kindly note that the rights provided by the GDPR and UK Privacy Law to get data discarded (i.e., the right to be forgotten) do not apply to such studies.

Scientific research	Scientific research includes technological development and demonstration, fundamental research, applied research and privately funded research as well as studies performed in the public interest in the area of public health. This means that we may use the data to advance our understanding of how to make new medicines, medical devices, diagnostic products, tools and/or other therapies, to treat diseases. We may also use this data to improve the design and execution of future clinical studies, services and drugs, for outcome research activities and to aid in pricing and reimbursement activities.
Deposit in scientific databases	To do more powerful research, it is helpful for researchers to share data by placing data into one or more scientific databases. Researchers can then study the data combined from several research projects and learn even more regarding health and disease. Researchers with an approved scientific research project may be able to see and use your coded data, along with that from many other people. Your name and other information that could directly identify you (like address or social security number) will never be placed into such a scientific database. Researchers will always have a duty to protect your privacy and to keep your information confidential.

Translated from Hindi to English Version 1.0 Dated 16 Mar
2026

STUDY INFORMATION AND INFORMED CONSENT FORM

Study Code:	D9106R00007	Site No:	
Sponsor:	AstraZeneca Pharma India Limited	Subject Id:	
Principal Investigator:			
Title of the Study:	A prospective, observational, multicenter, post marketing surveillance study to assess safety of Durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC)		

There are [3] parts to this document:

Part I: the “**Study Information**” essential to your decision to take part in the clinical study,

Part II: your “**Consent Form**” which summarises what you may agree to,

Part III: supplementary information in the “Additional information for patients” Section, which includes a glossary.

PART I: STUDY INFORMATION

D9106R00007, Durvalumab Post Marketing Safety Study

Observational Study to Assess the Safety of Durvalumab in Indian Adults with Removable Lung Cancer

Dear Madam/Sir,

Into this study, you are invited to take part because you have recently been diagnosed with a type of lung cancer called resectable (removable) non-small cell lung cancer (NSCLC). You have accepted the advised treatment approach, which includes durvalumab in combination with chemotherapy as pre-operative therapy, followed by durvalumab monotherapy after surgery. This treatment is designed to support shrink the tumour and reduce the risk of cancer from returning.

We are performing this study to evaluate the safety of durvalumab in patients with resectable NSCLC. In this post-marketing study, your treatment will continue as decided by your medical officer, and we will only collect your data. Participation needs your written consent. Prior you decide whether you want to take part in this study, you will be given an explanation regarding what the study involves.

The overall description of this study, which includes the collection, storage, and use of your data and documentation, etc. has been reviewed in your country by an independent Ethics Committee to make sure that the rights, safety, and well-being of study patients are protected.

Your state may or may not improve if you join the study. Although, the information we get from this study might support other patients with the same condition in the future.

1 What is this study regarding?

Durvalumab is a type of medicine known as immunotherapy. It works by supporting your body's immune system recognize and attack cancer cells. Some cancer cells protect themselves by using a signal called PD-L1 which "switch off" the immune system. Durvalumab blocks this signal, supporting your immune system find and destroy the cancer cells.

We are carried out this study to learn additional regarding how safe durvalumab is when used for the treatment of removable NSCLC, a type of lung cancer. This type of cancer arise when uncontrolled cells multiply in your lungs and form a tumour. Pre-operative therapy, like the combination of durvalumab and platinum chemotherapy, is given prior surgery to support shrink the tumour and enhance the body's defence. After surgery is done to remove a tumour, some small cancer cells that are too small to be detected by MRI, CT, or PET scans may remain. These residual cells can sometimes survive and cause the cancer to return later. After surgery, durvalumab monotherapy is given to strengthen the body's ability to fight against residual cancer cells and to reduce the risk of cancer from coming back.

The aim of the study is to make sure that durvalumab is safe, as shown in earlier studies, at the time of also looking out for any new or unexpected side effects. Durvalumab has been in the market since 2017 and is approved by the United States Food and Drug Administration (USFDA). .

Regarding 78 patients will participate in this study. The total duration of the study will be from the date of the first dose of durvalumab until the date of the last dose of durvalumab +90 days or the date of the first dose of subsequent anti-cancer therapy, until withdrawal of consent, lost to follow-up, or death, whichever is earlier.

2 Do I have to take part?

You have a choice whether or not you would like to take part.

Kindly take as much time as you need to decide whether or not you would like to take part in this study. It may be helpful to discuss with your friends and family as you make this decision.

If you join the study, you can leave it at any time (see "section 14" for additional details). Leaving will not affect your care. If you choose to leave the study, kindly let your study medical officer know as soon as possible.

Kindly consider the study time commitments and responsibilities as a research patient when you are deciding to take part.

If you don't join the study, you will continue to receive care for your lung cancer. Your study medical officer or treating physician will discuss to you regarding other possible drugs, their risks, and benefits.

3 If I join the study, what will happen?

Because this is an observational study, no medications or other treatments are provided to you by the Sponsor as part of this study.

You will be needed to continue with your routine medical officer's appointments and to take your regular medication as prescribed by your medical officer.

Prior you join the study drug you will undergo a series of tests. This is called screening. If you meet the screening criteria, you may enter the study. If you don't meet the screening criteria, the reasons will be described. Your study medical officer or treating physician will discuss to you regarding other possible treatments/options.

You will undergo routine biopsies and staging investigations and will be offered durvalumab as pre-operative and post-operative therapy in accordance with the approved prescribing information by your medical officer. Throughout the study, we will collect your data. You will be in the study from the date of the first dose of durvalumab until the date of the last dose of durvalumab +90 days or the date of the first dose of subsequent anti-cancer therapy, until the withdrawal of consent, lost to follow-up or death, whichever is earlier. Your participation in the study may need to be longer to get better answers to the study questions.

The total number of visits and the visit time will be determined at the judgement of the investigator based on the patient's condition.

At the time of the routine visits, information will be taken for the study, and this might add some extra time to your routine visit.

If you cannot come to a visit, you must inform your study medical officer.

Kindly note that the study, and your participation in the study, may be stopped earlier than expected, for example for scientific or safety reasons (see "Section 9" for additional details).

4 What are the needed tests and methods?

At the time of you are on the study, we will need to take your medical data from your records. As part of the standard of care examinations, the data from the below mentioned tests and methods will be noted:

Patient Demographics & Medical History

Your date of birth, gender, height, weight, presence of pregnancy and breastfeeding in event of female patients, and pregnancy status of female partners in event of male patients will be taken. Also, medical history of any other disease and date and type of anti-meningococcal vaccination, which includes boosters, will be taken. Disease medical history & baseline disease status (which includes EGFR/ALK status). Your disease history, such as staging information, ECOG performance status (your ability to function in daily life), and EGFR/ALK status (to check for the presence of change in the gene), if available, will be taken from your medical records.

Concomitant Medications

Information regarding any ongoing medications you have been taking will be noted from your medical records, which includes drug name, daily dose, route, and indication.

Physical examination and Vital signs

Any results of physical examinations carried out, or vital signs (specifically body weight) noted by your study medical officer will be noted.

ECG

ECG readings taken over the duration of the study, specifically at baseline, pre-surgery, and post-surgery, will be noted from your medical records.

Clinical & Radiological Assessments

All clinical and radiological assessments, such as MRI/CT/PET, carried out to evaluate the disease status or overall clinical response, and RECIST 1.1 assessments, which assess the response of the tumour to treatment in clinical trials, whenever available, will be noted for the study.

Laboratory assessments

Results of any laboratory tests carried out at baseline and at the time of durvalumab treatment as per prescribed treatment, which includes but not limited to clinical chemistry, haematology, kidney function test, liver function test, thyroid levels, urinalysis, Hepatitis B and C, HIV, pregnancy tests, etc., will be noted.

NSCLC Treatment details

All treatments given in line with the prescribed treatment, which includes surgery and chemotherapy prior and after surgery, will be noted. Details to be noted will include the total dose, total duration of treatment, ongoing or discontinuation status of treatment, and reason for discontinuation of treatment/ reason for changing the dose of treatment.

Safety assessment

The occurrence of any side effect you might be experiencing, although small it may be, will be assessed by your study medical officer. When a side effect occurs, information on the below mentioned items will be taken: what the side effect is, when it started and ended, how serious it is, how bad it felt, whether it is related to the study drug, what is done regarding the drug because of the side effect, what happened afterwards, what steps were taken regarding the side effect, and any comments from the medical officer.

The complete list of study tests and methods, which includes their detailed schedule is available in the “Part III: Additional information for patients”.

5. What are the optional tests and methods?

Since this is an observational study, we will only collect data from your medical records. There will be no additional or optional tests or methods.

6. What are the risks of the study joining?

This study will only capture the routine medical treatment provided to you by your medical officer. There is no immediate clinical benefit for you. Although, the information we get from this study may support us to describe how lung cancer patients are managed in real-life practice and to increase our knowledge regarding the disease and its symptoms. This will hopefully support us to better treat patients with lung cancer in the future.

Since Durvalumab is an immunotherapy that supports the immune system fight cancer. Since it activates the immune system, it may sometimes cause the immune system to affect normal organs and may cause some unwanted effects.

General Side Effects

- Low red blood cell count (anaemia)
- Nausea
- Constipation
- Tiredness
- Muscle or bone pain
- Skin rash

Possible Immune-Related Side Effects

Durvalumab may cause inflammation in different organs, which includes:

- Lungs (cough, shortness of breath)
- Liver (yellowing of skin/eyes, abnormal liver tests)
- Intestines (diarrhea, stomach pain)

- Hormone glands (thyroid or adrenal problems causing fatigue, dizziness, or weight changes)
- Kidneys
- Skin

These side effects may arise at the time of or after treatment. Most can be treated if detected early, but some may be serious and need hospitalization or stopping treatment. Rarely, severe complications may be life-threatening.

Side Effects of Other Treatments

If you receive chemotherapy, surgery, or radiation therapy as part of routine care, these treatments may cause additional side effects such as nausea, hair loss, infections, bleeding, pain, breathing problems, or fatigue. Your medical officer will explain these risks separately.

Risks of Routine Tests

Routine blood tests may cause mild pain or bruising. ECG may cause mild skin irritation. No major risks are expected from these methods. There is a risk that your lung cancer will not get better or even get worse at the time of the study.

It's important to note that any side effects you experience may be related to the treatment you have chosen and are not a result of participating in this study. This study is purely observational and involves only recording your routine medical data provided by your medical officer. Also, since the study is non-interventional, it will not change how your medical officer manages your treatment.

To read additional regarding risks, turn to the additional risk information provided in the "Additional information for patients".

7. Are there any other considerations or risks I need to know regarding?

Special Warnings

- Durvalumab may cause immune-related side effects that can affect organs such as the lungs, liver, intestines, kidneys, hormone glands, skin, heart, or nervous system.
- These reactions can occur at the time of treatment or even after treatment has stopped.
- Some side effects may become serious if not treated early.
- You should inform your medical officer immediately if you experience new or worsening symptoms such as breathing difficulty, persistent diarrhea, yellowing of the skin/eyes, severe fatigue, chest pain, confusion, or severe rash.

Other Medicines, Food, and Drinks

- You should inform your medical officer regarding all medicines you are taking, which includes prescription drugs, over-the-counter medicines, herbal products, and supplements.
- Some medicines (specifically steroids or medicines that affect the immune system) may need medical supervision at the time of you are receiving durvalumab.
- Do not start any new medicine without discussing it with your medical officer.
- There are no specific food or drink restrictions, but you should follow your medical officer's dietary advice at the time of treatment.

Driving, Machinery, Sports, and Activities

- Durvalumab may cause tiredness, dizziness, or weakness.
- If you feel not well, tired, or dizzy, you should avoid driving, operating machinery, or performing activities needed full alertness.
- There are no specific restrictions on sports or activities, but you should follow your medical officer's advice based on your state and overall health.

Pregnancy, contraception, and breast-feeding

Because the effects of durvalumab on an unborn child or infant are not known you (or your female partner if you are a male) must not get pregnant or breastfeed a child at the time of the study.

The study medical officer can discuss acceptable birth control methods with you.

For female patients:

If you become pregnant, you must inform the study medical officer straight away. You will have to immediately stop taking the study drug till you have spoken to your study medical officer. You will be asked to provide information regarding you and your baby. This may involve a separate consent to permit us to monitor your baby's health and development.

For male patients whose partners become pregnant:

If your partner becomes pregnant, you must inform the study medical officer immediately. Your partner will be asked, under a separate consent, to provide information regarding their health and your baby's health.

Fasting

For participation in this study, no specific fasting is needed unless advised by your treating medical officer for routine medical tests or methods.

Vaccinations

- Inform your medical officer prior receiving any vaccine.
- Live vaccines should generally be avoided at the time of treatment with durvalumab and for a period after treatment, as advised by your medical officer.
- Inactivated (non-live) vaccines may be given if advised by your medical officer.

Blood Donation

You should not donate blood or blood products at the time of treatment and for a period after the last dose of durvalumab, as advised by your medical officer.

8. What are the possible benefits of taking part?

The information the study sponsor receives from this study may support to better treat patients with lung cancer in the future.

It is not fix that you will directly benefit from the study participation. Your participation may, although, support other patients in the future by improving the knowledge of disease and improving medical care. We do not know if taking part will support your state, but we hope that it will.

9. What happens if something changes at the time of I am in the study, e.g. if new information is found?

Changes may happen in the study that could make you change your mind regarding continuing to take part in the study. If something changes, we will inform you as soon as possible.

At any time, you can choose to leave the study. For additional details, see section 14 below.

The study medical officer can also choose to take you out of the study if they believe that it is best for you.

Your participation in the study also stops when the Sponsor, Indian health authorities, the ethics or regulatory agencies decide that the study must be stopped.

10. What happens if I am harmed or injured at the time of the study?

Since this is an observational study, it does not involve any experimental treatments or methods beyond the routine medical care provided by your medical officer. Because of this, the risk of harm or injury from participating in the study is extremely low. Your medical officer will continue to provide the necessary care and manage your treatment as usual. If you have any concerns, you can contact the study team or your medical officer for additional assistance.

If there is an emergency, call your study medical officer as soon as you can. All relevant contact details can be found in part III: “Additional information for patients”.

If you become ill or are injured at the time of you are in this research study, you must inform your study medical officer straight away.

Injuries that have been caused by the study drug, tests, or methods are called ‘research injuries’. Injuries caused by your usual medical care or your lung cancer are not research injuries.

If you have medical insurance, kindly check with your insurance company that taking part in this research study will not affect your coverage.

By signing this form, you do not give up any legal right you may have.

11. What will happen to my data gathered in the study?

a. Which data are taken?

To carried out the study, the Study site will have to collect and register information regarding your identity, such as your medical condition and medical history (this may include information from your physicians / available in your medical records), your lifestyle, your demographics (age, gender, ethnic and racial background), clinical chemistry, haematology, kidney function test, liver function test, thyroid levels, urinalysis, Hepatitis B&C, HIV, pregnancy tests etc will be noted along with the medicines you are taking for any other disease. Also, ECG and data generated from the imaging techniques like MRI/PET/CT will be taken. The treatment you will receive, along with your response to the treatment and side effects or any discomfort you may have, will be taken.

b. What is my data needed for?

Your data is needed for the Sponsor to generate post-marketing safety evidence on the use of durvalumab to fulfil the post-approval regulatory commitment to the Indian Health Authority. Because of this, the data will be used as planned in this study as well as within related research activities necessary for the drug development programme in to better understand the studied disease and associated health problems. They may additional be used to publish research results in scientific journals or use them for educational objectives.

c. Who can access my data?

Only at the study site, your name and contact details will be accessible to the study medical officer and the study team to carry out the study. Non-medical personnel acting on behalf of the Sponsor and being bound by a duty of confidentiality as well as Health authorities and Ethics Committees may also be given access to this data only to verify that the study is carried out in

compliance with legal and quality needs. Some of your data may be accessed remotely, where permitted.

The study site will share your data with the Sponsor but only after they have been coded (which defines that your name, contact details or health insurance number, have been replaced by a code. For additional information regarding coding, see details at the end of this document in part III: “Additional information for patients”.

The Sponsor may share your coded data with its Research partners and Service providers for the objectives of the drug development programme.

In order to make sure proper carried out and accurate results of the study and to get permission to market the drug, the Sponsor will share your coded data with authorities and possibly with Ethics Committees. They may also be shared with scientific journals, so the study results can be reviewed by independent scientists and to make sure the accuracy of results.

In none of these events your identity will be revealed.

Some of the above-mentioned persons may be located outside your country. If this other country does not have equivalent personal data protection standards as your country, appropriate Safeguards (such as contracts and technical Security measures) will be adopted to protect and maintain the confidentiality of your data as additional described at the end of the document in part III: “Additional information for patients ”.

In event another organisation takes over development or commercialisation of the study drug, your coded data may be transmitted to them. They will then have to protect your data in the same way as described herein.

d. Who else may have access to my contact information and why?

Your name or contact details may be shared with service providers to collect information on your survival status.

The service providers must keep your name or contact details private and will NOT share any information that can directly identify you with the Sponsor.

e. How long will my coded data be kept?

The study site and the Sponsor are obliged to keep all study data for 15 years after the end of the study, to comply with study sites and Sponsor’s legal obligations. You can find out additional regarding how the sponsor keeps personal information at www.astrazenecapersonaldataretention.com. Your coded data will then be deleted or anonymised.

For additional details regarding anonymizing, see part 1 section 11g: What does anonymised data mean?”.

f. What are my rights under data protection law?

You have the right to review which of your data is taken and being used; you can also ask for a copy of this data, ask for restriction of use of this data, or ask to have incorrect data rectified.

To make sure the scientific integrity of the study, you will not be able to review some of the data or receive a copy of it until the study ends.

To exercise these restricted rights, kindly contact preferably the study medical officer.

g. What does anonymised data mean?

Health authorities as well as pharmaceutical companies believe that access to clinical studies data advances clinical science and medical knowledge and is in the best interest of patients and public health, provided that patient privacy is protected. Because of this, the Sponsor may generate and share internally or with other researchers an anonymised set of your data taken in the study (e.g., on www.vivli.org). This defines your coded data will be stripped of your Patient code as well as of any other information that could reasonably be used to identify you, such as your date of birth.

12. What are the costs of taking part?

Into this study, participating will not cost you anything additional than the costs related to your routine appointments with your medical officer. You will not be paid for being in this study. The cost of the study drug and lab investigations will not be covered through the study.

13. How to find out additional details after the study?

Trial Result Summaries are a short and easy to understand summary of the results of this study. These will be added to www.trialssummaries.com within 1 year of the last study patients last site visit. You can visit www.trialssummaries.com website anytime to sign up to be notified via email when the trial results summary of your study is available. Or kindly let your study medical officer know if you need a printed copy of the document.

Information in technical language related to study protocol and the results will be posted on <http://astrazenecaclinicaltrials> and <http://www.clinicaltrials.gov>. A details of this study is also available on <http://ctri.nic.in>. These websites do not contain any information regarding you.

14. What will happen if I want to quit the study?

Into this study, your participation is voluntary which defines you can stop your participation at any time. If you want to stop taking the study drug, want to have a modified visit plan or if you

want to stop your participation, you should inform the study medical officer and discuss available options.

If you stop participating in the study be aware that this is a “study discontinuation”, and not a withdrawal of / objection to consent for processing personal data, the study medical officer will stop the collection of your data, but your previously taken data will be kept and used to guarantee the validity of the study and to comply with regulatory needs, as permitted by law. The study medical officer will then invite you to have an end of study examination to check your wellbeing. If you don’t show up at a planned visit, the study medical officer will try to reach you. This is important for study results. It is not mandatory but would be helpful for the study if you describe to your study medical officer why you wish to stop your participation, in particular if you have felt discomforts.

We will continue to use your data and taken samples as originally consented, unless you would like your data not to be used after you quit the study. In such a event, you must inform the study medical officer, but your coded data previously taken will be kept as needed by clinical regulations.

15. Who can answer any questions I may have?

Remember, there are no silly questions! Feel free to ask at ANY TIME! It is your right to be fully informed prior deciding to take part in this study. You can contact the study medical officer at any time at the address indicated in part III: “Additional information for patients”.

PART II: CONSENT FORM

D9106R00007, Durvalumab

A prospective, observational, multicenter, post marketing surveillance study to assess the safety of Durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC)

Initials of Subject's:			
Name of Subject's:			
Date of Birth (dd-mm-yyyy):		Age (years):	
Address of the Subject:			
Qualification:			
Occupation: (Kindly tick as appropriate)	Student ☐ Self-Employed ☐ Service ☐ Housewife ☐ Others _____		
Annual Income of the subject:			
Name and address of the nominee(s) and his/her relation to the Subject:			

Please sign this consent form only after you have had a chance to ask questions and have received acceptable answers to all of your questions. By signing this page, you will be confirming the below mentioned statements:

INFORMED CONSENT FORM

Sl. No	Kindly provide your initials (short signature or signature) or thumb impression (as applicable) against each one of the below mentioned statements to confirm your consent to these statements.	
(i)	I agree that I have read and understood the Study Information and Informed Consent Form dated, Version Number for the above study and have had the chance to ask questions.	[]
(ii)	I know that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[]
(iii)	I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee, and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any additional research that may be carried out in relation to it, even if I withdraw from the trial. I agree to this access. Although, I understand that my identity will not be revealed in any information released to third parties or published.	[]
(iv)	I agree not to restrict the use of any data or results that arise from this study, provided such a use is only for scientific objective(s)	[]
(v)	Into the above study, I agree to take part.	[]

Signature (Or Thumb impression) of the Date of Signature subject/Legally Acceptable Representative (LAR)

Signatory's Name (Name of the subject or LAR who has signed)

Where a subject is not able to give informed consent (e.g., an unconscious person or a minor or those suffering from severe mental illness or disability), the same may be taken from a legally acceptable representative (a legally acceptable representative is a person who is able to give consent for or authorise an intervention in the patient as provided by the law(s) of India).

Relationship of legally acceptable representative to subject

Signature of the Investigator

Date of Signature

Study Investigator's Name

If the Subject or his/her legally acceptable representative is unable to read/write - an impartial witness should be present at the time of the complete informed consent process who must append his/her signatures to the consent form.

Impartial witness is a person who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form, and any other written information supplied to the subject.

Impartial Witness Signature

Date of Signature

Impartial Witness Name

The Patient Information Sheet (Adult Study Participant Master Information) and duly filled Informed Consent Form copy shall be handed over to the subject or his/her legally acceptable representative.

PART III: ADDITIONAL INFORMATION FOR PATIENTS

1. Contact details

Study medical officer	Study Coordinator (e.g. nurse appointed to the study)
Phone No.	Phone No.
Address	Address
Email address	Email address

Name of EC Member Secretary	
Phone No. of EC Member Secretary	

2. Detailed list of visits and Test/Methods

There is no protocol mandate in the present study, so you will not have any separate investigation apart from the treatment you are undergoing. We will gather information regarding your health from the first dose of durvalumab until the date of the last dose of durvalumab + 90 days or the date of the first dose of subsequent anti-cancer therapy, until withdrawal of consent, loss to follow-up, or death, whichever is earlier. At the time of the study, we will record any side-effects you may have, like fatigue, musculoskeletal pain, constipation, decreased appetite, nausea, peripheral oedema, urinary tract infection, or any unknown side effects. The number and timing of visits will depend on the medical officer's judgment based on the patient's condition. Information such as the patient's age, disease status, test results, durvalumab doses, and other treatments will be taken at the start and throughout the study.

3. Detailed Study Tests and Methods Plans

Here is the outline of what to expect at

Baseline/Screening

At the baseline, you will undergo the initial methods to assess your eligibility for the study. This includes signing the informed consent form, verifying inclusion/exclusion criteria, and recording details regarding demographics, medical history, and the medicines you are taking will be noted, and the patient will have a physical examination, vital sign checks, ECOG performance status assessment, and baseline clinical and radiological imaging. Initial tumour

measurements will be documented according to RECIST 1.1 guidelines, which provide a standardized set of rules for response assessment of the treatment, and necessary laboratory assessments will be carried out.

Neoadjuvant Therapy Period

Regular assessments will include recording concomitant medications, recording physical examinations, and vital sign checks. Clinical and radiological assessments will be carried out to monitor treatment response, and laboratory assessments will support track therapy-related changes. Any adverse events (AEs) or serious adverse events (SAEs) will be carefully documented.

Phase of Pre-Surgery

In preparation for surgery, eligibility criteria may be rechecked if necessary. Updated records of concomitant medications and clinical/radiological assessments, which includes RECIST 1.1 evaluations, will be noted. The pre-surgery phase will focus on ensuring the patient is optimally prepared for the surgical procedure. Safety monitoring for AEs and SAEs continues at the time of this phase.

Phase of Surgery

The surgery phase involves the actual surgical intervention to remove the tumour. At the time of this time, any necessary perioperative medications will be documented. Safety monitoring will focus on identifying surgery-related AEs or SAEs.

Post-Surgery Phase

Post-surgery, patients will undergo health monitoring to assess recovery and surgical outcomes. This includes recording concomitant medications, performing physical examinations, and performing vital sign checks. Clinical and radiological assessments will evaluate the surgical success and any residual disease, at the time of RECIST 1.1 evaluations and laboratory tests will provide additional insights. Monitoring for AEs and SAEs remains a priority at the time of this phase.

Durvalumab monotherapy Period

The adjuvant therapy period focuses on reducing the risk of disease recurrence. Patients will continue to receive treatment with regular evaluations, which includes updates on concomitant medications, physical examinations, clinical and radiological assessments, RECIST 1.1 tumour evaluations, and laboratory monitoring. Safety monitoring remains critical, with detailed documentation of any AEs or SAEs.

Follow-Up Period

In the follow-up period, patients will be monitored long-term to detect any recurrence or late complications. Clinical and radiological assessments, along with RECIST 1.1 evaluations, will continue. Concomitant medication updates and AE/SAE reporting will also be done throughout this phase till 90 days after the last dose of the treatment or the first day of the start of another treatment, until the withdrawal of consent, loss to follow-up, or death, whichever is earlier.

The table describing what to expect at each visit:

Data Collection and Entry	Baseline/ Screening	Neoadjuvant therapy period	Pre- Surgery	Surgery	Post- Surgery	Adjuvant therapy period	Follow-up period
Informed Consent	X						
Screening	X		X				
Pregnancy test ^a	X						
Patient Demographics and Medical History	X				X		
Disease medical history & Baseline disease status (which includes EGFR/ALK status)	X						
Medicine you are taking.	X	X	X	X	X	X	X
Physical examination and Vital signs	X	X				X	X
ECOG Performance Status	X						X
Clinical & Radiological Assessments	X	X	X		X	X	X
RECIST 1.1 assessment	X		X		X	X	X
ECG	As clinically indicated						
Laboratory assessments	X	X				X	X
NSCLC Treatment details		X				X	X
AE and SAE Reporting	X	X	X	X	X	X	X

^a Women of childbearing potential only

4. Complete List of Risks, Side Effects, and Discomforts

Since this is an observational study, there are no side effects or risks directly associated with participation in this study.

Durvalumab is an immunotherapy that supports the immune system fight cancer. Because it activates the immune system, it may sometimes cause the immune system to affect normal organs.

Common Side Effects

- Low red blood cell count (anemia)

- Nausea
- Constipation
- Tiredness
- Muscle or bone pain
- Skin rash

Possible Immune-Related Side Effects

Durvalumab may cause inflammation in different organs, which includes:

- Lungs (cough, shortness of breath)
- Liver (yellowing of skin/eyes, abnormal liver tests)
- Intestines (diarrhea, stomach pain)
- Hormone glands (thyroid or adrenal problems causing fatigue, dizziness, or weight changes)
- Kidneys
- Skin

These side effects may occur at the time of or after treatment. Most can be treated if detected early, but some may be serious and require hospitalization or stopping treatment. Rarely, severe complications may be life-threatening.

Side Effects of Other Treatments

If you receive chemotherapy, surgery, or radiation therapy as part of routine care, these treatments may cause additional side effects such as nausea, hair loss, infections, bleeding, pain, breathing problems, or fatigue. Your medical officer will explain these risks separately.

Risks of Routine Tests

Routine blood tests may cause mild pain or bruising. ECG may cause mild skin irritation. No major risks are expected from these methods.

5. Complete List of Personal Data taken

All data, as described in Part I Section 11a, will be taken at the time of the study.

6. Glossary

Your coded data	All your data taken at the study site, with your name and contact details, have been replaced by a code. This is done by the study medical officer who keeps the link between your name/ contact details and the code to make sure your safety and confidentiality. Coded information cannot identify you unless your study medical officer provides your name or contact details, where permitted by applicable law.
Sponsor details	Sponsor: AstraZeneca Pharma India Ltd. For this clinical study, the sponsor has the overall responsibility.
Study site details	The place where the clinical study is taking place and where you will have to go for the planned visits.
Health authorities	Authorities who supervise the study, who approve the commercialisation of the drug or who receive the adverse events reporting, whether in your country or in other countries.
Research partners	Any organisation which collaborates with the sponsor within the drug development programme or for future research.
Service providers	Any organisation bound to the sponsor by a contract, which may carried out activities on behalf of the sponsor under its strict instructions. This may include other researchers which includes so- called “contracted research organisations” (CROs) and IT companies hosting clinical data or providing IT services which includes developing new systems and services.

Safeguards	Appropriate safeguards will be implemented to protect coded data at the time of and after the study and may include that: – Access to the coded data will be limited to specific individuals subject to confidentiality obligations (which includes the obligation to not attempt to re-identify individuals/decode the clinical data). – The coded data will be protected with security measures to avoid data alteration, loss and unauthorised accesses and additional de-identification techniques may be applied. – A data protection impact assessment (DPIA) will apply to identify and mitigate privacy risks, if any, associated with each scientific research. – When needed by applicable law, scientific research is subject to the approval of Ethics Committees. – The coded data will not be shared for direct marketing objectives or other objectives that are not legal duties or are not considered scientific research according to the applicable data protection legislation. In particular, it will not be used to make decisions regarding future services available to you, such as insurance.
Security measures: How is my data protected in other countries?	The processing of your data starts at the study site. Your data will then be transferred to several data experts to be verified and for results to be calculated. In addition to having your data coded, your data is also protected by high standard technical security defines such as strong access control and encryption. Within the sponsor group, your coded data are protected by Binding Corporate Rules (BCR). You can find additional information regarding the Sponsors BCRs here: www.astrazenecabindingcorporaterules.com. You may obtain additional information as well as a copy of these measures by asking your study medical officer.

Restricted rights	Kindly note that the rights provided by the GDPR and UK Privacy Law to get data discarded (i.e., the right to be forgotten) do not apply to such studies.
Scientific research	Scientific research includes technological development and demonstration, fundamental research, applied research and privately funded research as well as studies carried out in the public interest in the area of public health. This defines that we may use the data to advance our understanding of how to make new medicines, medical devices, diagnostic products, tools and/or other therapies, to treat diseases. We may also use this data to improve the design and execution of future clinical studies, services and drugs, for outcome research activities and to aid in pricing and reimbursement activities.
Deposit in scientific databases	To do additional powerful research, it is supportful for researchers to share data by placing data into one or additional scientific databases. Researchers can then study the data combined from several research projects and learn even additional regarding health and disease. Researchers with an approved scientific research project may be able to see and use your coded data, along with that from many other people. Your name and other information that could directly identify you (such as address or social security number) will never be placed into such a scientific database. Researchers will always have a duty to protect your privacy and to keep your information confidential.

**Hindi ICD Translation and Back Translation
Certificate Dated version 1.0 dated 16-Mar-2026**

Prescribing Information

Rx
Durvalumab Solution for Infusion

IMFINZI[®] Vial 500 mg (500mg/10mL) and 120 mg (120 mg/2.4mL)

इम्फिन्ज़ि

"WARNING: To be sold by retail on the prescription of a "Registered Oncologist only".

1. NAME OF THE MEDICINAL PRODUCT

- IMFINZI[®] 500 mg (500 mg/10 mL) vial for intravenous infusion.
- IMFINZI[®] 120 mg (120 mg/2.4 mL) vial for intravenous infusion.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains 50 mg of IMFINZI.

Each vial of 2.4 mL contains 120 mg of durvalumab.

Each vial of 10 mL contains 500 mg of durvalumab.

IMFINZI is a human immunoglobulin (IgG1 κ) monoclonal antibody.

For a full list of excipient(s), see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for solution for infusion; 50 mg/mL in single-dose vial for intravenous administration.

Sterile, preservative-free, clear to opalescent, colourless to slightly yellow solution, free from visible particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Non-small Cell Lung Cancer (NSCLC)

IMFINZI in combination with chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy after surgery, is indicated for the treatment of patients with resectable (tumours $\geq$ 4 cm and/or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

IMFINZI is indicated for the treatment of patients with locally advanced, unresectable Non-small Cell Lung Cancer (NSCLC) whose disease has not progressed following platinum-based chemoradiation therapy.

Small Cell Lung Cancer (SCLC)

IMFINZI is indicated for the treatment of patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy (CRT).

IMFINZI in combination with etoposide and either carboplatin or cisplatin is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC).

Biliary Tract Cancer (BTC)

IMFINZI in combination with chemotherapy is indicated for the treatment of patients with locally advanced or metastatic biliary tract cancer (BTC).

Hepatocellular Carcinoma (HCC)

IMFINZI in combination with tremelimumab is indicated for the treatment of patients with unresectable hepatocellular carcinoma (uHCC).

Bladder Cancer

IMFINZI in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent IMFINZI as adjuvant treatment following radical cystectomy, for the treatment of adult patients with muscle invasive bladder cancer (MIBC).

Gastric or Gastroesophageal Junction Adenocarcinoma (GC/GEJC)

Durvalumab in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) as neoadjuvant and adjuvant treatment, followed by single-agent Durvalumab, is indicated for the treatment of adult patients with resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC).

Endometrial Cancer

Durvalumab in combination with carboplatin and paclitaxel is indicated for the first-line treatment of adults with primary advanced or recurrent endometrial cancer who are candidates for systemic therapy, followed by maintenance treatment with:

- Durvalumab as monotherapy in endometrial cancer that is mismatch repair deficient (dMMR)
- Durvalumab in combination with olaparib in endometrial cancer that is mismatch repair proficient (pMMR).

4.2 Posology and method of administration

MMR testing for patients with endometrial cancer

Patients with endometrial cancer should be evaluated for treatment based on tumour MMR status confirmed by a validated test (see section 5.1).

Posology

The recommended dose for IMFINZI monotherapy and IMFINZI combination therapy is presented in Table 1 IMFINZI is administered as an intravenous infusion over 1 hour.

When IMFINZI is administered in combination with other therapeutic agents, refer to the Prescribing Information of the therapeutic agents for further information.

Table 1. Recommended dosage of IMFINZI

Indication	Recommended IMFINZI dosage	Duration of Therapy
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LS-SCLC	1500 mg ^b every 4 weeks	Until disease progression, unacceptable toxicity or a maximum of 24 months.
Locally Advanced NSCLC	10 mg/kg every 2 weeks or 1500 mg every 4 weeks ^{a,b}	Until disease progression or unacceptable toxicity
ES-SCLC	1500 mg ^c in combination with chemotherapy every 3 weeks (21 days) for 4 cycles, followed by 1500 mg every 4 weeks as monotherapy	Until disease progression or unacceptable toxicity
Resectable NSCLC	1500 mg ^d in combination with chemotherapy every 3 weeks for up to 4 cycles prior to surgery, followed by 1500 mg monotherapy every 4 weeks for up to 12 cycles after surgery.	Until disease is deemed unresectable, recurrence, unacceptable toxicity, or a maximum of 12 cycles after surgery.
BTC	1500 mg ^e in combination with chemotherapy every 3 weeks (21 days), followed by 1500 mg every 4 weeks as monotherapy	Until disease progression or until unacceptable toxicity
uHCC	Single Tremelimumab Regular Interval Durvalumab (STRIDE): 300 mg ^e tremelimumab as a single priming dose in combination with IMFINZI 1500 mg ^b at Cycle 1/Day 1, followed by IMFINZI as monotherapy every 4 weeks	As long as clinical benefit is observed or until unacceptable toxicity
Endometrial cancer	1120 mg in combination with carboplatin and paclitaxel every 3 weeks (21 days) for a minimum of 4 and up to 6 cycles, followed by IMFINZI 1500 mg ^f every 4 weeks as monotherapy (dMMR patients) or in combination with Olaparib 300 mg twice daily (pMMR patients)	Until disease progression or until unacceptable toxicity
Neoadjuvant and Adjuvant Treatment of MIBC	Patients with a body weight of ≥ 30 kg: Neoadjuvant: 1,500 mg in combination with gemcitabine	Until disease progression that precludes definitive surgery, recurrence, or unacceptable toxicity or a maximum of 8 cycles after surgery

	and cisplatin^g every 3 weeks for 4 cycles prior to surgery Adjuvant: IMFINZI 1,500 mg as a single agent every 4 weeks for up to 8 cycles after surgery Patients with a body weight of < 30 kg: Neoadjuvant: 20 mg/kg in combination with gemcitabine and cisplatin^g every 3 weeks for 4 cycles prior to surgery Adjuvant: IMFINZI 20 mg/kg as a single agent every 4 weeks for up to 8 cycles after surgery	
Neoadjuvant and Adjuvant Treatment of Resectable GC/GEJC	Patients with a body weight of ≥ 30 kg: • Neoadjuvant: IMFINZI 1,500 mg every 4 weeks with FLOT^{*±} for up to 2 cycles prior to surgery • Adjuvant: IMFINZI 1,500 mg every 4 weeks with FLOT^{*±} for up to 2 cycles, followed by IMFINZI 1,500 mg as a single agent every 4 weeks for up to 10 cycles Patients with a body weight of < 30 kg: • Neoadjuvant: IMFINZI 20 mg/kg every 4 weeks with FLOT^{*±} for up to 2 cycles prior to surgery Adjuvant: IMFINZI 20 mg/kg every 4 weeks with FLOT^{*±} for up to 2 cycles, followed by IMFINZI 20 mg/kg as a single agent every 4 weeks for up to 10 cycles	Neoadjuvant: Until disease progression that precludes definitive surgery or unacceptable toxicity Adjuvant: Until progression or recurrence, unacceptable toxicity, or a maximum of 12 cycles after surgery

^a Patients with a body weight of 30 kg or less must receive weight-based dosing, equivalent to IMFINZI 10 mg/kg every 2 weeks as monotherapy until weight increases to greater than 30 kg.

^b Patients with a body weight of 30 kg or less must receive weight-based dosing, equivalent to IMFINZI 20 mg/kg every 4 weeks as monotherapy until weight increases to greater than 30 kg.

^c Patients with a body weight of 30 kg or less must receive weight-based dosing of IMFINZI 20 mg/kg in combination with chemotherapy dose every 3 weeks (21 days) followed by 20 mg/kg every 4 weeks as monotherapy until weight increases to greater than 30 kg.

- ^d Patients with a body weight of 30 kg or less must receive weight-based dosing of IMFINZI at 20 mg/kg. In combination with chemotherapy, dose at 20 mg/kg every 3 weeks (21 days) prior to surgery, followed by monotherapy at 20 mg/kg every 4 weeks after surgery until weight increases to greater than 30 kg.
- ^e Patients with a body weight of 30 kg or less must receive weight-based dosing, equivalent to IMFINZI 20 mg/kg and tremelimumab 4 mg/kg until weight increases to greater than 30 kg.
- ^f Endometrial cancer patients with a body weight of 30 kg or less during maintenance phase must receive weight-based dosing equivalent to IMFINZI at 20 mg/kg, until weight increases to greater than 30 kg.
- ^g Administer IMFINZI prior to chemotherapy on the same day. Refer to the Prescribing Information for the agent administered in combination with IMFINZI for recommended dosage information, as appropriate.

No dose reduction or escalation for IMFINZI is recommended. In general, withhold IMFINZI for severe (Grade 3) immune-mediated adverse reactions. Permanently discontinue IMFINZI for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks of initiating corticosteroids.

Immune-mediated and non-immune-mediated adverse reactions requiring specific management are summarized in Table 2.

Refer to section 4.4 for further management recommendations, monitoring and evaluation information.

Table 2. Treatment modifications for IMFINZI or IMFINZI in combination with other products

Adverse Reactions	Severity ^a	Treatment Modification
Immune-mediated adverse reactions		
Immune-mediated pneumonitis/interstitial lung disease	Grade 2	Withhold dose ^b
	Grade 3 or 4	Permanently discontinue
Immune-mediated hepatitis	ALT or AST > 3-≤5 x ULN or total bilirubin > 1.5-≤3 x ULN	Withhold dose ^b
	ALT or AST > 5 ≤ 10 x ULN	Withhold durvalumab ^b and permanently discontinue tremelimumab
	Concurrent ALT or AST > 3 x ULN and total bilirubin > 2 x ULN ^c	Permanently discontinue
	ALT or AST > 10 x ULN OR total bilirubin > 3 x ULN	
Immune-mediated hepatitis in HCC (or secondary tumour involvement of the liver with abnormal baseline values) ^d	ALT or AST > 2.5- ≤ 5 x BLV and ≤ 20 x ULN	Withhold dose ^b
	ALT or AST > 5- 7 x BLV and ≤ 20 x ULN OR concurrent ALT or AST 2.5-5 x BLV and	Withhold durvalumab ^b and permanently discontinue tremelimumab

Adverse Reactions	Severity ^a	Treatment Modification
Immune-mediated adverse reactions		
	≤ 20 x ULN and total bilirubin > 1.5- < 2 x ULN ^c	
	ALT or AST > 7 x BLV OR > 20 x ULN whichever occurs first OR bilirubin > 3 x ULN	Permanently discontinue
Immune-mediated colitis or diarrhoea	Grade 2	Withhold dose ^b
	Grade 3 for IMFINZI monotherapy	Withhold dose ^b
	Grade 3 for IMFINZI + tremelimumab	Permanently discontinue tremelimumab ^e
	Grade 4	Permanently discontinue
	Intestinal perforation ^d of ANY grade	Permanently discontinue
Immune-mediated Hyperthyroidism, Thyroiditis	Grade 2-4	Withhold dose until clinically stable
Immune-mediated Hypothyroidism	Grade 2-4	No changes
Immune-mediated Adrenal insufficiency, Hypophysitis/hypopituitarism	Grade 2-4	Withhold dose until clinically stable
Immune-mediate Type 1 diabetes mellitus	Grade 2-4	No changes
Immune-mediated nephritis	Grade 2 with serum creatinine > 1.5-3 x (ULN or baseline)	Withhold dose ^b
	Grade 3 with serum creatinine > 3 x baseline or > 3-6 x ULN; Grade 4 with serum creatinine > 6 x ULN	Permanently discontinue
Immune-mediated rash or dermatitis (including pemphigoid)	Grade 2 for > 1 week or Grade 3	Withhold dose ^b
	Grade 4	Permanently discontinue
Immune-mediated myocarditis	Grade 2-4	Permanently discontinue
	Grade 2 or 3	Withhold dose ^{b,f}

Adverse Reactions	Severity ^a	Treatment Modification
Immune-mediated adverse reactions		
Immune-mediated myositis/polymyositis/rhabdomyolysis	Grade 4	Permanently discontinue
Infusion-related reactions	Grade 1 or 2	Interrupt or slow the rate of infusion
	Grade 3 or 4	Permanently discontinue
Immune-mediated myasthenia gravis	Grade 2-4	Permanently discontinue
Immune-mediated encephalitis	Grade 2-4	Permanently discontinue
Immune-mediated Guillain-Barré syndrome	Grade 2-4	Permanently discontinue
Other immune-mediated adverse reactions ^g	Grade 2 or 3	Withhold dose ^b
	Grade 4	Permanently discontinue
Non-immune-mediated adverse reactions		
Pure red cell aplasia (PRCA) ^h	Any Grade	Permanently discontinue
Other non-immune-mediated adverse reactions	Grade 2 and 3	Withhold dose until $\leq$ Grade 1 or return to baseline
	Grade 4	Permanently discontinue ⁱ

^a Common Terminology Criteria for Adverse Events, version 4.03. ALT: alanine aminotransferase; AST: aspartate aminotransferase; ULN: upper limit of normal; BLV: baseline value.

^b After withholding, IMFINZI can be resumed within 12 weeks if the adverse reactions improved to $\leq$ Grade 1 and the corticosteroid dose has been reduced to $\leq$ 10 mg prednisone or equivalent per day. IMFINZI should be permanently discontinued for recurrent Grade 3, as applicable.

^cFor patients with alternative cause follow the recommendations for AST or ALT increases without concurrent bilirubin elevations.

^d If AST and ALT are less than or equal to ULN at baseline in patients with liver involvement, withhold or permanently discontinue durvalumab based on recommendations for hepatitis with no liver involvement. Permanently discontinue tremelimumab for Grade 3; however, treatment with durvalumab can be resumed once event has resolved.

^e Permanently treatment with durvalumab can be resumed once event has resolved.

^f Permanently discontinue IMFINZI if the adverse reaction does not resolve to $\leq$ Grade 1 within 30 days or if there are signs of respiratory insufficiency.

^g Includes immune thrombocytopenia, pancreatitis, immune-mediated arthritis, and uveitis.

^h Adverse drug reaction is only associated when olaparib maintenance treatment is used in combination with IMFINZI, following treatment with IMFINZI in combination with platinum-based chemotherapy.

ⁱ With the exception of Grade 4 laboratory abnormalities, about which the decision to discontinue should be based on accompanying clinical signs/symptoms and clinical judgment.

For non-immune-mediated adverse reactions, withhold IMFINZI for Grade 2 and 3 adverse reactions until $\leq$ Grade 1 or baseline. IMFINZI should be discontinued for Grade 4 adverse reactions (with the exception of Grade 4 laboratory abnormalities, about which the decision to discontinue should be based on accompanying clinical signs/symptoms and clinical judgment).

Special patient populations

Based on a population pharmacokinetic analysis, no dose adjustment of IMFINZI is recommended based on patient age, body weight, gender and race (see section 5.2).

Pediatric and adolescents

The safety and effectiveness of IMFINZI have not been established in children and adolescents aged less than 18 years.

Elderly (≥ 65 years)

No dose adjustment is required for elderly patients (≥ 65 years of age) (see sections 5.1 and 5.2)."

Renal impairment

Based on a population pharmacokinetic analysis, no dose adjustment of IMFINZI is recommended in patients with mild or moderate renal impairment (see section 5.2).

Hepatic impairment

Based on a population pharmacokinetic analysis, no dose adjustment of IMFINZI is recommended for patients with mild or moderate hepatic impairment. IMFINZI has not been studied in patients with severe hepatic impairment (see section 5.2).

Method of administration

For intravenous administration.

For instructions on dilution of the medicinal product before administration, see section 6.6.

IMFINZI in combination with chemotherapy

For resectable NSCLC, ES-SCLC, MIBC, BTC and endometrial cancer when IMFINZI is administered in combination with chemotherapy, administer IMFINZI prior to chemotherapy on the same day.

IMFINZI in combination with tremelimumab

For uHCC, when IMFINZI is administered in combination with tremelimumab, administer tremelimumab prior to IMFINZI on the same day. IMFINZI and tremelimumab are administered as separate intravenous infusions.

4.3 Contraindications

None.

4.4 Special warnings and special precautions for use

Refer to section 4.2, Table 2 for recommended treatment modifications.

For suspected immune-mediated adverse reactions, adequate evaluation should be performed to confirm etiology or exclude alternate etiologies. Based on the severity of the adverse reaction, IMFINZI should be withheld or permanently discontinued. Treatment with corticosteroids or endocrine therapy should be initiated. For events requiring corticosteroid therapy, and upon improvement to $\leq$ Grade 1, corticosteroid taper should be initiated and continued over at least 1 month. Consider increasing dose of corticosteroids and/or using additional systemic immunosuppressants if there is worsening or no improvement.

Immune-mediated pneumonitis

Immune-mediated pneumonitis or interstitial lung disease, defined as requiring use of systemic corticosteroids and with no clear alternate etiology, occurred in patients receiving IMFINZI, IMFINZI in combination with tremelimumab or IMFINZI in combination with platinum-based chemotherapy followed by IMFINZI in combination with olaparib (see section 4.8). Patients should be monitored for signs and symptoms of pneumonitis. Suspected pneumonitis should be confirmed with radiographic imaging and other infectious and disease-related etiologies excluded and managed as recommended in section 4.2. For Grade 2 events, an initial dose of 1 – 2 mg/kg/day prednisone or equivalent should be initiated followed by a taper. For Grade 3 or 4 events, an initial dose of 2 – 4 mg/kg/day methylprednisolone or equivalent should be initiated followed by a taper.

Pneumonitis and radiation pneumonitis

Radiation pneumonitis is frequently observed in patients receiving radiation therapy to the lung and the clinical presentation of pneumonitis and radiation pneumonitis is very similar. In the PACIFIC Study, in patients who had completed treatment with concurrent chemoradiation within 1 to 42 days prior to initiation of study treatment, pneumonitis and radiation pneumonitis, occurred in patients receiving IMFINZI. Pneumonitis or radiation pneumonitis occurred in 161 (33.9%) patients in the IMFINZI-treated group and 58 (24.8%) in the placebo group; including Grade 3 in 16 (3.4%) patients on IMFINZI vs. 7 (3.0%) patients on placebo and Grade 5 in 5 (1.1%) patients on IMFINZI vs. 4 (1.7%) patients on placebo. The median time to onset in the IMFINZI-treated group was 55 days (range: 1-406 days) vs. 55 days (range: 1-255 days) in the placebo group.

In the ADRIATIC Study, in patients who had completed treatment with chemoradiation within 1 to 42 days prior to initiation of study treatment, pneumonitis or radiation pneumonitis occurred in 100 (38.2%) patients in the IMFINZI-treated group and 80 (30.2%) in the placebo group; including Grade 3 in 8 (3.1%) patients on IMFINZI vs 6 (2.3%) patients on placebo, and Grade 5 in 1 (0.4%) patient on IMFINZI vs 0 patients on placebo.

Immune-mediated hepatitis

Immune-mediated hepatitis, defined as requiring use of systemic corticosteroids and with no clear alternate etiology, occurred in patients receiving IMFINZI or IMFINZI in combination with tremelimumab (see section 4.8). Patients should be monitored for abnormal liver tests prior to and periodically during treatment with IMFINZI. Immune-mediated hepatitis should be managed as

recommended in section 4.2. Corticosteroids should be administered with an initial dose of 1-2 mg/kg/day prednisone or equivalent followed by taper for all grades.

Immune-mediated colitis

Immune-mediated colitis or diarrhea, defined as requiring use of systemic corticosteroids and with no clear alternate etiology, occurred in patients receiving IMFINZI or IMFINZI in combination with tremelimumab (see section 4.8). Patients should be monitored for signs and symptoms of colitis/diarrhea or intestinal perforation and managed as recommended in section 4.2. Corticosteroids should be administered at an initial dose of 1-2 mg/kg/day prednisone or equivalent followed by a taper for Grades 2-4. Consult a surgeon immediately if intestinal perforation of ANY grade is suspected.

Immune-mediated endocrinopathies

Immune-mediated hypothyroidism/hyperthyroidism/thyroiditis

Immune-mediated hypothyroidism, hyperthyroidism or thyroiditis have occurred in patients receiving IMFINZI or IMFINZI in combination with tremelimumab (see section 4.8). Patients should be monitored for abnormal thyroid function tests prior to and periodically during treatment and managed as recommended in section 4.2. For immune-mediated hypothyroidism, initiate thyroid hormone replacement as clinically indicated for Grades 2-4. For immune-mediated hyperthyroidism/thyroiditis, symptomatic management can be implemented for Grades 2-4.

Immune-mediated adrenal insufficiency

Immune-mediated adrenal insufficiency occurred in patients receiving IMFINZI or IMFINZI in combination with tremelimumab (see section 4.8). Patients should be monitored for clinical signs and symptoms of adrenal insufficiency. For symptomatic adrenal insufficiency, patients should be managed as recommended in section 4.2. Corticosteroids should be administered with an initial dose of 1-2 mg/kg/day prednisone or equivalent followed by taper and a hormone replacement as clinically indicated for Grades 2-4.

Immune-mediated type 1 diabetes mellitus

Immune-mediated type 1 diabetes mellitus, which can present with diabetic ketoacidosis, occurred in patients receiving IMFINZI or IMFINZI in combination with tremelimumab (see section 4.8). Patients should be monitored for clinical signs and symptoms of type 1 diabetes mellitus. For symptomatic type 1 diabetes mellitus, patients should be managed as recommended in section 4.2. Treatment with insulin can be initiated as clinically indicated for Grades 2-4.

Immune-mediated hypophysitis/hypopituitarism

Immune-mediated hypophysitis or hypopituitarism occurred in patients receiving IMFINZI or IMFINZI in combination with tremelimumab (see section 4.8). Patients should be monitored for clinical signs and symptoms of hypophysitis or hypopituitarism. For symptomatic hypophysitis or hypopituitarism, patients should be managed as recommended in section 4.2. Corticosteroids should be administered with an initial dose of 1-2 mg/kg/day prednisone or equivalent followed by taper and a hormone replacement as clinically indicated for Grades 2-4.

Immune-mediated nephritis

Immune-mediated nephritis, defined as requiring use of systemic corticosteroids and with no clear alternate etiology, occurred in patients receiving IMFINZI or IMFINZI in combination with tremelimumab (see section 4.8). Patients should be monitored for abnormal renal function tests prior to and periodically during treatment with IMFINZI and managed as recommended in section 4.2.

Corticosteroids should be administered with an initial dose of 1-2 mg/kg/day prednisone or equivalent followed by taper for Grades 2-4.

Immune-mediated rash

Immune-mediated rash or dermatitis (including pemphigoid), defined as requiring use of systemic corticosteroids and with no clear alternate etiology, occurred in patients receiving IMFINZI or IMFINZI in combination with tremelimumab (see section 4.8). Patients should be monitored for signs and symptoms of rash or dermatitis and managed as recommended in section 4.2. Corticosteroids should be administered with an initial dose of 1-2 mg/kg/day prednisone or equivalent followed by taper for Grade 2 > 1 week or Grade 3 and 4.

Immune-mediated myocarditis

Immune-mediated myocarditis, which can be fatal, occurred in patients receiving IMFINZI or IMFINZI in combination with tremelimumab (see section 4.8). Patients should be monitored for signs and symptoms of immune-mediated myocarditis and managed as recommended in section 4.2. Corticosteroids should be administered with an initial dose of 2-4 mg/kg/day prednisone or equivalent followed by taper for Grades 2-4. If no improvement within 2 to 3 days despite corticosteroids, promptly start additional immunosuppressive therapy. Upon resolution (Grade 0), corticosteroid taper should be initiated and continued over at least 1 month.

Other immune-mediated adverse reactions

Given the mechanism of action of IMFINZI or IMFINZI in combination with tremelimumab, other potential immune-mediated adverse reactions may occur. Patients should be monitored for signs and symptoms and managed as recommended in section 4.2. Other immune-mediated adverse reactions are myasthenia gravis, myositis, polymyositis, rhabdomyolysis, Guillain-Barré syndrome and immune thrombocytopenia, pancreatitis, immune-mediated arthritis, uveitis and encephalitis (see section 4.8).

Infusion-related reactions

Patients should be monitored for signs and symptoms of infusion-related reactions. Severe infusion-related reactions have been reported in patients receiving IMFINZI or IMFINZI in combination with tremelimumab (see section 4.8). For Grade 1 or 2 severity, may consider pre-medications for prophylaxis of subsequent infusion reactions. For Grade 3 or 4, manage severe infusion-related reactions per institutional standard, appropriate clinical practice guidelines and/or society guidelines.

Treatment-specific precaution

Treatment-specific precaution (IMFINZI in combination with olaparib in endometrial cancer)

Haematological toxicity

Pure red cell aplasia (PRCA) (see section 4.8) was reported when olaparib maintenance treatment was used in combination with IMFINZI, following treatment with IMFINZI in combination with platinum-based chemotherapy. If PRCA is confirmed, treatment with IMFINZI and olaparib should be discontinued.

Autoimmune haemolytic anemia (AIHA) was reported when olaparib maintenance treatment was used in combination with IMFINZI, following treatment with IMFINZI in combination with platinum-based chemotherapy. If AIHA is confirmed, treatment with IMFINZI and olaparib should be discontinued.

4.5 Interaction with other medicinal products and other forms of interaction

Durvalumab is an immunoglobulin and the primary elimination pathways of durvalumab are protein catabolism via reticuloendothelial system or target mediated disposition, therefore no formal pharmacokinetic (PK) drug-drug interaction studies have been conducted with durvalumab since no metabolic drug-drug interactions are expected. PK drug-drug interaction between durvalumab and chemotherapy was assessed in the CASPIAN study and no clinically meaningful PK drug-drug interaction was identified. PK drug-drug interaction between durvalumab in combination with tremelimumab and platinum-based chemotherapy was assessed in the POSEIDON study and no clinically meaningful PK drug-drug interaction was identified. PK drug-drug interaction between durvalumab in combination with tremelimumab was assessed in the HIMALAYA study and no clinically meaningful PK drug-drug interaction was identified. Furthermore, in the DUO-E study, the exposure to durvalumab was similar in both treatment arms which indicates that there were no clinically meaningful PK drug-drug interactions between durvalumab and olaparib, although exposure to olaparib was not measured throughout the study.

4.6 Pregnancy and lactation

Pregnancy

In animal reproduction studies, administration of durvalumab to pregnant cynomolgus monkeys from the confirmation of pregnancy through delivery at exposure levels approximately 22 times higher than those observed at the clinical dose of 10 mg/kg of durvalumab (based on AUC) was not associated with maternal toxicity or effects on embryofetal development, pregnancy outcome or postnatal development (see section 5.3). There are no data on the use of durvalumab in pregnant women. Based on its mechanism of action, durvalumab has the potential to impact maintenance of pregnancy and may cause fetal harm when administered to a pregnant woman. Human IgG1 is known to cross the placental barrier. Durvalumab is not recommended during pregnancy and in women of childbearing potential not using effective contraception during treatment and for at least 3 months after the last dose.

Breast-feeding

There is no information regarding the presence of durvalumab in human milk, the absorption and effects on the breast-fed infant, or the effects on milk production. Human IgG is excreted in human milk. In animal reproduction studies, administration of durvalumab to pregnant cynomolgus monkeys was associated with dose-related low-level excretion of durvalumab in breast milk. Because of the potential for adverse reactions in breastfed infants from durvalumab, advise a lactating woman not to breast-feed during treatment and for at least 3 months after the last dose.

Fertility

There are no data on the potential effects of durvalumab on fertility in humans. In repeat-dose toxicology studies with durvalumab in sexually mature cynomolgus monkeys of up to 3 months duration, there were no notable effects on the male and female reproductive organs.

4.7 Effects on ability to drive and use machines

Based on its pharmacodynamic properties, durvalumab is unlikely to affect the ability to drive and use machines. However, if patients experience adverse reactions affecting their ability to concentrate and react, they should be advised to use caution when driving or operating machinery.

4.8 Undesirable effects

Overall summary of adverse drug reactions

The safety of IMFINZI as monotherapy is based on pooled data in 4 045 patients across multiple tumour types. The most frequent adverse reactions were cough (21.5%), diarrhoea (16.3%) and rash (16.0%).

IMFINZI in combination with chemotherapy

The safety of IMFINZI in combination with chemotherapy is based on pooled data in 838 patients from 3 studies (TOPAZ-1, CASPIAN and DUO-E). The most common (> 10%) adverse reactions were neutropenia (47.3%), anaemia (44.9%), fatigue (38.8%), nausea (38.4%), thrombocytopenia (28.0%), alopecia (27.4%), constipation (25.9%), decreased appetite (21.2%), neuropathy peripheral (21.2%), abdominal pain (20.3%), diarrhoea (19.1%), rash (18.5%), vomiting (18.0%), leukopenia (17.2%), pyrexia (13.4%), arthralgia (12.4%), cough/productive cough (12.4%), pruritus (11.8%), hypothyroidism (11.0%), aspartate aminotransferase increased/alanine aminotransferase increased (10.7%) and oedema peripheral (10.1%). The most common (> 2%) NCI CTCAE Grade ≥ 3 adverse reactions were neutropenia (30.7%), anaemia (17.1%), thrombocytopenia (9.9%), leukopenia (6.4%), fatigue (4.5%), febrile neutropenia (2.9%), aspartate aminotransferase increased/alanine aminotransferase increased (2.1%) and pneumonia (2.0%).

IMFINZI was discontinued due to adverse reactions in 3.6% of patients. The most common adverse reactions leading to treatment discontinuation were anaemia (0.5%), rash (0.5%) and fatigue (0.5%).

IMFINZI was delayed or interrupted due to adverse reactions in 31.0% of patients. The most common adverse reactions leading to dose delay or interruption were neutropenia (15.0%), thrombocytopenia (6.8%), anaemia (5.1%) and leukopenia (2.9%).

IMFINZI in combination with platinum-based chemotherapy followed by IMFINZI in combination with olaparib 300 mg twice daily

The safety of IMFINZI given in combination with platinum-based chemotherapy followed by IMFINZI in combination with olaparib 300 mg twice daily is based on data in 238 patients with endometrial cancer. The most common (> 20%) adverse reactions were anaemia (61.8%), nausea (54.6%), fatigue (54.2%), neuropathy peripheral (51.7%), alopecia (50.8%), neutropenia (39.5%), constipation (32.8%), thrombocytopenia (29.8%), diarrhoea (28.2%), vomiting (25.6%), arthralgia (24.4%), rash (23.5%), abdominal pain (23.5%), decreased appetite (23.1%) and leukopenia (20.2%).

The most common (> 2%) NCI CTCAE Grade ≥ 3 adverse reactions were neutropenia (25.2%), anaemia (23.5%), leukopenia (6.7%), thrombocytopenia (5.9%), fatigue (5.5%), febrile neutropenia (3.4%), nausea (2.9%), aspartate aminotransferase increased / alanine aminotransferase increased (2.9%) and neuropathy peripheral (2.5%).

IMFINZI was discontinued in 4.6% of patients. The most common adverse reaction leading to treatment discontinuation was pneumonitis (1.7%).

IMFINZI was interrupted in 38.2% of patients. The most common adverse reactions leading to dose interruption were anaemia (13.4%), thrombocytopenia (11.8%), neutropenia (10.1%), leukopenia (2.9%), hypothyroidism (2.1%) and upper respiratory tract infection (2.1%).

Tabulated list of adverse reactions

Table 3 lists the incidence of adverse reactions in the monotherapy safety dataset. Adverse drug reactions are listed according to system organ class in MedDRA. Within each system organ class, the adverse drug reactions are presented in decreasing frequency. Within each frequency grouping, adverse drug reactions are presented in order of decreasing seriousness. In addition, the corresponding frequency category for each ADR is based on the CIOMS III convention and is defined as: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1000$); very rare ($< 1/10,000$); not determined (cannot be estimated from available data).

Table 3. Adverse drug reactions in patients treated with IMFINZI monotherapy

System Class	Organ	Adverse Drug Reaction	Frequency of any Grade		Frequency of Grade 3-4	
Respiratory, thoracic and mediastinal disorders		Cough/ Productive Cough	Very common	646 (21.5%)	Uncommon	11 (0.4%)
		Pneumonitis ^a	Common	114 (3.8%)	Uncommon	26 (0.9%)
		Dysphonia	Common	93 (3.1%)	Rare	2 (<0.1%)
		Interstitial lung disease	Uncommon	18 (0.6%)	Uncommon	4 (0.1%)
Hepatobiliary disorders		Aspartate aminotransferase increased or Alanine aminotransferase increased ^{a,b}	Common	244 (8.1%)	Common	69 (2.3%)
		Hepatitis ^{a,c}	Uncommon	25 (0.8%)	Uncommon	12 (0.4%)
Gastrointestinal disorders		Abdominal pain ^d	Very common	383 (12.7%)	Common	53 (1.8%)
		Diarrhea	Very common	491 (16.3%)	Uncommon	19 (0.6%)
		Colitis ^e	Uncommon	28 (0.9%)	Uncommon	10 (0.3%)
		Pancreatitis ^f	Uncommon	6 (0.23%)	Uncommon	5 (0.17%)
Endocrine disorders		Hypothyroidism ^g	Very common	305 (10.1%)	Uncommon	5 (0.2%)
		Hyperthyroidism ^h	Common	137 (4.6%)		0
		Thyroiditis ⁱ	Uncommon	23 (0.8%)	Rare	2 (<0.1%)
		Adrenal insufficiency	Uncommon	18 (0.6%)	Rare	3 (<0.1%)
		Hypophysitis/ Hypopituitarism	Rare	2 (<0.1%)	Rare	2 (<0.1%)
		Type 1 diabetes mellitus	Rare	1 (< 0.1%)	Rare	1 (< 0.1%)
		Diabetes insipidus	Rare	1 (< 0.1%)	Rare	1 (<0.1%)
Eye disorders		Uveitis	Rare	1 (<0.1%)		0
Renal and urinary disorders		Blood creatinine increased	Common	105 (3.5%)	Rare	3 (<0.1%)
		Dysuria	Common	39 (1.3%)		0
		Nephritis ^j	Uncommon	9 (0.3%)	Rare	2 (<0.1%)
Skin and subcutaneous tissue disorders		Rash ^k	Very common	480 (16.0%)	Uncommon	18 (0.6%)
		Pruritus ^l	Very common	325 (10.8%)	Rare	1 (<0.1%)
		Night sweats	Common	47 (1.6%)	Rare	1 (<0.1%)
		Dermatitis	Uncommon	22 (0.7%)	Rare	2 (<0.1%)
		Pemphigoid ^m	Rare	3 (<0.1%)		0
Cardiac disorders		Myocarditis	Rare	1 (<0.1%)	Rare	1 (<0.1%)
General disorders and administration site conditions		Pyrexia	Very common	414 (13.8%)	Uncommon	10 (0.3%)
		Oedema peripheral ⁿ	Common	291 (9.7%)	Uncommon	9 (0.3%)
Infections and infestations		Upper respiratory tract infections ^o	Very common	407 (13.5%)	Uncommon	6 (0.2%)

System Class	Organ	Adverse Reaction	Drug	Frequency of any Grade		Frequency of Grade 3-4	
		Pneumonia ^{a-p}		Common	269 (8.9%)	Common	106 (3.5%)
		Oral candidiasis		Common	64 (2.1%)		0
		Dental and oral soft tissue infections ^q		Common	50 (1.7%)	Rare	1 (<0.1%)
		Influenza		Common	47 (1.6%)	Rare	2 (<0.1%)
Musculoskeletal and connective tissue disorders		Myalgia		Common	178 (5.9%)	Rare	2 (<0.1%)
		Myositis ^r		Uncommon	6 (0.2%)	Rare	1 (<0.1%)
		Polymyositis ^r		Not determined ^s		Not determined ^s	
		Immune-mediated arthritis		Not determined ^t		Not determined ^t	
Nervous system disorders		Myasthenia gravis		Not determined ^t		Not determined ^t	
		Encephalitis		Not determined ^u		Not determined ^u	
		Guillain-Barré syndrome ^a		Not determined ^t		Not determined ^t	
Blood and lymphatic system disorders		Immune thrombocytopenia ^a		Rare	2 (<0.1%)	Rare	1 (<0.1%)
Injury, poisoning and procedural complications		Infusion-related reaction ^v		Common	49 (1.6%)	Uncommon	5 (0.2%)

^a Including fatal outcome.

^b Includes alanine aminotransferase increased, aspartate aminotransferase increased, hepatic enzyme increased, and transaminases increased.

^c Includes hepatitis, autoimmune hepatitis, hepatitis toxic, hepatocellular injury, hepatitis acute, hepatotoxicity and immune-mediated hepatitis.

^d Includes abdominal pain, abdominal pain lower, abdominal pain upper, and flank pain.

^e Includes colitis, enteritis, enterocolitis, and proctitis.

^f Includes pancreatitis and pancreatitis acute.

^g Includes autoimmune hypothyroidism and hypothyroidism

^h Includes hyperthyroidism and Basedow's disease.

ⁱ Includes autoimmune thyroiditis, thyroiditis, and thyroiditis subacute.

^j Includes autoimmune nephritis, tubulointerstitial nephritis, nephritis, glomerulonephritis and glomerulonephritis membranous.

^k Includes rash erythematous, rash generalized, rash macular, rash maculopapular, rash papular, rash pruritic, rash pustular, erythema, eczema and rash.

^l Includes pruritus generalized and pruritus.

^m Includes pemphigoid, dermatitis bullous and pemphigus. Reported frequency from completed and ongoing trials is uncommon.

ⁿ Includes oedema peripheral and peripheral swelling.

^o Includes laryngitis, nasopharyngitis, peritonsillar abscess, pharyngitis, rhinitis, sinusitis, tonsillitis, tracheobronchitis, and upper respiratory tract infection.

^p Includes lung infection, pneumocystis jirovecii pneumonia, pneumonia, candida pneumonia, pneumonia legionella, pneumonia adenoviral, pneumonia bacterial, pneumonia cytomegaloviral, pneumonia haemophilus, pneumonia pneumococcal and pneumonia streptococcal.

^q Includes gingivitis, oral infection, periodontitis, pulpitis dental, tooth abscess and tooth infection.

^r Includes rhabdomyolysis (as single medical concept with myositis/polymyositis).

^s Polymyositis (fatal) was observed in a patient treated with IMFINZI from an ongoing sponsored clinical study outside of the pooled dataset: rare in any grade, rare in Grade 3 or 4 or 5.

^tReported frequency from AstraZeneca-sponsored clinical studies outside of the pooled dataset is rare.

^uReported frequency from ongoing AstraZeneca-sponsored clinical studies outside of the pooled dataset is rare and includes two events of encephalitis, one was Grade 5 (fatal) and one was Grade 2.

^v Includes infusion-related reaction and urticaria with onset on the day of dosing or 1 day after dosing.

Table 3 lists the incidence of adverse reactions in the IMFINZI monotherapy pooled safety dataset (N=4 045), in patients treated with IMFINZI in combination with chemotherapy (N=838) and in patients treated with IMFINZI in combination with platinum-based chemotherapy followed by IMFINZI in combination with olaparib (platinum-based chemotherapy + IMFINZI + olaparib) (N=238).

Table 3. Adverse drug reactions in patients treated with IMFINZI

	IMFINZI as monotherapy	IMFINZI in combination with chemotherapy	Platinum-based chemotherapy + IMFINZI + olaparib[*]
Infections and infestations			
Very common	Upper respiratory tract infections ^a		Upper respiratory tract infection ^a
Common	Pneumonia ^{b,c} , Influenza, Oral candidiasis, Dental and oral soft tissue infections ^d	Pneumonia ^{b,c} , Upper respiratory tract infections ^a , Dental and oral soft tissue infections ^d	Pneumonia, Oral candidiasis, Dental and oral soft tissue infections ^d
Uncommon		Oral candidiasis, Influenza,	Influenza
Blood and lymphatic system disorders			
Very Common		Anaemia, Leukopenia ^e , Neutropenia ^f , Thrombocytopenia ^g	Anaemia ^h , Leukopenia ^h , Neutropenia ^h , Thrombocytopenia ^h
Common		Febrile neutropenia, Pancytopenia ^c	Aplasia pure red cell, Febrile neutropenia ^h , Lymphopenia ⁱ
Uncommon		Immune thrombocytopenia	Pancytopenia ^h
Rare	Immune thrombocytopenia ^c		
Immune system disorders			
Common			Hypersensitivity ^{i,j}
Endocrine disorders			
Very common	Hypothyroidism ^k	Hypothyroidism ^k	Hypothyroidism
Common	Hyperthyroidism ^l	Hyperthyroidism ^l , Thyroiditis ^m	Hyperthyroidism, Thyroiditis
Uncommon	Thyroiditis ^m , Adrenal insufficiency	Adrenal insufficiency, Type 1 diabetes mellitus	
Rare	Type 1 diabetes mellitus, Hypophysitis/Hypopituitarism, Diabetes insipidus		
Eye disorders			
Uncommon		Uveitis	Uveitis
Rare	Uveitis		
Metabolism and nutrition disorders			
Very common		Decreased appetite	Decreased appetite ^h
Nervous System Disorders			
Very common		Neuropathy peripheral ⁿ	Neuropathy peripheral, Dizziness ⁱ , Headache ⁱ , Dysgeusia ^{i,o}

	IMFINZI as monotherapy	IMFINZI in combination with chemotherapy	Platinum-based chemotherapy + IMFINZI + olaparib*
Uncommon		Myasthenia gravis	
Rare	Myasthenia gravis, Meningitis ^p		
Not known	Noninfective encephalitis ^q , Guillain-Barré syndrome, Myelitis transverse ^r		
Vascular disorders			
Common			Venous thromboembolic events ^{i,s}
Cardiac disorders			
Uncommon	Myocarditis		
Respiratory, thoracic and mediastinal disorders			
Very common	Cough/Productive Cough	Cough/Productive Cough	Cough/Productive cough, Dyspnoea ^{i,t}
Common	Pneumonitis ^c , Dysphonia	Pneumonitis	Pneumonitis, Dysphonia
Uncommon	Interstitial lung disease	Interstitial lung disease, Dysphonia	Interstitial lung disease
Gastrointestinal disorders			
Very common	Diarrhoea, Abdominal pain ^u	Diarrhoea, Abdominal pain ^u , Constipation, Nausea, Vomiting	Diarrhoea, Abdominal pain ^u , Constipation ^h , Nausea ^h , Vomiting ^h , Stomatitis ^h
Common		Stomatitis ^v	Dyspepsia ⁱ , Colitis ^w
Uncommon	Colitis ^w , Pancreatitis ^x	Colitis ^w , Pancreatitis ^x	
Rare	Coeliac disease ^r	Coeliac disease ^r	
Hepatobiliary disorders			
Very common		Aspartate aminotransferase increased or Alanine aminotransferase increased ^y	Aspartate aminotransferase increased or Alanine aminotransferase increased
Common	Hepatitis ^{c,z} , Aspartate aminotransferase increased or Alanine aminotransferase increased ^{c,y}	Hepatitis ^{c,z}	
Uncommon			Hepatitis ^z
Skin and subcutaneous tissue disorders			
Very common	Rash ^{aa} , Pruritus	Rash ^{aa} , Alopecia, Pruritus	Rash ^{aa} , Alopecia ^h , Pruritus
Common	Night sweats	Dermatitis	Dermatitis ^{bb}
Uncommon	Dermatitis, Psoriasis, Pemphigoid ^{cc}	Pemphigoid ^{cc} , Night sweats, Psoriasis	Night sweats
Musculoskeletal and connective tissue disorders			
Very common	Arthralgia	Arthralgia	Arthralgia ^h , Myalgia
Common	Myalgia	Myalgia	
Uncommon	Myositis ^{dd}	Immune-mediated arthritis, Myositis	Myositis
Rare	Polymyositis ^{ee} , Immune-mediated arthritis		
Renal and urinary disorders			
Very common			Blood creatinine increased
Common	Blood creatinine increased, Dysuria	Blood creatinine increased, Dysuria	Dysuria
Uncommon	Nephritis ^{ff}	Cystitis noninfective	Cystitis noninfective ^h
Rare	Cystitis noninfective		
General disorders and administration site conditions			

	IMFINZI as monotherapy	IMFINZI in combination with chemotherapy	Platinum-based chemotherapy + IMFINZI + olaparib*
Very common	Pyrexia	Pyrexia, Fatigue ^{gg} , Peripheral oedema ^{hh}	Pyrexia, Fatigue ^h , Peripheral oedema ^{hh}
Common	Peripheral oedema ^{hh}		
Injury, poisoning and procedural complications			
Common	Infusion-related reaction ⁱⁱ	Infusion-related reaction ⁱⁱ	Infusion-related reaction

Adverse reaction frequencies may not be fully attributed to durvalumab alone but may contain contributions from the underlying disease or from other medicinal products used in a combination.

* overall study of treatment with up to six 21-day cycles with platinum-based chemotherapy in combination with IMFINZI, followed by IMFINZI in combination with olaparib.

^a includes laryngitis, nasopharyngitis, peritonsillar abscess, pharyngitis, rhinitis, sinusitis, tonsillitis, tracheobronchitis and upper respiratory tract infection.

^b includes pneumocystis jirovecii pneumonia, pneumonia, pneumonia adenoviral, pneumonia bacterial, pneumonia cytomegaloviral, pneumonia haemophilus, pneumonia pneumococcal, pneumonia streptococcal, candida pneumonia and pneumonia legionella.

^c including fatal outcome.

^d includes gingivitis, oral infection, periodontitis, pulpitis dental, tooth abscess and tooth infection.

^e includes leukopenia and white blood cell count decreased.

^f includes neutropenia and neutrophil count decreased.

^g includes thrombocytopenia and platelet count decreased.

^h adverse reaction only applies to chemotherapy ADRs in the DUO-E study.

ⁱ adverse reaction only applies to olaparib ADRs in the DUO-E study.

^j includes drug hypersensitivity and hypersensitivity.

^k includes autoimmune hypothyroidism, hypothyroidism, immune-mediated hypothyroidism, blood thyroid stimulating hormone increased.

^l includes hyperthyroidism, Basedow's disease, immune-mediated hyperthyroidism and blood thyroid stimulating hormone decreased.

^m includes autoimmune thyroiditis, immune-mediated thyroiditis, thyroiditis, and thyroiditis subacute.

ⁿ includes neuropathy peripheral, paraesthesia and peripheral sensory neuropathy.

^o includes dysgeusia and taste disorder.

^p includes meningitis and noninfective meningitis.

^q reported frequency from ongoing AstraZeneca-sponsored clinical studies outside of the pooled dataset is rare and includes fatal outcome.

^r events were reported from post-marketing data.

^s includes deep vein thrombosis, embolism, embolism venous, pelvic venous thrombosis, superficial vein thrombosis and thrombosis.

^t includes dyspnoea and dyspnoea exertional.

- ^u includes abdominal pain, abdominal pain lower, abdominal pain upper and flank pain.
- ^v includes stomatitis and mucosal inflammation.
- ^w includes colitis, enteritis, enterocolitis, and proctitis.
- ^x includes pancreatitis and pancreatitis acute.
- ^y includes alanine aminotransferase increased, aspartate aminotransferase increased, hepatic enzyme increased and transaminases increased.
- ^z includes hepatitis, autoimmune hepatitis, hepatitis toxic, hepatocellular injury, hepatitis acute, hepatotoxicity and immune-mediated hepatitis.
- ^{aa} includes rash erythematous, rash macular, rash maculopapular, rash papular, rash pruritic, rash pustular, erythema, eczema and rash.
- ^{bb} includes dermatitis and immune-mediated dermatitis.
- ^{cc} includes pemphigoid, dermatitis bullous and pemphigus. Reported frequency from completed and ongoing studies is uncommon.
- ^{dd} includes rhabdomyolysis, myositis, and polymyositis.
- ^{ee} polymyositis (fatal) was observed in a patient treated with IMFINZI from an ongoing sponsored clinical study outside of the pooled dataset.
- ^{ff} includes autoimmune nephritis, tubulointerstitial nephritis, nephritis, glomerulonephritis and glomerulonephritis membranous.
- ^{gg} includes fatigue and asthenia.
- ^{hh} includes oedema peripheral and peripheral swelling.
- ⁱⁱ includes infusion-related reaction and urticaria with onset on the day of dosing or 1 day after dosing.

Table 5 lists the incidence of laboratory abnormalities reported in the IMFINZI monotherapy safety dataset.

Table 5. Laboratory abnormalities worsening from baseline in patients treated with IMFINZI monotherapy

Laboratory Abnormalities	n	Any Grade	Grade 3 or 4
Alanine aminotransferase increased	2866	813 (28.4%)	69 (2.4%)
Aspartate aminotransferase increased	2858	891 (31.2%)	102 (3.6%)
Blood creatinine increased	2804	642 (22.9%)	13 (0.5%)
TSH elevated > ULN and ≤ ULN at baseline	3006	566 (18.8%)	NA
TSH decreased < LLN and ≥ LLN at baseline	3006	545 (18.1%)	NA

ULN = upper limit of normal; LLN = lower limit of normal

Muscle Invasive Bladder Cancer (MIBC)

Neoadjuvant and adjuvant treatment of MIBC – NIAGARA

The safety of IMFINZI in combination with neoadjuvant gemcitabine and cisplatin followed by surgery and continued IMFINZI treatment as adjuvant, single-agent therapy was evaluated in NIAGARA, a

randomized, open-label, multicenter trial. Patients received IMFINZI in combination with chemotherapy (n=530) or received chemotherapy alone (n=526) [see *Clinical Studies*].

The median duration of exposure to IMFINZI 1,500 mg every 3 weeks in the neoadjuvant phase was 12 weeks (range: 1.1 to 84 weeks). The median duration of exposure to IMFINZI 1,500 mg every 4 weeks in the adjuvant phase was 32 weeks (range: 2.4 to 50 weeks).

The most common adverse reactions, including laboratory abnormalities, in the overall study (occurring in $\geq 20\%$ of patients) were decreased hemoglobin, decreased neutrophils, increased blood creatinine, decreased sodium, nausea, increased ALT, decreased calcium, decreased platelets, fatigue, increased potassium, decreased lymphocytes, increased AST, constipation, decreased magnesium, decreased appetite, increased alkaline phosphate, rash, pyrexia, diarrhea, vomiting, and abdominal pain.

In patients treated with platinum-based chemotherapy in combination with IMFINZI, followed by IMFINZI either as monotherapy (platinum-based chemotherapy + IMFINZI arm) or in combination with olaparib (platinum-based chemotherapy + IMFINZI + olaparib arm), the proportion of patients who experienced a shift from baseline to a Grade 3 or 4 laboratory abnormality was as follows in the platinum-based chemotherapy + IMFINZI arm: 3.5% for alanine aminotransferase increased, 3.0% for aspartate aminotransferase increased and 0.4% for blood creatinine increased, and as follows in the platinum-based chemotherapy + IMFINZI + olaparib arm: 3.8% for alanine aminotransferase increased, 3.4% for aspartate aminotransferase increased and 1.7% for blood creatinine increased. The proportion of patients who experienced a TSH shift from baseline that was $\leq$ ULN to $>$ ULN was 27.2% and a TSH shift from baseline that was $\geq$ LLN to $<$ LLN was 24.3% in the platinum-based chemotherapy + IMFINZI arm and the proportion of patients who experienced a TSH shift from baseline that was $\leq$ ULN to $>$ ULN was 28.6% and a TSH shift from baseline that was $\geq$ LLN to $<$ LLN was 20.1% in the platinum-based chemotherapy + IMFINZI + olaparib arm.

Table 6 summarizes the adverse reactions that occurred in patients treated with IMFINZI plus chemotherapy

Table 6. Adverse Reactions Occurring in $\geq 10\%$ of Patients in the NIAGARA Study

	IMFINZI with gemcitabine and cisplatin N = 530		Gemcitabine and cisplatin N = 526	
Adverse Reaction	All Grades* (%)	Grade* 3-4 (%)	All Grades* (%)	Grade* 3-4 (%)
Gastrointestinal disorders				
Nausea	54	1.5	48	1
Constipation	39	0.8	39	0.8
Diarrhea	21	1.5	14	0.4
Vomiting [†]	20	0.9	19	0.2
Abdominal pain [†]	20	0.9	13	1
General disorders and administration site conditions				
Fatigue [†]	52	2.3	49	3
Pyrexia [†]	22	0.4	17	0
Edema [†]	13	0.4	13	0
Metabolism and nutrition disorders				
Decreased appetite	27	0.6	25	0.6
Skin and subcutaneous tissue disorders				
Rash [†]	23	1.3	12	0.6
Pruritus	15	0	7	0
Nervous system disorders				
Peripheral neuropathy [†]	16	0.2	14	0
Headache [†]	11	0	11	0
Dizziness [†]	11	0	10	0.2
Endocrine disorders				
Hypothyroidism [†]	13	0.4	2.3	0
Vascular disorders				
Hypertension [†]	12	4.5	9	2.9
Hemorrhage [†]	11	0.9	10	2.1

* Graded according to NCI CTCAE version 5.0.

[†] Includes multiple similar terms.

Table 7 summarizes the laboratory abnormalities in patients treated with IMFINZI plus chemotherapy.

Table 7. Select Laboratory Abnormalities That Worsened from Baseline in $\geq 20\%$ of Patients Who Received IMFINZI with Chemotherapy in the NIAGARA study

Laboratory Abnormality	IMFINZI with gemcitabine and cisplatin [†]		Gemcitabine and cisplatin [†]	
	All Grades [†] (%)	Grade [†] 3 or 4 (%)	All Grades [†] (%)	Grade [†] 3 or 4 (%)
Chemistry				
Increased blood creatinine	63	9	58	7
Decreased sodium	54	9	55	10

Increased ALT	53	2.3	54	4.0
Decreased calcium	52	1.3	43	1.2
Increased potassium	51	4.2	49	4.4
Increased AST	42	1.5	39	2.1
Decreased magnesium	38	1.9	37	2.3
Increased alkaline phosphate	26	0.8	25	0.4
Hematology				
Decreased hemoglobin	88	13	87	13
Decreased neutrophils	76	31	74	34
Decreased platelets	52	6	50	7
Decreased lymphocytes	44	10	40	8

‡ Each test incidence is based on the number of patients who had both baseline and at least one on-study laboratory measurement available: IMFINZI plus chemotherapy (range: 482 to 528), and chemotherapy (range: 467 to 521).

† Graded per NCI CTCAE V5.

Neoadjuvant Phase of NIAGARA

A total of 530 patients received at least 1 dose of IMFINZI in combination with chemotherapy as neoadjuvant treatment in the IMFINZI treatment arm, and 526 patients received at least 1 dose of chemotherapy as neoadjuvant treatment in the chemotherapy treatment arm. In the neoadjuvant phase, serious adverse reactions occurred in 24% of patients who received IMFINZI in combination with chemotherapy; the most frequent ($\geq 1\%$) serious adverse reactions were pulmonary embolism (1.9%), febrile neutropenia (1.5%), acute kidney injury (1.3%), thrombocytopenia (1.3%), urinary tract infection (1.3%) and pneumonia (1.3%). Fatal adverse reactions occurred in 1.1% of patients including sepsis (0.2%), myocardial infarction (0.2%), and pulmonary embolism (0.2%). One fatal adverse reaction of pneumonia was reported in 1 (0.2%) patient in the post-surgery phase before adjuvant treatment started.

Permanent discontinuation of IMFINZI due to an adverse reaction in the neoadjuvant phase occurred in 9% of patients while receiving IMFINZI in combination with chemotherapy. The most frequent ($\geq 0.5\%$) adverse reactions that led to permanent discontinuation of IMFINZI were blood creatinine increased (0.9%), neutropenia (0.6%), acute kidney injury (0.6%), asthenia (0.6%) and fatigue (0.6%). Of the 530 patients in the IMFINZI treatment arm and 526 patients in the chemotherapy treatment arm who received neoadjuvant treatment, 1 (0.2%) patient in each treatment arm did not receive surgery due to adverse reactions. The adverse reaction that led to cancellation of surgery in the IMFINZI treatment arm was interstitial lung disease.

Of the 469 patients in the IMFINZI treatment arm who underwent radical cystectomy, 4 (0.8%) patients experienced delay of surgery (defined as occurring more than 56 days after the last dose of neoadjuvant treatment) due to adverse reactions.

Adjuvant Phase of NIAGARA

A total of 383 patients (72%) in the IMFINZI treatment arm received at least 1 dose of adjuvant treatment.

Serious adverse reactions occurred in 26% of patients receiving IMFINZI as adjuvant treatment. The most frequent serious adverse reactions (occurring in $\geq 1\%$ of patients) were urinary tract infection (7%), acute kidney injury (3.7%), hydronephrosis (2.1%), pyelonephritis (2.1%), urosepsis (1.8%), and sepsis (1.6%). Fatal adverse reactions occurred in 1.8% of patients, including COVID-19 (0.3%), severe acute respiratory syndrome (0.3%), cardiopulmonary failure (0.3%), gastrointestinal haemorrhage (0.3%), and chronic hepatic failure (0.3%).

Permanent discontinuation of adjuvant IMFINZI due to an adverse reaction occurred in 5% of patients. The most frequent ($\geq 0.5\%$) adverse reactions that led to permanent discontinuation of adjuvant IMFINZI were nephritis (0.8%), fatigue (0.5%), diarrhea (0.5%), decreased appetite (0.5%) and pneumonitis (0.5%).

Gastric or Gastroesophageal Junction Adenocarcinoma (GC/GEJC)

Neoadjuvant and Adjuvant Treatment of Resectable GC/GEJC – MATTERHORN

The safety of IMFINZI with FLOT as neoadjuvant and adjuvant treatment, followed by single-agent IMFINZI, was evaluated in MATTERHORN, a randomized, double-blind, placebo-controlled, multicenter study of patients with resectable GC/GEJC (Stage II to Stage IVA [AJCC, 8th edition]) [see *Clinical Studies* (14.7)].

Safety data are available for the 944 patients who received IMFINZI with FLOT (n=475) or placebo with FLOT (n=469).

The median duration of exposure to IMFINZI 1,500 mg every 4 weeks in the neoadjuvant phase was 8 weeks (range: 1.4 to 8.7 weeks). The median duration of exposure to IMFINZI 1,500 mg every 4 weeks in the adjuvant phase was 48 weeks (range: 1.9 to 50.1 weeks).

The most common adverse reactions (occurring in $\geq 20\%$ of patients) were diarrhea, nausea, peripheral neuropathy, fatigue, alopecia, decreased appetite, rash, abdominal pain, vomiting, musculoskeletal pain, pyrexia, and stomatitis.

Table 8 summarizes the adverse reactions that occurred in $\geq 10\%$ of patients treated with IMFINZI in combination with FLOT chemotherapy.

Table 8: Adverse Reactions Occurring in $\geq 10\%$ of Patients in the MATTERHORN study

Adverse Reaction	IMFINZI with FLOT Chemotherapy N=475		Placebo with FLOT Chemotherapy N=469	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Gastrointestinal disorders				
Diarrhea [†]	64	8	59	7
Nausea	51	2.5	51	1.5
Vomiting [†]	26	2.1	26	3
Abdominal pain [†]	27	2.3	29	1.3
Stomatitis [†]	20	1.1	15	0.6
Constipation	16	0	17	0.9
Dysphagia	10	1.5	8	1.5
Nervous system disorders				
Peripheral neuropathy [†]	51	3.6	47	2.3
Dysgeusia [†]	19	0	15	0
General disorders and administration site conditions				

Adverse Reaction	IMFINZI with FLOT Chemotherapy N=475		Placebo with FLOT Chemotherapy N=469	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Fatigue [†]	47	5	45	5
Pyrexia [†]	20	0.8	16	1.3
Skin and subcutaneous tissue disorders				
Alopecia	31	0	32	0
Rash [†]	30	1.5	20	0.4
Pruritus [†]	11	0	5	0
Metabolism and nutrition disorders				
Decreased appetite [†]	31	3.2	30	2.1
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain [†]	21	1.5	19	0.6
Infections and infestations				
COVID-19 [†]	19	1.7	16	0.6
Pneumonia [†]	11	3.8	10	4.3
Investigations				
Weight decreased	15	2.1	19	3.4
Vascular disorders				
Hemorrhage [†]	14	2.5	15	2.8
Respiratory, thoracic and mediastinal disorders				
Cough [†]	10	0	10	0

[†] Includes multiple similar terms.

Table 9 summarizes the laboratory abnormalities in patients treated with IMFINZI in combination with FLOT chemotherapy.

Table 9: Laboratory Abnormalities (≥ 20%) That Worsened from Baseline in Patients with Disease Who Received IMFINZI with FLOT Chemotherapy in MATTERHORN

Laboratory Abnormality*	IMFINZI with FLOT Chemotherapy [†]		Placebo with FLOT Chemotherapy ^b	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Hematology				
Decreased leukocytes	75	14	79	17
Decreased neutrophils	70	41	74	44
Decreased hemoglobin	68	7	73	8
Decreased lymphocytes	49	13	45	13
Decreased platelets	47	1.1	46	1.9
Chemistry				
Increased AST	72	6	69	6
Increased ALT	70	7	65	6
Increased GGT	57	10	51	6
Increased lipase	55	16	55	15
Increased alkaline phosphatase	53	3.2	51	1.5
Decreased calcium	45	0.8	47	2.6
Increased amylase	42	6	39	4.5
Decreased potassium	39	8	40	8
Decreased sodium	33	4.4	32	4.7
Decreased albumin	31	1.5	31	0.2
Increased potassium	22	0.6	26	1.3

* Graded per NCI CTCAE v5.0.

[†] The denominator used to calculate the rate varied from 444 to 472 based on the number of patients with a baseline value and at least one post-treatment value.

[‡] The denominator used to calculate the rate varied from 443 to 468 based on the number of patients with a baseline value and at least one post-treatment value.

Adverse Reactions by Phase of Treatment

Table 10 summarizes safety profile by Phase of treatment.

Table 10: Safety Profile by Phase of Treatment

	IMFINZI with FLOT Chemotherapy	Placebo with FLOT Chemotherapy
Neoadjuvant Phase		
Number of Patients	475	469
Serious Adverse Reactions	21%	18%
Deaths during Treatment-emergent period	1.9%	1.7%
Permanent discontinuation of IMFINZI or Placebo	2.5%	2.1%
No surgery due to Adverse Reaction	0.6%	0.4%
Delay in surgery due to Adverse Reaction	2.3%	2.6%
Adjuvant Phase		
Number of Patients	365	351
Serious Adverse Reactions	29%	26%
Deaths during Treatment-emergent period	2.2%	2.6%
Permanent discontinuation of IMFINZI or Placebo	7%	4.6%
Adjuvant Phase (IMFINZI as a single-agent)		
Number of Patients	345	331
Serious Adverse Reactions	14%	15%
Deaths during Treatment-emergent period	1.7%	2.4%
Permanent discontinuation of IMFINZI or Placebo	6%	2.7%

Serious adverse reactions ($\geq 2\%$) in the IMFINZI arm were diarrhea (2.5%) during the neoadjuvant phase, and pneumonia (2.5%) in the adjuvant phase.

Deaths (≥ 2 patients) in the IMFINZI arm were septic shock (0.6%) and acute coronary syndrome (0.4%) during the neoadjuvant phase; gastrointestinal perforation (0.5%) and COVID-19 (0.5%) during adjuvant phase; and gastrointestinal perforation (0.6%) and COVID-19 (0.6%) in the single-agent adjuvant phase.

Permanent discontinuation of IMFINZI (≥ 2 patients) due an adverse reaction in the IMFINZI arm were nephritis (0.4%) during the neoadjuvant phase; hepatitis (1.1%), pneumonitis (1.1%), rash (0.8%), musculoskeletal pain (0.5%), and renal failure (0.5%) during adjuvant phase; and hepatitis (0.9%), pneumonitis (0.9%), musculoskeletal pain (0.6%), and renal failure (0.6%) during the single-agent adjuvant phase.

The safety of IMFINZI in combination with chemotherapy in patients with ES-SCLC is based on data in 265 patients from the CASPIAN study, and was consistent with IMFINZI monotherapy and known chemotherapy safety profile.

The safety of IMFINZI in combination with chemotherapy as neoadjuvant treatment in patients with resectable NSCLC, is based on data in 401 patients from the AEGEAN (resectable NSCLC) study and was consistent with known IMFINZI monotherapy and known chemotherapy safety profiles.

The safety of IMFINZI in combination with chemotherapy in patients with BTC is based on data in 338 patients from the TOPAZ-1 study and was consistent with IMFINZI monotherapy and known chemotherapy safety profiles.

The safety of STRIDE treatment in patients with uHCC is based on data in 462 patients from the HCC pool, and was consistent with known IMFINZI + tremelimumab safety profile.

The safety of IMFINZI monotherapy in patients with LS-SCLC is based on data in 262 patients from the ADRIATIC study. The safety profile was consistent with IMFINZI monotherapy.

Description of selected adverse reactions

The data below reflect information for significant adverse reactions for IMFINZI as monotherapy in the pooled safety dataset across tumour types (n=3006), IMFINZI in combination with tremelimumab (75 mg Q4W) in the pooled safety dataset across tumour types (n=2280) and STRIDE in the HCC pool (n=462).

The management guidelines for these adverse reactions are described in sections 4.2 and 4.4.

Immune-mediated pneumonitis

In patients receiving IMFINZI monotherapy, immune-mediated pneumonitis occurred in 92 (3.1%) patients, including Grade 3 in 25 (0.8%) patients, Grade 4 in 2 (< 0.1%) patients, and Grade 5 in 6 (0.2%) patients. The median time to onset was 55 days (range: 2-785 days). Sixty-nine of the 92 patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day), 2 patients also received infliximab and 1 patient also received cyclosporine. IMFINZI was discontinued in 38 patients. Resolution occurred in 53 patients. Immune-mediated pneumonitis occurred more frequently in patients in the PACIFIC Study who had completed treatment with concurrent chemoradiation within 1 to 42 days prior to initiation of the study (9.9%), compared to the other patients in the combined safety database (1.8%).

In the PACIFIC Study, in patients with locally advanced, unresectable NSCLC (n = 475 in the IMFINZI arm, and n = 234 in the placebo arm) who had completed treatment with concurrent chemoradiation within 1 to 42 days prior to initiation of study treatment, immune-mediated pneumonitis occurred in 47 (9.9%) patients in the IMFINZI-treated group and 14 (6.0%) patients in the placebo group, including Grade 3 in 9 (1.9%) patients on IMFINZI vs. 6 (2.6%) patients on placebo and Grade 5 in 4 (0.8%) patients on IMFINZI vs. 3 (1.3%) patients on placebo. The median time to onset in the IMFINZI-treated group was 46 days (range: 2-342 days) vs. 57 days (range: 26-253 days) in the placebo group. In the IMFINZI-treated group 30 patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day) and 2 patients also received infliximab. In the placebo group, 12 patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day) and 1 patient also received cyclophosphamide and tacrolimus. Resolution occurred for 29 patients in the IMFINZI treated group vs 6 in placebo.

In the ADRIATIC study in patients with LS-SCLC (n=262 in the IMFINZI arm, and n=265 in the placebo arm), who had completed treatment with chemoradiation within 1 to 42 days prior to initiation 341 patients in Arm 1 and 344 patients in Arm 2 of study treatment, immune-mediated pneumonitis occurred in 31 (11.8%) patients in the IMFINZI-treated group and 8 (3%) patients in the placebo group, including Grade 3 in 5 (1.9%) patients on IMFINZI vs. 1 (0.4%) patient on placebo, and Grade 5 in 1

(0.4%) patient on IMFINZI. The median time to onset in the IMFINZI-treated group was 55 days (range: 1-375 days) vs. 65.5 days (range: 24-124 days) in the placebo group. In the IMFINZI-treated group, 25 patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day) and 1 patient also received infliximab. In the placebo group, 7 patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). Resolution occurred in 18 patients in the IMFINZI-treated group vs 3 in placebo.

HCC pool

In patients receiving STRIDE, immune-mediated pneumonitis occurred in 6 (1.3%) patients, including Grade 3 in 1 (0.2%) patient and Grade 5 (fatal) in 1 (0.2%) patient. The median time to onset was 29 days (range: 5-774 days). Six patients received systemic corticosteroids, and 5 of the 6 patients received high dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). One patient also received other immunosuppressants. Treatment was discontinued in 2 patients. Resolution occurred in 3 patients.

In the DUO-E Study, out of 238 patients treated with platinum-based chemotherapy in combination with IMFINZI, followed by IMFINZI in combination with olaparib (platinum-based chemotherapy + IMFINZI + olaparib arm) immune-mediated pneumonitis occurred in 5 (2.1%) patients, including Grade 3 in 3 (1.3%) patients. The median time to onset was 85 days (range: 65-321 days). Five patients received systemic corticosteroids, including 4 patients who received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). Resolution occurred in all 5 patients.

Immune-mediated hepatitis

In patients receiving IMFINZI monotherapy, immune-mediated hepatitis occurred in 67 (2.2%) patients, including Grade 3 in 35 (1.2%) patients, Grade 4 in 6 (0.2%) and Grade 5 in 4 (0.1%) patients. The median time to onset was 36 days (range: 3-333 days). Forty-four of the 67 patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). Three patients also received mycophenolate treatment. IMFINZI was discontinued in 9 patients. Resolution occurred in 29 patients.

HCC pool

In patients receiving STRIDE, immune mediated hepatitis occurred in 34 (7.4%) patients, including Grade 3 in 20 (4.3%) patients, Grade 4 in 1 (0.2%) patient and Grade 5 (fatal) in 3 (0.6%) patients. The median time to onset was 29 days (range: 13-313 days). All patients received systemic corticosteroids, and 32 of the 34 patients received high dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). Nine patients also received other immunosuppressants. Treatment was discontinued in 10 patients. Resolution occurred in 13 patients.

Immune-mediated colitis

In patients receiving IMFINZI monotherapy, immune-mediated colitis or diarrhea occurred in 58 (1.9%) patients, including Grade 3 in 9 (0.3%) patients and Grade 4 in 2 (< 0.1%) patients. The median time to onset was 70 days (range: 1-394 days). Thirty-eight of the 58 patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). One patient also received infliximab treatment and one patient also received mycophenolate treatment. IMFINZI was discontinued in 9 patients. Resolution occurred in 43 patients.

HCC pool

In patients receiving STRIDE, immune mediated colitis or diarrhoea occurred in 31 (6.7%) patients, including Grade 3 in 17 (3.7%) patients. The median time to onset was 23 days (range: 2-479 days). All patients received systemic corticosteroids, and 28 of the 31 patients received high dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). Four patients also received other immunosuppressants. Treatment was discontinued in 5 patients. Resolution occurred in 29 patients.

Intestinal perforation was not observed in patients receiving STRIDE.

Immune-mediated endocrinopathies

Immune-mediated hypothyroidism

In patients receiving IMFINZI monotherapy, immune-mediated hypothyroidism occurred in 245 (8.2%) patients, including Grade 3 in 4 (0.1%) patients. The median time to onset was 85 days (range: 1-562 days). Of the 245 patients, 240 patients received hormone replacement therapy, 6 patients received high-dose corticosteroids (at least 40 mg prednisone or equivalent per day) for immune-mediated hypothyroidism followed by hormone replacement. No patients discontinued IMFINZI due to immune-mediated hypothyroidism. Immune-mediated hypothyroidism was preceded by immune-mediated hyperthyroidism in 20 patients or immune-mediated thyroiditis in 3 patients.

HCC pool

In patients receiving STRIDE, immune-mediated hypothyroidism occurred in 46 (10.0%) patients. The median time to onset was 85 days (range: 26-763 days). One patient received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). All patients required other therapy (thiamazole, carbimazole, propylthiouracil, perchlorate, calcium channel blocker, or beta-blocker). Resolution occurred in 6 patients. Immune-mediated hypothyroidism was preceded by immune-mediated hyperthyroidism in 4 patients.

Immune-mediated hyperthyroidism

In patients receiving IMFINZI monotherapy, immune-mediated hyperthyroidism occurred in 50 (1.7%) patients, there were no Grade 3 or 4 cases. The median time to onset was 43 days (range: 1-253 days). Forty-six of the 50 patients received medical therapy (thiamazole, carbimazole, propylthiouracil, perchlorate, calcium channel blocker, or beta-blocker), 11 patients received systemic corticosteroids and 4 of the 11 patients received high-dose systemic corticosteroid treatment (at least 40 mg prednisone or equivalent per day). One patient discontinued IMFINZI due to immune-mediated hyperthyroidism. Resolution occurred in 39 patients.

HCC pool

In patients receiving STRIDE, immune-mediated hyperthyroidism occurred in 21 (4.5%) patients, including Grade 3 in 1 (0.2%) patient. The median time to onset was 30 days (range: 13-60 days). Four patients received systemic corticosteroids, and all of the four patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). Twenty patients required other therapy (thiamazole, carbimazole, propylthiouracil, perchlorate, calcium channel blocker, or beta-blocker). One patient discontinued treatment due to hyperthyroidism. Resolution occurred in 17 patients.

Immune-mediated thyroiditis

In patients receiving IMFINZI monotherapy, immune-mediated thyroiditis occurred in 12 (0.4%) patients, including Grade 3 in 2 (<0.1%) patients. The median time to onset was 49 days (range: 14-106 days). Of the 12 patients, 10 patients received hormone replacement therapy, 1 patient received high-dose corticosteroids (at least 40 mg prednisone or equivalent per day). One patient discontinued IMFINZI due to immune-mediated thyroiditis.

HCC pool

In patients receiving STRIDE, immune-mediated thyroiditis occurred in 6 (1.3%) patients. The median time to onset was 56 days (range: 7-84 days). Two patients received systemic corticosteroids, and 1 of the 2 patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). All patients required other therapy including hormone replacement therapy, thiamazole, carbimazole, propylthiouracil, perchlorate, calcium channel blocker, or beta-blocker. Resolution occurred in 2 patients.

Immune-mediated adrenal insufficiency

In patients receiving IMFINZI monotherapy, immune-mediated adrenal insufficiency occurred in 14 (0.5%) patients, including Grade 3 in 3 (< 0.1%) patients. The median time to onset was 145.5 days (range: 20-547 days). All 14 patients received systemic corticosteroids; 4 of the 14 patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). No patients discontinued IMFINZI due to immune-mediated adrenal insufficiency. Resolution occurred in 3 patients.

HCC pool

In patients receiving STRIDE, immune-mediated adrenal insufficiency occurred in 6 (1.3%) patients, including Grade 3 in 1 (0.2%) patient. The median time to onset was 64 days (range: 43-504 days). All patients received systemic corticosteroids, and 1 of the 6 patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). Resolution occurred in 2 patients.

Immune-mediated type 1 diabetes mellitus

In patients receiving IMFINZI monotherapy, Grade 3 immune-mediated type 1 diabetes mellitus occurred in 1 (< 0.1%) patient. This patient required long-term insulin therapy and IMFINZI was permanently discontinued due to immune-mediated type 1 diabetes mellitus.

HCC pool

In patients receiving STRIDE, immune-mediated type 1 diabetes mellitus was not observed.

Immune-mediated hypophysitis/hypopituitarism

In patients receiving IMFINZI monotherapy, immune-mediated hypophysitis/hypopituitarism occurred in 2 (< 0.1%) patients both Grade 3. The time to onset for the events was 44 days and 50 days. Both patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day) and one patient discontinued IMFINZI due to immune-mediated hypophysitis/hypopituitarism.

HCC pool

In patients receiving STRIDE, immune-mediated hypophysitis/hypopituitarism occurred in 5 (1.1%) patients. The median time to onset for the events was 149 days (range: 27-242 days). Four patients received systemic corticosteroids, and 1 of the 4 patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). Three patients also required endocrine therapy. Resolution occurred in 2 patients.

Immune-mediated nephritis

In patients receiving IMFINZI monotherapy, immune-mediated nephritis occurred in 14 (0.5%) patients, including Grade 3 in 2 (< 0.1%) patients. The median time to onset was 71 days (range: 4-393 days). Nine patients received high-dose corticosteroid treatment (at least 40 mg prednisone or

equivalent per day) and 1 patient also received mycophenolate. IMFINZI was discontinued in 5 patients. Resolution occurred in 8 patients.

HCC pool

In patients receiving STRIDE, immune-mediated nephritis occurred in 4 (0.9%) patients, including Grade 3 in 2 (0.4%) patients. The median time to onset was 53 days (range: 26-242 days). All patients received systemic corticosteroids, and 3 of the 4 received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). Treatment was discontinued in 2 patients. Resolution occurred in 3 patients.

Immune-mediated rash

In patients receiving IMFINZI monotherapy, immune-mediated rash or dermatitis (including pemphigoid) occurred in 50 (1.7%) patients, including Grade 3 in 12 (0.4%) patients. The median time to onset was 43 days (range: 4-333 days). Twenty-four of the 50 patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). IMFINZI was discontinued in 3 patients. Resolution occurred in 31 patients.

HCC pool

In patients receiving STRIDE, immune-mediated rash or dermatitis (including pemphigoid) occurred in 26 (5.6%) patients, including Grade 3 in 9 (1.9%) patients and Grade 4 in 1 (0.2%) patients. The median time to onset was 25 days (range: 2-933 days). All patients received systemic corticosteroids and 14 of the 26 patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). One patient received other immunosuppressants. Treatment was discontinued in 3 patients. Resolution occurred in 19 patients.

In the DUO-E Study, out of 238 patients treated with platinum-based chemotherapy in combination with IMFINZI, followed by IMFINZI in combination with olaparib (platinum-based chemotherapy + IMFINZI + olaparib arm) immune mediated rash occurred in 8 (3.4%) patients, including Grade 3 in 2 (0.8%) patients. The median time to onset was 155 days (range: 2-308 days). All patients received high-dose corticosteroid treatment (at least 40 mg prednisone or equivalent per day). Resolution occurred in all 8 patients.

Infusion-related reactions

In patients receiving IMFINZI monotherapy, infusion-related reactions occurred in 49 (1.6%) patients, including Grade 3 in 5 (0.2%) patients. There were no Grade 4 or 5 events.

In the DUO-E Study, out of 238 patients treated with platinum-based chemotherapy in combination with IMFINZI, followed by IMFINZI in combination with olaparib (platinum-based chemotherapy + IMFINZI + olaparib arm), infusion-related reactions occurred in 13 (5.5%) patients, including Grade 3 in 1 (0.4%) patient. There were no Grade 4 or 5 events.

Pure Red Cell Aplasia

Pure Red Cell Aplasia (PRCA) has been reported when IMFINZI has been used in combination with olaparib. In a clinical study of patients with endometrial cancer treated with IMFINZI in combination with olaparib, the incidence of PRCA was 1.6%. All events were CTCAE Grade 3 or 4. Events were manageable following discontinuation of both IMFINZI and olaparib. The majority of events were managed with blood transfusion and immunosuppression and recovered; there were no fatal events. For management see section 4.4.

HCC pool

In patients receiving STRIDE, infusion-related reactions occurred in 13 (2.8%) patients.

Paediatric and adolescents

The safety of IMFINZI in combination with tremelimumab in children and adolescents aged less than 18 years has not been established. No new safety signals were observed in a clinical study evaluating 50 paediatric patients (< 18 years), relative to the known safety profiles of IMFINZI and tremelimumab in adults. Of the 50 patients enrolled in the study, 42 received IMFINZI in combination with tremelimumab and 8 received IMFINZI only (see section 5.1).

4.9 Overdose

There is no specific treatment in the event of durvalumab overdose, and symptoms of overdose are not established. In the event of an overdose, physicians should follow general supportive measures and should treat symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Expression of programmed cell death ligand-1 (PD-L1) protein is an adaptive immune response that helps tumours evade detection and elimination by the immune system. PD-L1 can be induced by inflammatory signals (e.g. IFN-gamma) and can be expressed on both tumour cells and tumour-associated immune cells in tumour microenvironment. PD-L1 blocks T-cell function and activation through interaction with PD-1 and CD80 (B7.1). By binding to its receptors, PD-L1 reduces cytotoxic T-cell activity, proliferation, and cytokine production.

Durvalumab is a fully human, high affinity, immunoglobulin G1 kappa (IgG1κ) monoclonal antibody that selectively blocks the interaction of PD-L1 with PD-1 and CD80 (B7.1) while leaving PD-1/PD-L2 interaction intact. Durvalumab does not induce antibody dependent cell-mediated cytotoxicity (ADCC). Selective blockade of PD-L1/PD-1 and PD-L1/CD80 interactions enhances antitumour immune responses. These antitumour responses may result in tumour elimination.

In preclinical studies, PD-L1 blockade led to increased T-cell activation and decreased tumour size.

The combination of durvalumab, a PD-L1 inhibitor, and tremelimumab, a CTLA-4 inhibitor functions to enhance anti-tumour T-cell activation and function at multiple stages of the immune response, maximizing anti-tumour immunity.

Clinical efficacy and safety

Durvalumab doses of 10 mg/kg every 2 weeks, 120 mg every 3 weeks or 1500 mg every 4 weeks were evaluated in NSCLC, ES-SCLC and endometrial cancer clinical studies. Based on the modelling and simulation of exposure, exposure-safety relationships and exposure-efficacy data comparisons, there are no anticipated clinically significant differences in efficacy and safety between durvalumab doses of 10 mg/kg every 2 weeks, 120 mg every 3 weeks or 1500 mg every 4 weeks.

Locally Advanced NSCLC – PACIFIC Study

The efficacy of IMFINZI was evaluated in the PACIFIC Study, a randomised, double-blind, placebo-controlled, multicenter study in 713 patients with histologically or cytologically confirmed locally advanced, unresectable NSCLC. Patients had completed at least 2 cycles of definitive platinum-based chemoradiation within 1 to 42 days prior to initiation of study treatment and had a ECOG performance status of 0 or 1. Ninety-two percent of patients had received a total dose of 54 to 66 Gy of radiation. The study excluded patients who had progressed following chemoradiation therapy, patients with active or prior documented autoimmune disease within 2 years of initiation of the study; a history of immunodeficiency; a history of severe immune-mediated adverse reactions; medical conditions that required systemic immunosuppression, except physiological dose of systemic corticosteroids; active tuberculosis or hepatitis B or C or HIV infection or patients receiving live attenuated vaccine within 30 days before or after the start of IMFINZI. Patients were randomised 2:1 to receive 10 mg/kg IMFINZI (n = 476) or 10 mg/kg placebo (n = 237) via intravenous infusion every 2 weeks for up to 12 months or until unacceptable toxicity or confirmed disease progression. Randomisation was stratified by gender, age (< 65 years vs. ≥ 65 years) and smoking status (smoker vs. non-smoker). Patients with disease control at 12 months were given the option to be re-treated upon disease progression. Tumour assessments were conducted every 8 weeks for the first 12 months and then every 12 weeks thereafter.

The demographics and baseline disease characteristics were well balanced between study arms. Baseline demographics of the overall study population were as follows: male (70%), age ≥ 65 years (45%), white (69%), Asian (27%), other (4%), current smoker (16%), past smoker (75%), and never smoker (9%), WHO/ECOG PS 0 (49%), WHO/ECOG PS 1 (51%). Disease characteristics were as follows: Stage IIIA (53%), Stage IIIB (45%), histological sub-groups of squamous (46%), non-squamous (54%), PD-L1 expression TC ≥ 25% (22%), PD-L1 expression TC < 25% (41%). (PD-L1 status was retrospectively analysed in 451 patients with available samples, taken prior to concurrent chemoradiation therapy).

The two primary endpoints of the study were OS) and progression-free survival (PFS) of IMFINZI vs. placebo. Secondary efficacy endpoints included ORR, DoR and Time to Death or Distant Metastasis (TTDM). PFS, ORR, DoR and TTDM were assessed by BICR according to RECIST v1.1.

At the primary analysis the study demonstrated a statistically significant and clinically meaningful improvement in OS in the IMFINZI-treated group compared with the placebo group [HR = 0.68 (95% CI: 0.53, 0.87), p = 0.00251]. Median OS was not reached in the IMFINZI-treated group and was 28.7 months in the placebo group. The study demonstrated a statistically significant and clinically meaningful improvement in OS in the IMFINZI-treated group compared with the placebo group [HR = 0.68 (95% CI: 0.53, 0.87), p = 0.00251]. Median OS was not reached in the IMFINZI-treated group and was 28.7 months in the placebo group. The study demonstrated a statistically significant and clinically meaningful improvement in PFS in the IMFINZI-treated group compared with the placebo group [hazard ratio (HR) = 0.52 (95% CI: 0.42, 0.65), p < 0.0001]. Median PFS was 16.8 months (95% CI: 13.0, 18.1 in the IMFINZI treated group and 5.6 months (95% CI: 4.6, 7.8) in the placebo group. In the 5-year follow-up analysis, with a median follow-up of 34.2 months, IMFINZI continued to demonstrate improved OS and PFS compared to placebo. See Table 11 and Figures 1 and 2.

Table 11. Efficacy results for the PACIFIC study

	Primary Analysis ^a		5 Year Follow-up Analysis ^b	
	IMFINZI (n = 476)	Placebo (n = 237)	IMFINZI (n = 476)	Placebo (n = 237)
OS				
Number of deaths (%)	183 (38.4%)	116 (48.9%)	264 (55.5%)	155 (65.4%)
Median OS (months) (95% CI)	NR (34.7, NR)	28.7 (22.9, NR)	47.5 (38.1, 52.9)	29.1 (22.1, 35.1)
HR (95% CI)	0.68 (0.53, 0.87)		0.72 (0.59, 0.89)	
2- sided p-value	0.00251			
OS at 24 months (%) (95% CI)	66.3% (61.7%, 70.4%)	55.6% (48.9%, 61.8%)	66.3% (61.8%,70.4%)	55.3% (48.6%,61.4%)
p-value	0.005			
OS at 48 months (%) (95% CI)	NA		49.7% (45.0%, 54.2%)	36.3% (30.1%, 42.6%)
OS at 60 months (%) (95% CI)	NA		42.9% (38.2%,47.4%)	33.4% (27.3%,39.6%)
PFS				
Number of events (%)	214 (45.0%)	157 (66.2%)	268 (56.3%)	175 (73.8%)
Median PFS (months) (95% CI)	16.8 (13.0, 18.1)	5.6 (4.6, 7.8)	16.9 (13.0, 23.9)	5.6 (4.8, 7.7)
HR (95% CI)	0.52 (0.42, 0.65)		0.55 (0.45, 0.68)	
p-value	p < 0.0001			
PFS at 12 months (%) (95% CI)	55.9% (51.0%, 60.4%)	35.3% (29.0%, 41.7%)	55.7% (51.0%, 60.2%)	34.5% (28.3%, 40.8%)
PFS at 18 months (%) (95% CI)	44.2% (37.7%, 50.5%)	27.0% (19.9%, 34.5%)	49.1% (44.2%, 53.8%)	27.5% (21.6%, 33.6%)
PFS at 60 months (%) (95% CI)	NA	NA	33.1% (28.0%, 38.2%)	19.0% (13.6%, 25.2%)
PFS2^c				
Number of events (%)	217 (45.6%)	144 (60.8%)	NA	NA
Median PFS2 (months) (95% CI)	28.3 (25.1, 34.7)	17.1 (14.5, 20.7)	NA	NA
HR (95% CI)	0.58 (0.46, 0.73)		NA	
p-value	p < 0.0001		NA	
TTDM^d				
Number of events (%)	182 (38.2%)	126 (53.2%)	NA	NA
Median TTDM (months) (95% CI)	28.3 (24.0, 34.9)	16.2 (12.5, 21.1)	NA	NA

	Primary Analysis ^a		5 Year Follow-up Analysis ^b	
	IMFINZI (n = 476)	Placebo (n = 237)	IMFINZI (n = 476)	Placebo (n = 237)
HR (95% CI)	0.53 (0.41, 0.68)		NA	
p-value	p < 0.0001		NA	
TFST ^e				
Number of events (%)	267 (56.1%)	169 (71.3%)	Not reported	Not reported
Median TFST (months) (95% CI)	21.0 (16.6, 25.5)	10.4 (8.3, 12.5)	NA	NA
HR (95% CI)	0.58 (0.47, 0.72)		NA	
p-value	p < 0.0001		NA	
ORR ^f n (%) (95% CI)	133 (30.0%) (25.79%, 34.53%)	38 (17.8%) (12.95%, 23.65%)	NA	NA
p-value	p < 0.001		NA	
Complete Response n (%)	8 (1.8%)	1 (0.5%)	NA	NA
Partial Response n (%)	125 (28.2%)	37 (17.4%)	NA	NA
Median DoR (months) (95% CI)	NR (27.4, NR)	18.4 (6.7, 24.5)	NA	NA

^a Primary analysis of OS, PFS2 and an updated analysis of TTDM, TFST, ORR and DoR data cut-off 22 March 2018. Primary analysis of PFS at data cut-off 13 February 2017.

^b Follow-up OS and PFS analysis at data cut-off 11 January 2021.

^c PFS2 is defined as the time from the date of randomisation until the date of second progression (defined by local standard clinical practice) or death.

^d TTDM is defined as the time from the date of randomisation until the first date of distant metastasis or death in the absence of distant metastasis. Distant metastasis is defined as any new lesion that is outside of the radiation field according to RECIST v1.1 or proven by biopsy.

^e TFST is defined as the time from randomisation to the start date of the first subsequent therapy after discontinuation of treatment, or death.

^f Based on sub-group of ITT population with measurable disease at baseline according to RECIST v1.1; IMFINZI (n = 443), Placebo (n = 213) assessed within 0-42 days after concurrent chemoradiation and before the start of study drug.

NR = Not Reached

Figure 1. Kaplan-Meier curve of OS (DCO 11 Jan 2021)

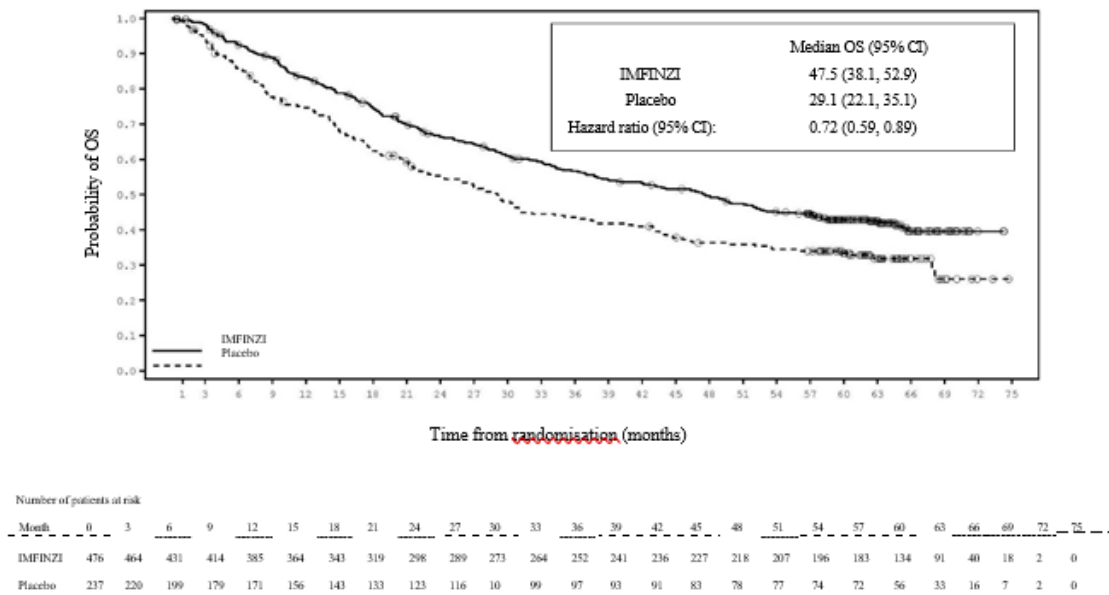
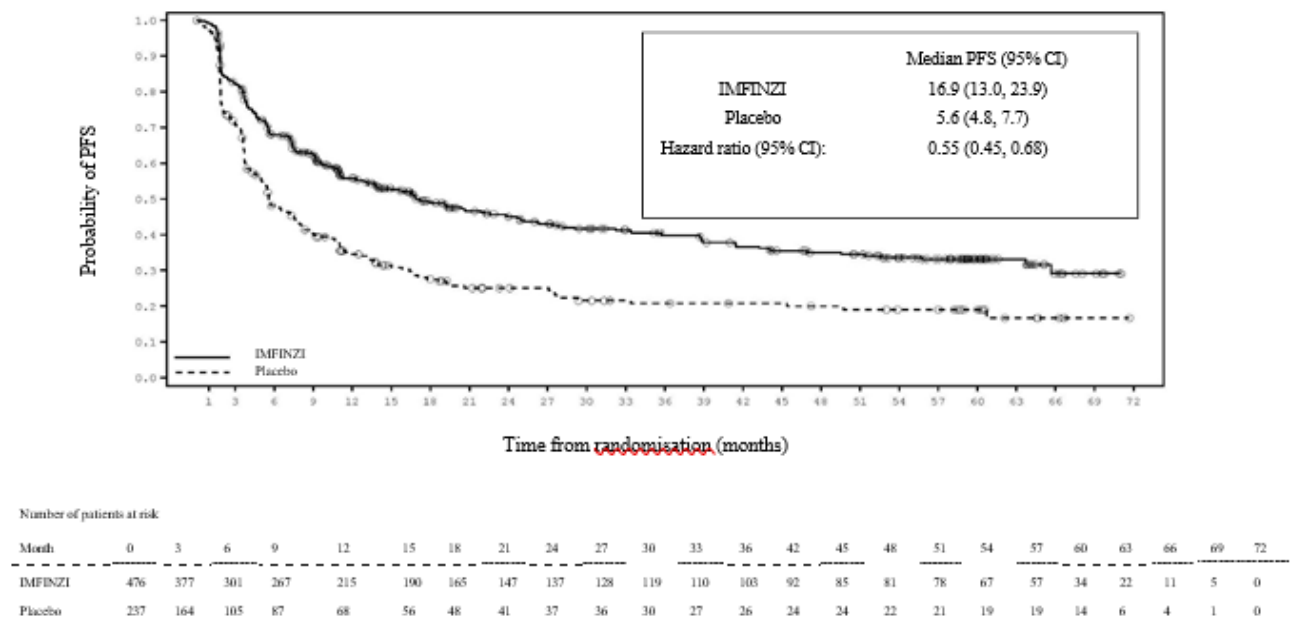


Figure 2. Kaplan-Meier curve of PFS (DCO 11 Jan 2021)



The improvements in OS and PFS in favor of patients receiving IMFINZI compared to those receiving placebo were consistently observed across predefined subgroups analyzed. Sensitivity analyses of OS and PFS demonstrated a consistent treatment effect with that observed in the primary analysis.

Patient-reported outcomes

Patient-reported symptoms, function and health-related quality of life (HRQoL) were collected using the EORTC QLQ-C30 and its lung cancer module (EORTC QLQ-LC13). The LC13 and C30 were assessed at baseline, every 4 weeks for the first 8 weeks, followed by every 8 weeks until completion of the treatment period or discontinuation of study drug due to toxicity or disease progression. Compliance was high and very similar between the IMFINZI and placebo treatment groups.

At baseline, no differences in patient-reported symptoms, function and HRQoL were observed between IMFINZI and placebo groups. Throughout the duration of the study to Week 48, there was no clinically meaningful difference between IMFINZI and placebo groups in symptoms, functioning and HRQoL (as assessed by a difference of greater than or equal to 10 points).

SCLC – CASPIAN Study

CASPIAN was a study designed to evaluate the efficacy of IMFINZI with or without tremelimumab in combination with etoposide and either carboplatin or cisplatin. CASPIAN was a randomized, open-label, multicenter study in 805 treatment naïve ES-SCLC patients with WHO/ECOG Performance status of 0 or 1, suitable to receive a platinum-based chemotherapy regimen as first-line treatment for SCLC, with life expectancy ≥ 12 weeks, at least one target lesion by RECIST 1.1 and adequate organ and bone marrow function. Patients with asymptomatic or treated brain metastases were eligible. The study excluded patients with a history of chest radiation therapy; a history of active primary immunodeficiency; autoimmune disorders including paraneoplastic syndrome (PNS); active or prior documented autoimmune or inflammatory disorders; use of systemic immunosuppressants within 14 days before the first dose of the treatment except physiological dose of systemic corticosteroids; active tuberculosis or hepatitis B or C or HIV infection; or patients receiving live attenuated vaccine within 30 days before or after the start of IMFINZI.

Randomisation was stratified by the planned platinum-based therapy in cycle 1 (carboplatin or cisplatin).

Patients were randomised 1:1:1 to receive:

- Arm 1: IMFINZI 1500 mg + tremelimumab 75 mg + etoposide and either carboplatin or cisplatin
- Arm 2: IMFINZI 1500 mg + etoposide and either carboplatin or cisplatin
- Arm 3: Either carboplatin (AUC 5 or 6 mg/mL/min) or cisplatin (75-80 mg/m²) on Day 1 and etoposide (80-100 mg/m²) intravenously on Days 1, 2, and 3 of each 21-day cycle for between 4 – 6 cycles.

For patients randomised to Arm 1 and 2, etoposide and either carboplatin or cisplatin was limited to 4 cycles on every 3 week schedule subsequent to randomisation. IMFINZI monotherapy continued until disease progression or unacceptable toxicity. Administration of IMFINZI monotherapy was permitted beyond disease progression if the patient was clinically stable and deriving clinical benefit as determined by the investigator.

Patients randomised to Arm 3, were permitted to receive a total of up to 6 cycles of etoposide and either carboplatin or cisplatin. After completion of chemotherapy, prophylactic cranial irradiation (PCI) was permitted only in Arm 3 per investigator discretion.

Tumour assessments were conducted at Week 6 and Week 12 from the date of randomisation, and then every 8 weeks until confirmed objective disease progression. Survival assessments were conducted every 2 months following treatment discontinuation.

The primary endpoints of the study were OS of IMFINZI + chemotherapy (Arm 2) vs. chemotherapy alone (Arm 3) and IMFINZI + tremelimumab + chemotherapy (Arm 1) vs. chemotherapy alone (Arm

3). The key secondary endpoint was PFS. Other secondary endpoints were ORR, OS and PFS landmarks and Patient-Reported Outcomes (PRO). PFS and ORR were assessed using Investigator assessments according to RECIST v1.1.

At a planned interim (primary) analysis, IMFINZI + chemotherapy (Arm 2) vs chemotherapy (Arm 3) met the efficacy boundary of the primary endpoint of OS. The results are summarised below.

The demographics and baseline disease characteristics were well balanced between the two study arms (268 patients in Arm 2 and 269 patients in Arm 3). Baseline demographics of the overall study population were as follows: male (69.6%), age $\geq$ 65 years (39.6%), median age 63 years (range: 28 to 82 years), white (83.8%), Asian (14.5%), black or African American (0.9%), other (0.6 %), non-Hispanic or Latino (96.1%), current or past-smoker (93.1%), never smoker (6.9%), WHO/ECOG PS 0 (35.2%), WHO/ECOG PS 1 (64.8%), Stage IV 90.3%, 24.6% of the patients received cisplatin and 74.1% of the patients received carboplatin. In Arm 3, 56.8% of the patients received 6 cycles of chemotherapy and 7.8% of the patients received PCI.

At the primary analysis the study demonstrated a statistically significant and clinically meaningful improvement in OS with IMFINZI + chemotherapy (Arm 2) vs. chemotherapy alone (Arm 3) [HR=0.73 (95% CI: 0.591, 0.909), $p=0.0047$]. IMFINZI + chemotherapy demonstrated an improvement in PFS vs. chemotherapy alone [HR=0.78 (95% CI: 0.645, 0.936) nominal p -value=0.0078].

In the long-term follow-up analysis, with a median follow-up of 39.3 months, IMFINZI + etoposide + platinum (Arm 2) vs etoposide + platinum (Arm 3) continued to demonstrate sustained improvement in OS. Results are presented in Table 12, Figure 3 and Figure 4.

Table 12. Efficacy Results for the CASPIAN Study

	Primary Analysis^a		Long-term follow-up analysis^b	
	Arm 2: IMFINZI + etoposide and either carboplatin or cisplatin (n=268)	Arm 3: etoposide and either carboplatin or cisplatin (n=269)	Arm 2: IMFINZI + etoposide and either carboplatin or cisplatin (n=268)	Arm 3: etoposide and either carboplatin or cisplatin (n=269)
OS				
Number of deaths (%)	155 (57.8)	181 (67.3)	221 (82.5)	248 (92.2)
Median OS (months) (95% CI)	13.0 (11.5, 14.8)	10.3 (9.3, 11.2)	12.9 (11.3, 14.7)	10.5 (9.3, 11.2)
HR (95% CI) ^d	0.73 (0.591, 0.909)		0.71 (0.595, 0.858)	
p -value ^c	0.0047			
OS at 12 months (%) (95% CI)	53.7 (47.4, 59.5)	39.8 (33.7, 45.8)	52.8 (46.6, 58.5)	39.3 (33.4, 45.1)
OS at 18 months (%) (95% CI)	33.9 (26.9, 41.0)	24.7 (18.4, 31.6)	32.0 (26.5, 37.7)	24.8 (19.7, 30.1)
OS at 24 months (95% CI)	NA	NA	22.9 (18.1, 28.2)	13.9 (10.1, 18.4)
OS at 36 months (%) (95% CI)	NA	NA	17.6 (13.3, 22.4)	5.8 (3.4, 9.1)
PFS				
Number of events (%)	226 (84.3)	233 (86.6)	NA	NA
Median PFS (months) (95% CI)	5.1 (4.7, 6.2)	5.4 (4.8, 6.2)	NA	NA

HR (95% CI) ^d	0.78 (0.645, 0.936)		NA	
p-value ^b	0.0078		NA	NA
PFS at 6 months (%) (95% CI)	45.4 (39.3, 51.3)	NA	NA	NA
PFS at 12 months (%) (95% CI)	17.5 (13.1, 22.5)	NA	NA	NA
ORR n (%)^a	182 (67.9)	NA	NA	NA
Complete Response n (%)	6 (2.2)	2 (0.7)	NA	NA
Partial Response n (%)	176 (65.7)	153 (56.9)	NA	NA
Odds ratio (95% CI) ^c	1.56 (1.095, 2.218)		NA	NA
p-value ^b	0.0136		NA	
Median DoR (months) (95% CI)^a	5.1 (4.9, 5.3)	5.1 (4.8, 5.3)	NA	NA
DoR at 12 months (%)^a	22.7	6.3	NA	NA

^a Primary OS, PFS, ORR and DoR analysis at data cut-off 11 March 2019.

^b Long-term survival analysis at data cut-off 22 March 2021. RECIST data were not collected at this follow up DCO.

^c The analysis was performed using the stratified log-rank test, adjusting for planned platinum therapy in Cycle 1 (carboplatin or cisplatin), and using the rank tests of association approach.

^d Based on a Lan-DeMets alpha spending function with O'Brien Fleming type boundary with the actual number of events observed, the boundary for declaring statistical significance is 0.0178.

^e Nominal p-value. PFS was included in the Multiple Testing Procedure (MTP) hierarchy at the second level. It was not able to be tested within the MTP as both Arm 1 and Arm 2 were required to achieve statistical significance prior to stepping down to PFS. ORR was not included in the MTP.

^f Confirmed Objective Response.

^g The analysis was performed using a logistic regression model adjusting for planned platinum therapy in Cycle 1 (carboplatin or cisplatin) with 95% CI calculated by profile likelihood.

Figure 3. Kaplan-Meier curve of OS (DCO 22 March 2021)

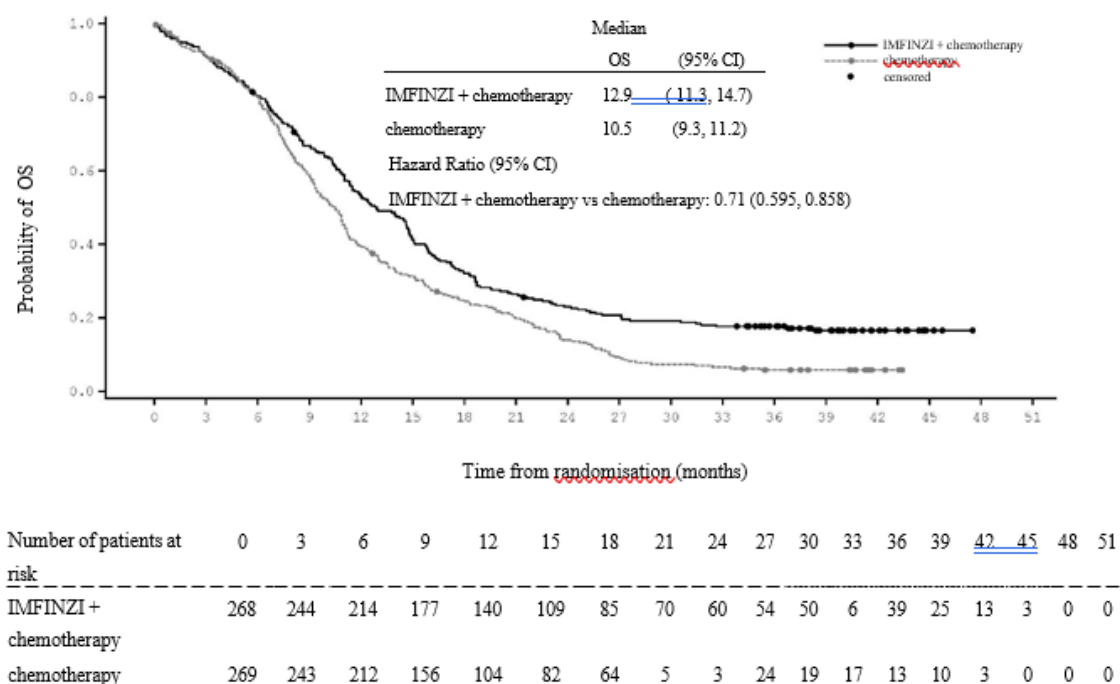
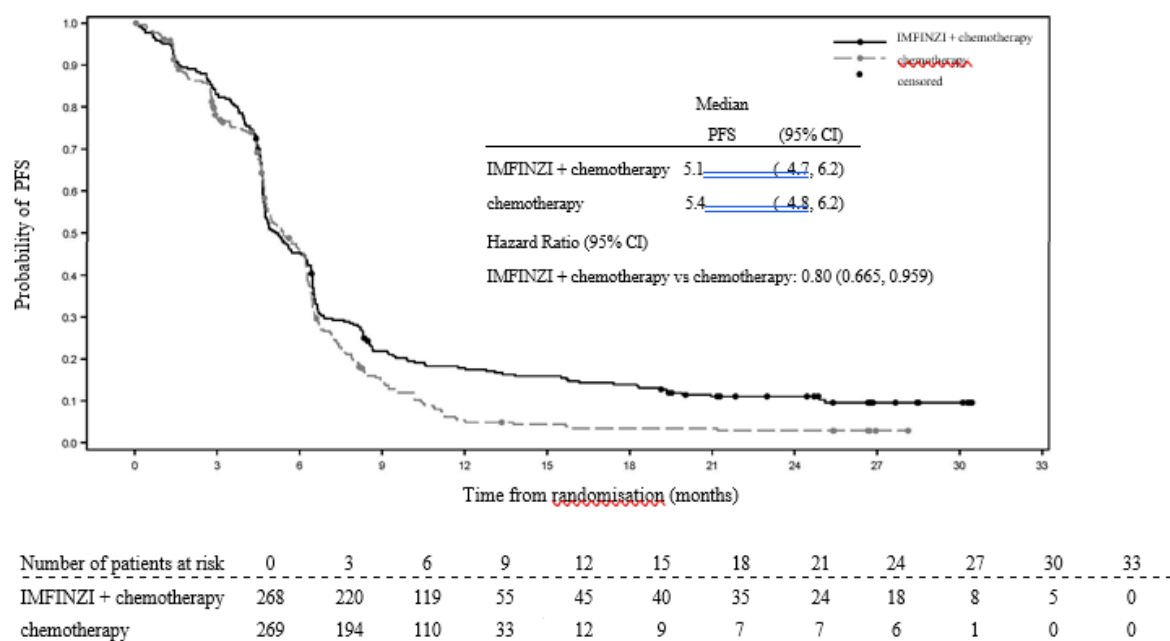


Figure 4. Kaplan-Meier curve of PFS (DCO 27 Jan 2020)



Subgroup analysis

The improvements in OS in favor of patients receiving IMFINZI + chemotherapy compared to those receiving chemotherapy alone, were consistently observed across the prespecified subgroups based on demographics, geographical region, carboplatin or cisplatin use and disease characteristics.

Patient-Reported Outcomes

Patient-reported symptoms, function and health-related quality of life (HRQoL) were collected using the EORTC QLQ-C30 and its lung cancer module (EORTC QLQ-LC13). Both questionnaires were administered up to second disease progression (PFS2) or death (whichever came first). At baseline, patient-reported symptoms, functioning or HRQoL scores were comparable between the study arms. Compliance was 60% or higher over 84 weeks in IMFINZI + chemotherapy and 20 weeks in the chemotherapy only arm.

Delay in time to deterioration of symptoms, functioning, and global health status/QoL:

IMFINZI + chemotherapy demonstrated improvement by delaying time to deterioration in a broad range of patient-reported symptoms, function, and global health status/QoL compared to chemotherapy alone (see Tables 13 and 14).

Table 13: Delay in median time to deterioration in global health status/QoL and function (EORTC QLQ-C30)^a

	Time to deterioration (months) Arm 2 (N=261) vs. Arm 3 (N=260)
Global health status/QoL	8.4 vs. 7.2 0.81 (0.63, 1.05); p=0.1166
Physical	8.5 vs. 6.5 0.75 (0.58, 0.97); p=0.0276
Cognitive	8.4 vs. 6.0 0.61 (0.47, 0.78); p<0.00001
Role	7.4 vs. 5.9 0.71 (0.55, 0.90); p=0.0059
Emotional	12.9 vs. 7.3 0.61 (0.46, 0.80); p=0.0003
Social	7.6 vs. 6.2 0.70 (0.55, 0.90); p=0.0048

^a p-values for time to deterioration based on stratified log-rank test and were not adjusted for multiplicity

Table 14: Delay in median time to deterioration in symptoms (EORTC QLQ-C30 and QLQ-LC13)^a

Symptom scale	Delay in time to deterioration (months) Arm 2 (N=261) vs. Arm 3 (N=260)
Coughing	9.3 vs. 7.7 0.78 (0.60, 1.03); p=0.0747
Dyspnoea (QLQ-C30)	9.0 vs. 7.4 0.75 (0.57, 0.99); p=0.0406
Dyspnoea (QLQ-LC13)	6.5 vs. 5.5 0.79 (0.63, 1.01); p=0.0578
Pain	7.8 vs. 6.7 0.79 (0.62, 1.02); p=0.0718
Chest pain	10.6 vs. 7.8 0.76 (0.58, 1.00); p=0.0464
Arm or shoulder pain	9.9 vs. 7.5 0.70 (0.54, 0.92); p=0.0088
Pain in other parts of body	7.8 vs. 6.4 0.72 (0.56, 0.92); p=0.0096
Fatigue	5.5 vs. 4.3 0.82 (0.65, 1.03); p=0.0835
Insomnia	8.6 vs. 7.3 0.75 (0.57, 0.98); p=0.0349

Appetite loss	8.3 vs. 6.6 0.70 (0.54, 0.90); p=0.0054
Constipation	11.1 vs. 7.3 0.65 (0.50, 0.86); p=0.0018
Diarrhea	14.6 vs. 7.7 0.59 (0.44, 0.77); p=0.0002
Nausea/vomiting	8.4 vs. 6.6 0.80 (0.63, 1.03); p=0.0809
Haemoptysis	18.3 vs. 10.5 0.64 (0.47, 0.88); p=0.0049

^a p-values for time to deterioration based on stratified log-rank test and were not adjusted for multiplicity

Change from baseline in lung cancer symptoms over 12 months (mixed model for repeated measures):

IMFINZI + chemotherapy improved appetite loss by demonstrating a statistically significant difference in mean change from baseline versus chemotherapy alone during the overall time period from randomisation until 12 months (Estimated mean difference -4.5; 99% CI -9.04, -0.04; p=0.009). Both treatment arms demonstrated numerical symptom reduction in cough, chest pain, dyspnea and fatigue over the same time period.

Patient-reported outcome results should be interpreted in the context of the open-label study design.

BTC – TOPAZ-1 Study

TOPAZ-1 was a study designed to evaluate the efficacy of IMFINZI in combination with gemcitabine and cisplatin. TOPAZ-1 was a randomised, double-blind, placebo-controlled, multicentre study in 685 patients with histologically confirmed locally advanced or metastatic BTC and ECOG performance status of 0 or 1. Patients who developed recurrent disease more than 6 months after surgery and/or completion of adjuvant therapy were included. Patients must have had at least one target lesion by RECIST v1.1 and adequate organ and bone marrow function.

The study excluded patients with ampullary carcinoma, active or prior documented autoimmune or inflammatory disorders, HIV infection or active infections, including tuberculosis or hepatitis C or patients with current or prior use of immunosuppressive medication within 14 days before the first dose of IMFINZI.

Randomization was stratified by disease status and primary tumour location.

Patients were randomized 1:1 to receive:

- Arm 1: IMFINZI 1500 mg administered intravenously on Day 1+ gemcitabine 1000 mg/m² and cisplatin 25 mg/m² (each administered on Days 1 and 8) every 3 weeks (21 days) for up to 8 cycles, followed by IMFINZI 1500 mg every 4 weeks as long as clinical benefit is observed or until unacceptable toxicity, or
- Arm 2: Placebo administered intravenously on Day 1+ gemcitabine 1000 mg/m² and cisplatin 25 mg/m² (each administered on Days 1 and 8) every 3 weeks (21 days) for up to 8 cycles, followed by placebo every 4 weeks as long as clinical benefit is observed or until unacceptable toxicity.

Tumour assessments were conducted every 6 weeks for the first 24 weeks after the date of randomisation, and then every 8 weeks until confirmed objective disease progression.

The primary endpoint of the study was OS and the key secondary endpoint was PFS. Other secondary endpoints were ORR, DoR and PRO. PFS, ORR and DoR were Investigator assessed according to RECIST v1.1.

The demographics and baseline disease characteristics were well balanced between the two study arms (341 patients in Arm 1 and 344 patients in Arm 2). Baseline demographics of the overall study population were as follows: male (50.4%), age <65 years (53.3%), white (37.2%), Asian (56.4%), black or African American (2.0%), other (4.2%), non-Hispanic or Latino (93.1%), ECOG PS 0 (49.1%), vs. PS 1 (50.9%), primary tumour location intrahepatic cholangiocarcinoma (55.9%), extrahepatic cholangiocarcinoma (19.1%) and gallbladder cancer (25.0%), disease status recurrent (19.1%) vs. initially unresectable (80.7%), metastatic (86.0%) vs. locally advanced (13.9%).

The study demonstrated a statistically significant and clinically meaningful improvement in OS and PFS at a pre-planned interim (primary) analysis based on a Lan-DeMets alpha spending function with O'Brien Fleming type boundary and the actual number of events observed (Lan and DeMets 1983). The results in OS were [HR=0.80, (95% CI: 0.66, 0.97), p=0.021] and in PFS [HR=0.75, (95% CI: 0.63, 0.89), p=0.001]. The maturity for OS was 61.9% and the maturity for PFS was 83.6%. The boundary for declaring statistical significance for OS was 0.03 for an 4.9% overall alpha. Results from this analysis for PFS, ORR and DoR are presented in Table 10. PFS is also presented in Figure 5.

An additional OS analysis was performed 6.5 months after the interim analysis with an OS maturity of 76.9%. The observed treatment effect was consistent with the interim analysis. The OS HR was 0.76 (95% CI: 0.64, 0.91) and median survival was 12.9 months (95% CI: 11.6, 14.1) for the IMFINZI + gemcitabine and cisplatin arm. Results from this analysis are presented in the Table 15 and Figure 5.

Table 15. Efficacy Results for the TOPAZ-1 Study

	Primary Analysis ^a		Follow up Analysis ^b	
	IMFINZI + gemcitabine and cisplatin (n=341)	Placebo + gemcitabine and cisplatin (n=344)	IMFINZI + gemcitabine and cisplatin (n=341)	Placebo + gemcitabine and cisplatin (n=344)
OS				
Number of deaths (%)	198 (58.1)	226 (65.7)	248 (72.7)	279 (81.1)
Median OS (months) (95% CI)^c	12.8 (11.1, 14)	11.5 (10.1, 12.5)	12.9 (11.6, 14.1)	11.3 (10.1, 12.5)
HR (95% CI) ^d	0.80 (0.66, 0.97)		0.76 (0.64, 0.91)	
p-value ^{d,e}	0.021			
OS at 12 months (%) (95% CI)^c	54.1 (48.4, 59.4)	48 (42.4, 53.4)	54.3 (48.8, 59.4)	47.1 (41.7, 52.3)
OS at 18 months (%) (95% CI)^c	35.1	25.6	34.8	24.1

	(29.1, 41.2)	(19.9, 31.7)	(29.6, 40.0)	(19.6, 28.9)
OS at 24 months (%) (95% CI)^c	24.9 (17.9, 32.5)	10.4 (4.7, 18.8)	23.6 (18.7, 28.9)	11.5 (7.6, 16.2)
PFS				
Number of events (%)	276 (80.9)	297 (86.3)	NA	NA
Median PFS (months) (95% CI)^c	7.2 (6.7, 7.4)	5.7 (5.6, 6.7)	NA	NA
HR (95% CI) ^d	0.75 (0.63, 0.89)		NA	NA
p-value ^{d,f}	0.001		NA	NA
PFS at 9 months (%) (95% CI)^c	34.8 (29.6, 40.0)	24.6 (20.0, 29.5)	NA	NA
PFS at 12 months (%) (95% CI)^c	16.0 (12.0, 20.6)	6.6 (4.1, 9.9)	NA	NA
ORR n (%)^g	91 (26.7)	64 (18.7)	NA	NA
Complete Response n (%)	7 (2.1)	2 (0.6)	NA	NA
Partial Response n (%)	84 (24.6)	62 (18.1)	NA	NA
Odds ratio (95 % CI) ^h	1.60 (1.11, 2.31)		NA	NA
p-value ^h	0.011		NA	NA
DoR^g				
Median DoR (months) (95% CI)^c	6.4 (5.9, 8.1)	6.2 (4.4, 7.3)	NA	NA
DoR at 9 months (%)^c	32.6	25.3	NA	NA
DoR at 12 months (%)^c	26.1	15.0	NA	NA

^a Final OS, PFS, ORR and DoR analysis at data cut-off 11 Aug 2021.

^b Follow-up OS analysis at data cut-off 25 Feb 2022.

^c Calculated using the Kaplan-Meier technique. CI for median derived based on Brookmeyer-Crowley method.

^d The analysis for HR was performed using a stratified Cox proportional hazards model and 2-sided p-value is based on a stratified log-rank test, both are adjusted for disease status and primary tumor location.

^e p-value based on the results from the pre-planned interim (primary) analysis. Based on a Lan-DeMets alpha spending function with O'Brien Fleming type boundary for OS and the actual number of events

observed, the boundary for declaring statistical significance was 0.03 for an 4.9% overall alpha. (Lan^oand^oDeMets 1983)

^f p-value based on the results from the pre-planned interim analysis. Based on a Lan-DeMets alpha spending function with Pocock type boundary and the actual number of events observed, the boundary for declaring statistical significance was 0.0481 for an 4.9% overall alpha. (Lan^oand^oDeMets 1983)

^g Confirmed objective response by Investigator per RECIST 1.1. Based on patients with measurable disease at baseline IMFINZI + gemcitabine and cisplatin (n = 341), Placebo + gemcitabine and cisplatin (n = 343).

^h The analysis was performed using a stratified CMH test with factors for disease status and tumor location. Nominal 2-sided p-value.

Figure 5: Kaplan-Meier curve of OS (DCO: 25 Feb 2022)

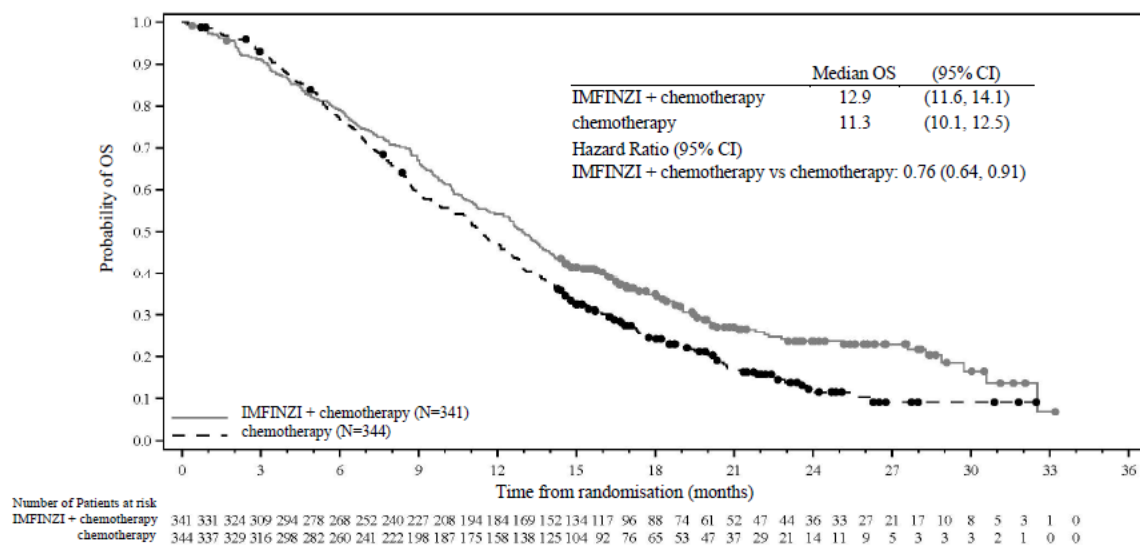
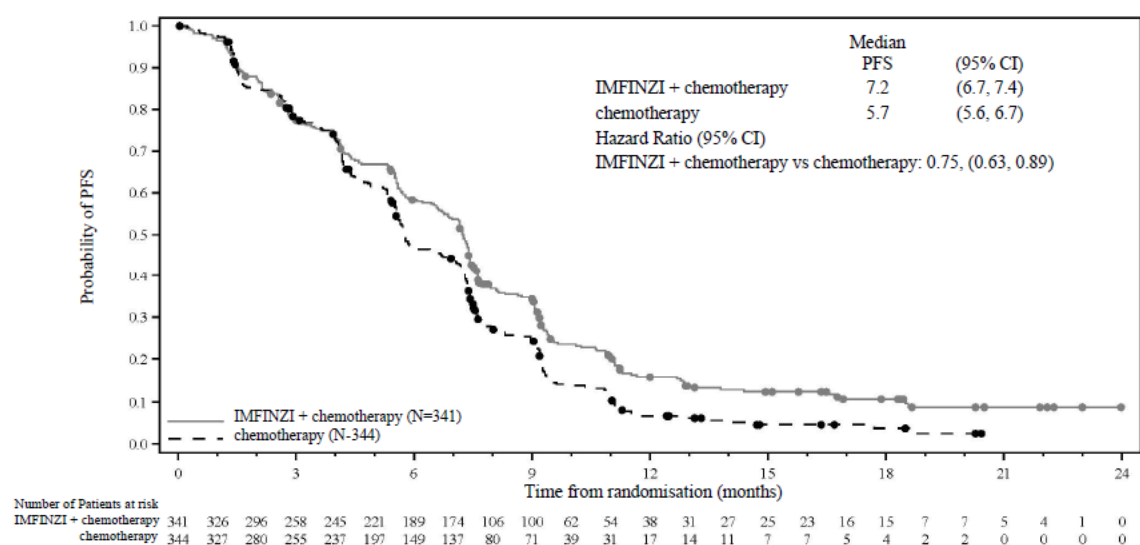


Figure 6: Kaplan-Meier curve of PFS (DCO: 11 Aug 2021)



Subgroup analysis

The improvements in OS and PFS in favour of patients receiving IMFINZI + chemotherapy compared to those receiving placebo + chemotherapy, were consistently observed across the prespecified subgroups based on demographics, geographical region, primary tumour location, disease status, ECOG PS, and PD-L1 expression levels.

Patient-Reported Outcomes

Patient-reported symptoms, function and global health status/QoL (GHS/QoL) were collected using the EORTC QLQ-C30 and its biliary tract cancer module (EORTC QLQ-BIL21). At baseline, patient-reported symptoms, functioning and GHS/QoL scores were comparable between the study arms. Time to deterioration and change from baseline analyses were consistent with no detriment in symptoms, function and GHS/QoL per EORTC QLQ-C30 and EORTC QLQ-BIL21 in the IMFINZI + chemotherapy group compared to the placebo + chemotherapy group.

Resectable NSCLC – AEGEAN Study

AEGEAN was a randomised, double-blind, placebo-controlled, multicentre, Phase III study designed to evaluate the efficacy of IMFINZI in combination with chemotherapy as neoadjuvant treatment, then continued as IMFINZI monotherapy after surgery, in patients with resectable NSCLC (Stage IIA to select Stage IIIB [AJCC, 8th edition]). The study enrolled previously untreated patients with documented squamous or non-squamous NSCLC and no prior exposure to immune-mediated therapy, a WHO/ECOG Performance status of 0 or 1, and at least one RECIST 1.1 target lesion. Prior to randomization, patients had tumour PD-L1 expression status confirmed using the Ventana PD-L1 (SP263) Assay.

The study excluded patients with active or prior documented autoimmune disease, or use of immunosuppressive medication within 14 days of the first dose of durvalumab. The study population for efficacy analysis (modified intent-to-treat [mITT]) excluded patients with known EGFR mutations or ALK rearrangements.

Randomisation was stratified by disease stage (Stage II vs. Stage III) and by PD-L1 expression (TC<1% vs. TC≥1%) status.

The AEGEAN study randomised 802 patients in a 1:1 ratio to receive perioperative IMFINZI (Arm 1) or placebo (Arm 2) in combination with neoadjuvant chemotherapy. Crossover between the study arms was not permitted. Efficacy analysis was conducted based on 740 patients in the mITT population.

- Arm 1: IMFINZI 1500 mg + chemotherapy every 3 weeks for up to 4 cycles prior to surgery, followed by IMFINZI 1500 mg every 4 weeks for up to 12 cycles after surgery.
- Arm 2: Placebo + chemotherapy every 3 weeks for up to 4 cycles prior to surgery, followed by Placebo every 4 weeks for up to 12 cycles after surgery.

A RECIST 1.1 tumour assessment was performed at baseline, and upon completion of the neoadjuvant period (prior to surgery). The first post-surgical CT/MRI scan of the chest and abdomen (including the entire liver and both adrenals) was acquired 5 weeks ±2 weeks after surgery and prior to, but as close as possible to the start of adjuvant therapy. Tumour assessments were then conducted every 12 weeks (relative to the date of surgery) until week 48, every 24 weeks (relative to the date of surgery) until week 192 (approximately 4 years), and then every 48 weeks (relative to the date of surgery) thereafter until RECIST 1.1 defined radiological PD, consent withdrawal, or death.

Survival assessments were conducted at month 2, 3, and 4 following treatment discontinuation and then every 2 months until month 12 followed by every 3 months.

The primary endpoints of the study were pathological complete response (pCR) by blinded central pathology review, and event-free survival (EFS) by blinded independent central review (BICR) assessment. The key secondary endpoints were major pathological response (MPR) by blinded central pathology review, DFS by BICR, and OS. Other secondary efficacy objectives included were EFS (PD-L1-TC $\geq 1\%$ analysis set), pCR (PD-L1-TC $\geq 1\%$ analysis set), and Patient Reported Outcomes (PRO).

At the planned interim analysis of pCR, the study met its prespecified boundary for declaring statistical significance for pCR and MPR. Subsequently, at the first planned interim analysis of EFS, the study met its prespecified boundary for declaring statistical significance for EFS.

The demographics and baseline disease characteristics were well balanced between the two study arms (366 patients in Arm 1 and 374 patients in Arm 2 of the mITT set). Baseline demographics and disease characteristics of the population for efficacy analysis (mITT) were as follows: male (71.6%), female (28.4%), age ≥ 65 years (51.6%), median age 65 years (range: 30 to 88), WHO/ECOG PS 0 (68.4%), WHO/ECOG PS 1 (31.6%), White (53.6%), Asian (41.5%), Black or African American (0.9%), American Indian or Alaska Native (1.4%), Other Race (2.6%), Hispanic or Latino (16.1%), Not Hispanic or Latino (83.9%), current or past smokers (85.5%), never smoker (14.5%), squamous histology (48.6%) and nonsquamous histology (50.7%), Stage II (28.4%), Stage III (71.6%), PD-L1 expression status TC $\geq 1\%$ (66.6%), PD-L1 expression status TC $< 1\%$ (33.4%). The demographics and baseline characteristics for the mITT population were similar to the ITT population except for the absence of patients with known EGFR mutations or ALK rearrangements.

In the mITT population there were 295 (80.6%) patients in Arm 1 who underwent curative intent surgery compared to 302 (80.7%) patients in Arm 2. There were 284 (77.6%) patients in Arm 1 who completed curative intent surgery compared to 287 (76.7%) patients in Arm 2. The resection margin status within the mITT population, who completed surgery, was (Arm 1 vs. Arm 2):

- R0 (no residual tumour): 94.7% vs. 91.3%
- R1 (microscopic residual tumour): 4.2% vs. 7.7%
- R2 (macroscopic residual tumour): 0.7% vs. 0.7%

The study demonstrated a statistically significant and clinically meaningful improvement in EFS [HR=0.68 (95% CI: 0.53, 0.88), $p = 0.003902$] of the IMFINZI arm compared to the placebo arm. The study also demonstrated a statistically significant and meaningful improvement in pCR [Difference in proportions, 12.96% (95% CI: 8.67, 17.57)] of the IMFINZI arm compared to the placebo arm. Overall survival (OS) data were not mature at the time of EFS analysis. See Table 16 and Figure 7.

Table 16: Efficacy Results for the AEGEAN Study (mITT)

	IMFINZI + chemotherapy (N=366)	Placebo + chemotherapy (N = 374)
EFS^a		
Number of events, n (%)	98 (26.8)	138 (36.9)
Median EFS (95% CI) (months)	NR (31.9, NR)	25.9 (18.9, NR)
EFS at 12 months, % (95% CI)	73.4 (67.9, 78.1)	64.5 (58.8, 69.6)
	IMFINZI + chemotherapy (N=366)	Placebo + chemotherapy (N = 374)
EFS at 24 months, % (95% CI)	63.3 (56.1, 69.6)	52.4 (45.4, 59.0)

Hazard ratio (95% CI)	0.68 (0.53, 0.88)	
2-sided p-value ^d	0.003902	
pCR^{a,b,d}		
Number of patients with response	63	16
Response rate, % (95% CI)	17.21 (13.49, 21.48)	4.28 (2.46, 6.85)
Difference in proportions, % (95% CI)	12.96 (8.67, 17.57)	
MPR^{a,c,d}		
Number of patients with response	122	46
Response rate, % (95% CI)	33.33 (28.52, 38.42)	12.30 (9.15, 16.06)
Difference in proportions, % (95% CI)	21.03 (15.14, 26.93)	

^a Results are based on planned EFS interim analysis and pCR/MPR final analysis (DCO: 10 November 2022) which occurred 46.3 months after study initiation.

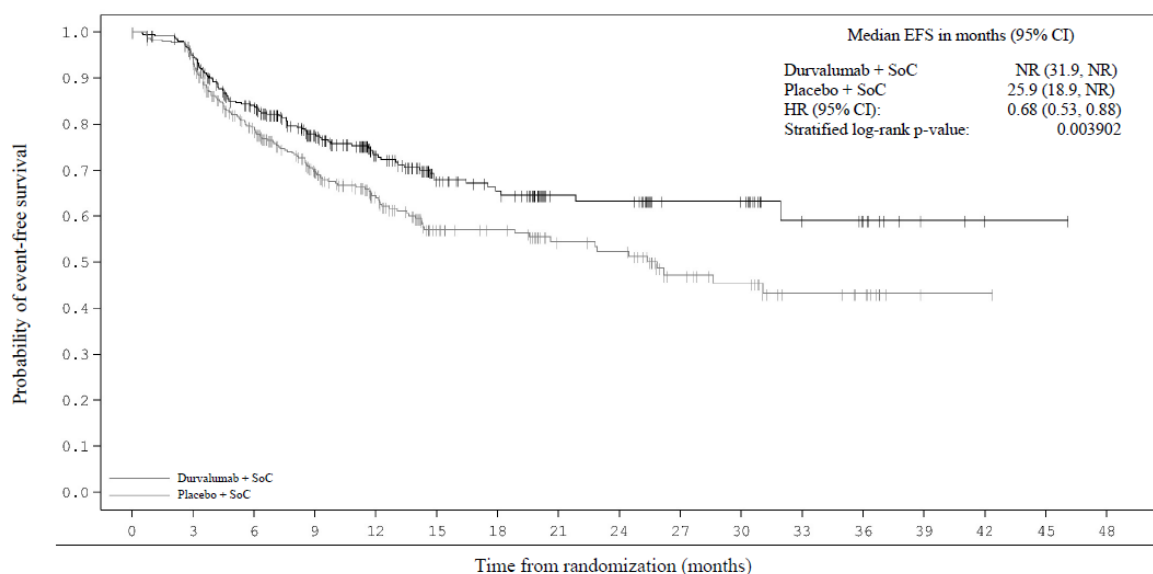
^b Based on a pre-specified pCR interim analysis (DCO: 14 January 2022) in n =402, the pCR rate was statistically significant (p = 0.000036) compared to significance level of 0.0082%.

^c Based on a pre-specified MPR interim analysis (DCO: 14 January 2022) in n=402, the MPR rate was statistically significant (p= 0.000002) compared to significance level of 0.0082%.

^d The 2-sided p-value for pCR and MPR was calculated based on a stratified CMH test. The 2-sided p-value for EFS was calculated based on based on a stratified log-rank test. Stratification factors include PD-L1 and disease stage.

The boundary for declaring statistical significance for each of the efficacy endpoints were determined by a Lan-DeMets alpha spending function that approximates an O'Brien Fleming approach (EFS = 0.9899%, pCR = 0.0082%, MPR = 0.0082%, 2-sided).

Figure 7: Kaplan-Meier Curve of EFS



Subgroup analysis

The improvement in EFS and pCR favouring patients in Arm 1 compared to patients in Arm 2 were consistently observed across prespecified subgroups based on demographic and baseline disease characteristics, histology, and planned chemotherapy.

Patient Reported Outcomes (PRO)

Patient-reported symptoms, function, and health related quality of life (HRQoL) were collected using the EORTC QLQ-C30, complementary EORTC QLQ-LC13, and exploratory PGIS, EQ-5D-5L, and PRO-CTCAE. These questionnaires were administered before discussion of disease progression and dosing and collected on month 1, 2, 3, and 6 post last dose. Overall compliance rates were high at neoadjuvant baseline (>90%) in the IMFINZI in combination with chemotherapy arm and the placebo in combination with chemotherapy arm.

Overall, the PRO/HRQoL data was generally similar between treatment arms throughout the neoadjuvant period. The proportion of patients with a clinically meaningful (≥ 10 point change) improvement in EORTC QLQ-C30 GHS/QoL was similar over the neoadjuvant period (reported for approximately a quarter of patients in both treatment arms). Clinically meaningful changes (≥ 10 point from baseline) were observed in only two scales: worsening fatigue (EORTC QLQ-C30) in the D + CTx arm (12.57 points [D + CTx] vs 8.50 points [placebo + CTx]) and decreased coughing (EORTC QLQ-LC13) in the placebo + CTx arm (-9.26 points [D + CTx] vs -11.60 points [placebo + CTx]).

HCC - HIMALAYA Study

The efficacy of STRIDE was evaluated in the HIMALAYA study, a randomised, open-label, multicenter study in patients with confirmed uHCC who did not receive prior systemic treatment for HCC. The study included patients with BCLC Stage C or B (not eligible for locoregional therapy) and Child-Pugh Score Class A.

The study excluded patients with co-infection of viral hepatitis B and hepatitis C; active or prior documented GI bleeding within 12 months; ascites requiring non-pharmacologic intervention within 6

months; hepatic encephalopathy within 12 months before the start of treatment; active or prior documented autoimmune or inflammatory disorders.

Patients with esophageal varices were included except those with active or prior documented GI bleeding within 12 months prior to study entry.

Randomisation was stratified by macrovascular invasion (MVI) (yes vs. no), etiology of liver disease (confirmed hepatitis B virus vs. confirmed hepatitis C virus vs. others) and ECOG performance status (0 vs. 1).

The HIMALAYA study randomized 1171 patients 1:1:1 to receive:

- IMFINZI: durvalumab 1500 mg every 4 weeks
- STRIDE: tremelimumab 300 mg as a single priming dose + IMFINZI 1500 mg; followed by IMFINZI 1500 mg every 4 weeks
- S: Sorafenib 400 mg twice daily

Treatment continued as long as clinical benefit was observed or until unacceptable toxicity. Patients in all arms could continue to receive treatment after evidence of disease progression if, in the Investigator's opinion, they were benefiting from study drug and met all inclusion and exclusion criteria for treatment beyond progression. In addition, patients in the STRIDE arm who continued treatment beyond progression were allowed to be rechallenged once with an additional single dose of tremelimumab 300 mg after cycle five of IMFINZI. Of the 182 patients enrolled to the STRIDE arm who received IMFINZI beyond progression, the median OS was 19.5 months (95% CI: 15.4, 23.4). Of the 30 patients who were enrolled to the STRIDE arm who were rechallenged with tremelimumab, the median OS was 30.4 months (95% CI: 23.4, NR).

Tumour assessments were conducted every 8 weeks for the first 12 months and then every 12 weeks thereafter. Survival assessments were conducted every month for the first 3 months following treatment discontinuation and then every 2 months.

The primary endpoint was OS. Key secondary endpoints were PFS, Investigator assessed ORR and DoR according to RECIST v1.1. PROs were also assessed.

The demographics and baseline disease characteristics were generally representative for patients with uHCC. The baseline demographics of the overall study population were as follows: male (83.7%), age <65 years (50.4%), white (44.6%), Asian (50.7%), black or African American (1.7%), other (2.3%), ECOG PS 0 (62.6%); Child-Pugh Class score A (99.5%), macrovascular invasion (25.2%), extrahepatic spread (53.4%), viral etiology; hepatitis B (30.6%), hepatitis C (27.2%), uninfected (42.2%).

The study demonstrated a statistically significant and clinically meaningful improvement in OS with STRIDE vs. S [HR=0.78 [95% CI 0.66, 0.92]; p=0.0035].

See Table 17 and Figure 8.

Table 17. Efficacy Results for the HIMALAYA Study for STRIDE vs. S

	STRIDE (n=393)	S (n=389)
Follow up duration		
Median follow up	33.2	32.2
Range	(31.7–34.5)	(30.4–33.7)

OS		
Number of deaths (%)	262 (66.7)	293 (75.3)
Median OS (months) (95% CI)	16.4 (14.2-19.6)	13.8 (12.3-16.1)
HR (95% CI)	0.78 (0.66, 0.92)	
p-value ^a	0.0035	
OS at 12 months (%) (95% CI)	60.2 (55.2 - 64.9)	56.2 (51.0 - 61.0)
OS at 18 months (%) (95% CI)	48.7 (43.6-53.5)	41.5 (36.5-46.4)
OS at 24 months (%) (95% CI)	40.5 (35.6-45.3)	32.6 (27.9-37.4)
OS at 36 months (%) (95% CI)	30.7 (25.8-35.7)	20.2 (15.8-25.1)
p-value	0.0029	
Number of patients treated beyond progression	182	192
PFS		
Number of events (%)	335 (85.2)	327 (84.1)
Median PFS (months) (95% CI)	3.78 (3.68-5.32)	4.07 (3.75-5.49)
HR (95% CI)	0.90 (0.77 - 1.05)	
p-value ^c	0.1625	
ORR		
ORR n (%)^{c,d}	79 (20.1)	20 (5.1)
Complete Response n (%)	12 (3.1)	0
Partial Response n (%)	67 (17.0)	20 (5.1)
Odds ratio 95% CI	4.69 (2.85, 8.04)	
p-value	<0.0001 ^c	
DoR		
Median DoR (months)	22.3	18.4
Sample size (n)	79	20
% with duration ≥6 months	82.3	78.9
% with duration ≥12 months	65.8	63.2

^a Based on a Lan-DeMets alpha spending function with O'Brien Fleming type boundary and the actual number of events observed, the boundary for declaring statistical significance for STRIDE vs. S was 0.0398 (Lan and DeMets 1983).

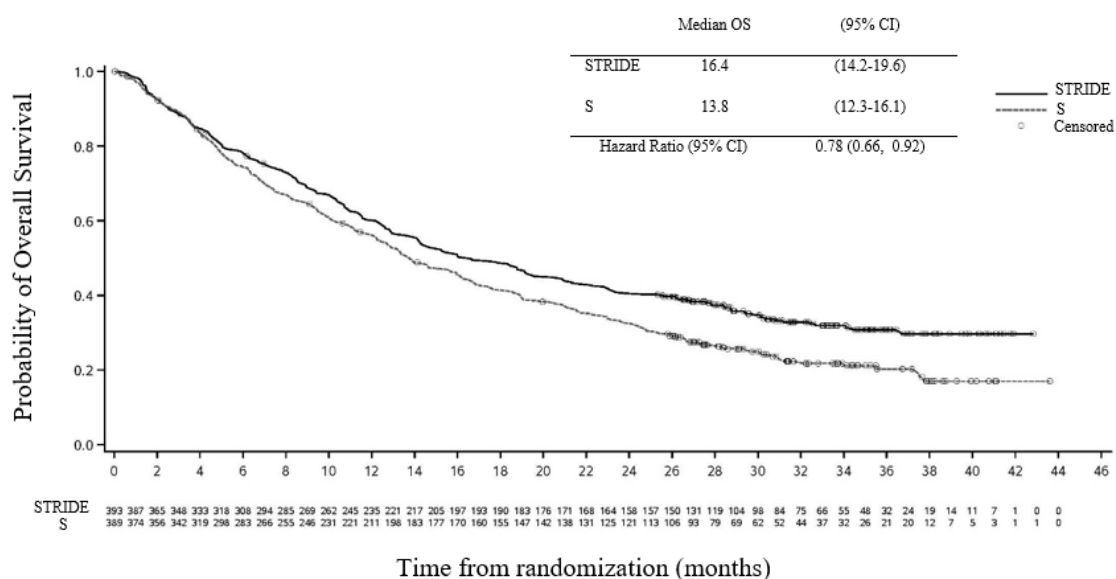
^b p-value is for the superiority test of IMFINZI vs. S. Based on a Lan-DeMets alpha spending function with O'Brien Fleming type boundary and the actual number of events observed, the boundary for declaring statistical significance for IMFINZI vs. S was 0.0433 (Lan and DeMets 1983).

^c Nominal p-value. PFS and ORR were not included in the Multiple Testing Procedure (MTP).

^d Confirmed complete response.

NR=Not Reached, CI=Confidence Interval

Figure 8. Kaplan-Meier curve of OS



Patient reported outcomes

Patient-reported symptoms, function and health-related quality of life (HRQoL) were collected using the EORTC QLQ-C30 and its hepatocellular carcinoma module (EORTC QLQ-HCC18). At baseline, patient-reported symptoms, functioning or HRQoL scores were comparable between the study arms.

Delay in time to deterioration of symptoms, functioning, and global health status/QoL:

STRIDE vs. S demonstrated a clinically meaningful improvement by delaying time to deterioration in a broad range of patient-reported symptoms, function, and global health status/QoL compared to S. Longer time to deterioration (median in months) was observed in the STRIDE arm compared to S for the following symptoms: Global Health Status (7.5 vs. 5.7 months, HR 0.76, $p = 0.0306$); physical functioning (12.9 vs. 7.4 months, HR 0.68; $p = 0.0020$), fatigue (7.4 vs. 5.4 months, HR 0.71; $p = 0.0026$), nausea (25.0 vs. 11.0 months, HR 0.65; $p = 0.0033$), appetite loss (12.6 vs. 6.9 months, HR 0.59; $p < 0.0001$), abdominal pain (16.8 vs. 8.9 months, HR 0.61; $p = 0.0008$) and abdominal swelling (20.9 vs. 11.1 months, HR 0.74; $p = 0.0431$).

Change from baseline in patient-reported symptoms (mixed model for repeated measures):

STRIDE improved patient-reported HRQoL functioning and diarrhoea by demonstrating a nominal difference and clinically meaningful mean change from baseline vs. S from randomisation until 8 months (Estimated mean difference at 8 months: -18.5 95% CI: -23.24, -13.84 and p -value: < 0.0001).

Patient-reported outcome results should be interpreted in the context of the open-label study design.

HCC – Study 22

The safety and efficacy of STRIDE was evaluated in Study 22, an open-label, multi-part, multicenter study in 75 immunotherapy naïve patients with uHCC who had progressed on, are intolerant to, or have refused sorafenib. The study included patients with BCLC Stage C or B (not eligible for locoregional therapy), ECOG performance status of 0 or 1 and Child-Pugh Score Class A.

The study excluded patients with co-infection of viral hepatitis B and hepatitis C; active or prior documented GI bleeding within 12 months; ascites requiring non-pharmacologic intervention within 6

months; hepatic encephalopathy within 12 months before the start of treatment; active or prior documented autoimmune or inflammatory disorders.

Treatment continued as long as clinical benefit was observed or until unacceptable toxicity. Patients who completed the assigned dosing cycles and were benefiting from study drug in the Investigator's opinion and subsequently had evidence of disease progression during the IMFINZI monotherapy phase could be rechallenged with tremelimumab 300 mg.

Tumour assessments were conducted every 8 weeks.

The primary objective was safety and tolerability. Key secondary endpoints included OS, ORR and DoR. ORR, DoR and PFS were based on Investigator assessments and BICR according to RECIST 1.1.

The baseline demographics of the study population (STRIDE) were as follows: male (86.7%); age <65 years (45.3%), white (36.0%); Asian (58.7%); black or African American (5.3%); other (0%), ECOG PS 0 (61.3%), Child-Pugh Class/Score A/5 (68.0%), Child-Pugh Class/Score A/6 (30.7%), macrovascular invasion (21.3%); extrahepatic spread (70.7%), viral etiology; hepatitis B (36.0%), hepatitis C (28.0%), uninfected (36.0%); prior systemic therapy (73.3%).

Efficacy results are shown in Table 18.

Table 18. Efficacy results for Study 22^a

	STRIDE (n=75)	D (n=104)
ORR		
ORR n (%)^{b,c}	18 (24.0)	12 (11.5)
95% CI	14.9, 35.3	6.1, 19.3
DoR^b		
Median DoR (months) (95% CI)	18.4 (5.6, 24.0)	15.0 (8.5, NR)
% with duration ≥6 months	71.8	83.3
% with duration ≥12 months	64.6	56.3
OS		
Number of deaths (%)	49 (65.3)	78 (75.0)
Median OS (months) (95% CI)	17.05 (10.6-22.8)	12.9 (8.7-16.8)
OS at 12 months (%) (95% CI)	57.6 (45.5-68.0)	50.4 (40.3-59.7)
OS at 18 months (%) (95% CI)	47.8 (35.9-58.7)	34.0 (24.9-43.3)
OS at 24 months (%) (95% CI)	38.3 (26.9-49.6)	26.2 (17.9-35.3)

^a DCO of Final analysis: 6 Nov 2020.

^b Confirmed by BICR per RECIST v1.1.

^c Confirmed complete response.

NR=Not Reached, CI=Confidence Interval

ADRIATIC was a study designed to evaluate the efficacy of IMFINZI with or without tremelimumab. ADRIATIC was a randomised, double-blind, placebo-controlled multicentre study in 730 patients with histologically or cytologically confirmed LS-SCLC (Stage I to III according to AJCC, 8th edition) who had not progressed following concurrent chemoradiation therapy. Patients who were Stage I or II had to be medically inoperable as determined by the investigator. Patients completed 4 cycles of definitive platinum-based chemoradiation, 60-66 Gy once daily (QD) over 6 weeks or 45 Gy twice daily (BID) over 3 weeks, within 1 to 42 days prior to the first dose of study treatment. Prophylactic cranial irradiation (PCI) could be delivered at the discretion of the investigator after chemoradiation therapy and within 1 to 42 days prior to the first dose of study treatment.

The study excluded patients with active or prior documented autoimmune disease within 5 years of initiation of the study; a history of active primary immunodeficiency; a history of Grade ≥ 2 pneumonitis or active tuberculosis or hepatitis B or C or HIV infection and patients with active interstitial lung disease. Patients with mixed SCLC and NSCLC histology were also excluded.

Randomisation was stratified by stage (I/II versus III) and receipt of PCI (yes versus no). Patients were randomised 1:1:1 to receive:

- Arm 1: IMFINZI 1500 mg + placebo every 4 weeks for 4 cycles, followed by IMFINZI 1500 mg every 4 weeks.
- Arm 2: Placebo + a second placebo every 4 weeks for 4 cycles, followed by a single placebo every 4 weeks.
- Arm 3: IMFINZI 1500 mg + tremelimumab 75 mg every 4 weeks for 4 cycles, followed by IMFINZI 1500 mg every 4 weeks.

Once 600 patients had been randomised across all three arms, subsequent patients were randomised 1:1 to either arm 1 or 2, and received either IMFINZI 1500 mg every 4 weeks or placebo every 4 weeks.

Treatment continued until disease progression, until unacceptable toxicity, or for a maximum of 24 months. Tumour assessments were conducted every 8 weeks for the first 72 weeks, then every 12 weeks up to 96 weeks, and then every 24 weeks thereafter.

The demographics and baseline disease characteristics were well balanced between study arms. Baseline demographics and disease characteristics of the IMFINZI and placebo arms were as follows: male (69.1%), age ≥ 65 years (39.2%), White (50.4%), Black or African-American (0.8%), Asian (47.5%), other (1.3%), Hispanic or Latino (4.2%), current smoker (22.3%), past-smoker (68.5%), never smoker (9.2%), WHO/ECOG PS 0 (48.7%), WHO/ECOG PS 1 (51.3%), Stage I (3.6%), Stage II (9.1%), Stage III (87.4%).

Prior to randomisation, all patients received platinum-based chemotherapy (66.2% cisplatin-etoposide, 33.8% carboplatin-etoposide); 72.1% of patients received RT QD (of which 92.4% received $\geq 60 - \leq 66$ Gy QD); 27.9% received RT BID (of which 96.6% received 45 Gy BID) and 53.8% patients received PCI. Response to CRT was as follows: complete response (12.3%), partial response (73.8%), stable disease (14.0%).

The dual primary endpoints of the study were OS and PFS of IMFINZI vs. placebo. Secondary efficacy endpoints included ORR of IMFINZI vs. placebo. PFS and ORR were assessed by BICR according to RECIST v1.1.

At a planned interim analysis, the study demonstrated a statistically significant and clinically meaningful improvement in OS for IMFINZI compared with placebo [HR=0.73 (95% CI: 0.569, 0.928), $p=0.01042$]. The study also demonstrated a statistically significant and clinically meaningful improvement in PFS for IMFINZI compared with placebo [HR=0.76 (95% CI: 0.606, 0.950), $p=0.01608$]. See Table 19 and Figures 9 and 10.

Table 19. Efficacy results for the ADRIATIC study

	Arm 1: IMFINZI (n=264)	Arm 2: Placebo (n=266)
OS^a		
Number of deaths (%)	115 (43.6)	146 (54.9)
Median OS (months) (95% CI)^b	55.9 (37.3, NR)	33.4 (25.5, 39.9)
HR (95% CI) ^c	0.73 (0.569, 0.928)	
p-value ^d	0.01042	
OS at 24 months (%) (95% CI)^b	68.0 (61.9, 73.3)	58.5 (52.3, 64.3)
OS at 36 months (%) (95% CI)^b	56.5 (50.0, 62.5)	47.6 (41.3, 53.7)
PFS^e		
Number of events (%)	139 (52.7)	169 (63.5)
Median PFS (months) (95% CI)^b	16.6 (10.2, 28.2)	9.2 (7.4, 12.9)
HR (95% CI) ^f	0.76 (0.606, 0.950)	
p-value ^d	0.01608	
PFS at 18 months (%) (95% CI)^b	48.8 (42.2, 55.0)	36.1 (29.9, 42.2)
PFS at 24 months (%) (95% CI)^b	46.2 (39.6, 52.5)	34.2 (28.2, 40.3)
ORR^e		
ORR^g n (%)	53/175 (30.3)	54/169 (32.0)
Complete Response n (%)	5 (2.9)	4 (2.4)
Partial Response n (%)	48 (27.4)	50 (29.6)
Odds ratio (95% CI)	-1.2 (-11.0, 8.5)	
Median DoR^{b,e} (months) (95% CI)	33.0 (22.4, NR)	27.7 (9.6, NR)
Proportion of patients in response at 12 months ^{b,e} (%) (95% CI)	73.7 (59.0, 83.8)	60.3 (44.5, 72.9)
Proportion of patients in response at 18 months ^{b,e} (%) (95% CI)	71.5 (56.6, 82.0)	55.2 (39.4, 68.5)

^a Median duration of OS follow up in censored patients was 37.19 months in the IMFINZI arm and 37.24 months in the placebo arm.

^b Calculated using the Kaplan Meier technique. CI for median derived based on Brookmeyer-Crowley method.

^c The analysis for HR was performed using a stratified Cox proportional hazards model and the 2-sided p-value is based on a stratified log-rank test, both are adjusted for receipt of PCI.

^d p-value based on the results from the pre-planned interim analysis. Based on a Lan-DeMets alpha spending function O'Brien Fleming type boundary and the actual number of events observed, the boundary for declaring statistical significance for OS was 0.01679 for a 4.5% overall alpha and for PFS was 0.02805 for a 5% overall alpha (Lan and DeMets 1983).

^e Assessed by BICR according to RECIST v1.1.

^f The analysis for HR was performed using a stratified Cox proportional hazards model and the 2-sided p-value is based on a stratified log-rank test, both are adjusted for TNM stage and receipt of PCI.

^g Based on sub-group of full analysis set with measurable disease at baseline according to RECIST v1.1; IMFINZI (n=175), Placebo (n=169).

Figure 9: Kaplan-Meier Curve of OS for IMFINZI vs. placebo

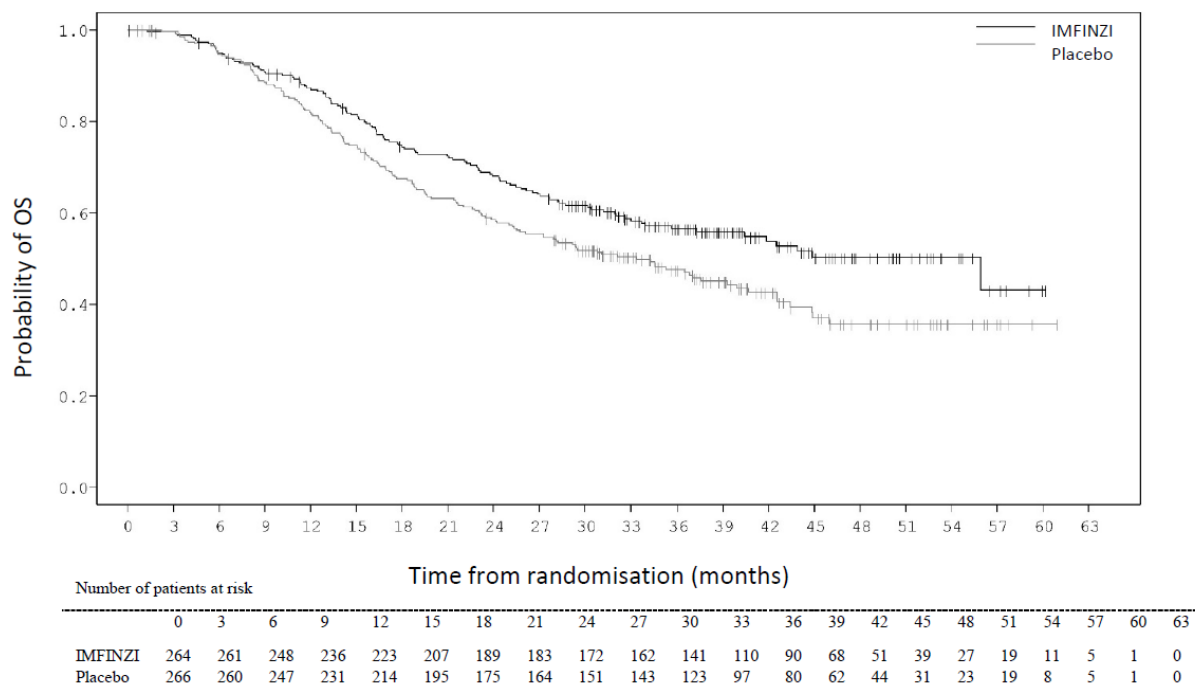
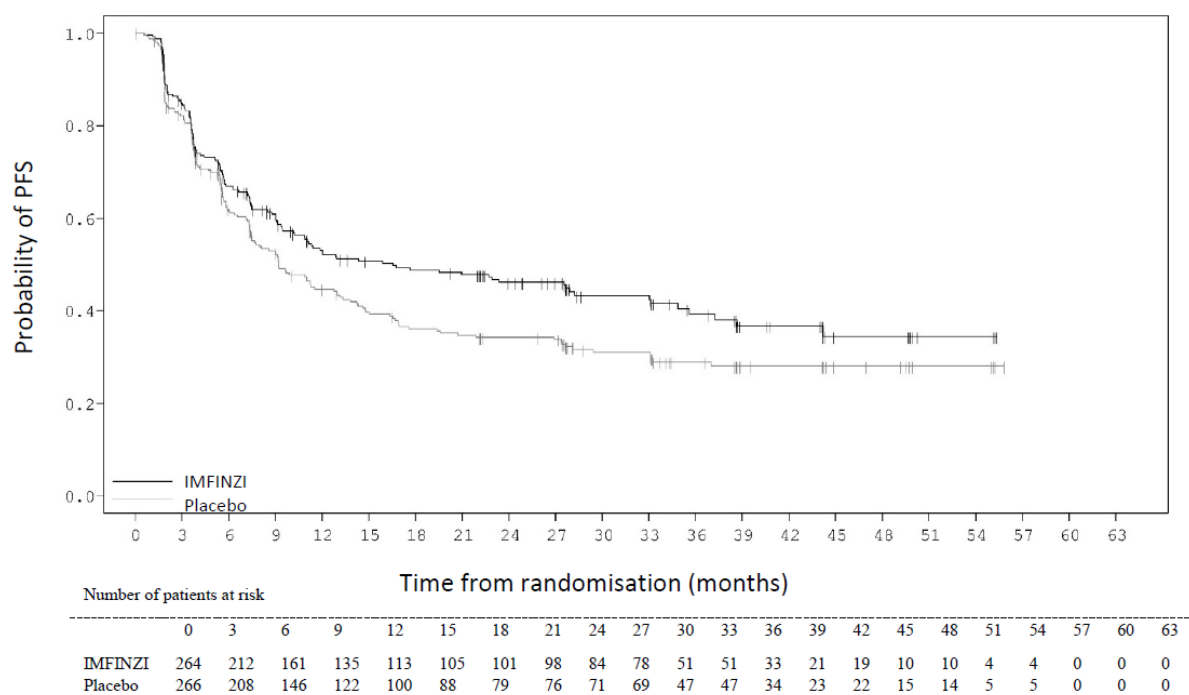


Figure 10: Kaplan-Meier Curve of PFS for IMFINZI vs. placebo



The improvements in OS and PFS in favour of patients receiving IMFINZI compared to those receiving placebo were generally consistent across predefined subgroups analysed.

Patient Reported Outcomes

Patient-reported physical functioning and disease-related symptoms and health-related quality of life (HRQoL) were collected using the EORTC QLQ-C30 and its lung cancer module (EORTC QLQ LC13). The LC13 and C30 scores were assessed at baseline, weekly for the first 8 weeks (LC13 only, C30 was assessed every 4 weeks), followed by every 4 weeks until completion of the treatment period or discontinuation of study drug due to toxicity or disease progression. At baseline, patient-reported physical functioning and symptoms were comparable between IMFINZI and placebo arms.

Throughout the duration of the study to Week 48, there was no clinically meaningful difference between IMFINZI and placebo arms in symptoms, functioning and HRQoL (as assessed by a difference of greater than or equal to 10 points).

Endometrial Cancer – DUO-E Study

DUO-E was a randomised, multicentre, double-blind, placebo-controlled, Phase III study of first-line platinum-based chemotherapy in combination with IMFINZI, followed by maintenance IMFINZI with or without olaparib in patients with advanced or recurrent endometrial cancer. For patients with recurrent disease, prior chemotherapy was allowed only if it was administered in the adjuvant setting and there was at least 12 months from the date of last dose of chemotherapy administered to the date of subsequent relapse. The study included patients with epithelial endometrial carcinomas of all histologies, including carcinosarcomas. Patients with endometrial sarcoma were excluded.

Randomisation was stratified by tumour tissue's mismatch repair (MMR) status (proficient versus deficient), disease status (recurrent versus newly diagnosed), and geographic region (Asia versus rest of the world). Patients were randomised 1:1:1 to one of the following arms:

- Arm 1 (Platinum-based chemotherapy): Platinum-based chemotherapy (paclitaxel and carboplatin) every 3 weeks for a maximum of 6 cycles with durvalumab placebo every 3 weeks. Following completion of chemotherapy treatment, patients without objective disease progression received durvalumab placebo every 4 weeks and olaparib placebo tablets twice daily as maintenance treatment until disease progression.
- Arm 2 (Platinum-based chemotherapy + IMFINZI): Platinum-based chemotherapy (paclitaxel and carboplatin) every 3 weeks for a maximum of 6 cycles with 1120 mg IMFINZI every 3 weeks. Following completion of chemotherapy treatment, patients without objective disease progression received 1500 mg durvalumab every 4 weeks with olaparib placebo tablets twice daily as maintenance treatment until disease progression.
- Arm 3 (Platinum-based chemotherapy + IMFINZI + olaparib): Platinum-based chemotherapy (paclitaxel and carboplatin) every 3 weeks for a maximum of 6 cycles with 1120 mg IMFINZI every 3 weeks. Following completion of chemotherapy treatment, patients without objective disease progression received 1500 mg durvalumab every 4 weeks with 300 mg olaparib tablets twice daily as maintenance treatment until disease progression.

Patients who discontinued either product (durvalumab/placebo or olaparib/placebo) for reasons other than disease progression could continue treatment with the other product if appropriate based on toxicity considerations and investigator discretion.

Treatment was continued until RECIST v1.1-defined progression of disease or unacceptable toxicity. Assessment of tumour status was performed every 9 weeks for the first 18 weeks relative to randomisation and every 12 weeks thereafter.

The primary endpoint was PFS, determined by investigator assessment using RECIST v1.1. Secondary efficacy endpoints included OS, ORR and DoR.

The study demonstrated a statistically significant improvement in PFS in the ITT population, for patients treated with platinum-based chemotherapy + IMFINZI + olaparib compared to platinum-based chemotherapy [HR=0.55 (95% CI: 0.43, 0.69), $p<0.0001$], and for patients treated with platinum-based chemotherapy + IMFINZI compared to platinum-based chemotherapy [HR=0.71 (95% CI: 0.57, 0.89), $p=0.003$]. At the time of PFS analysis, interim OS data were 28% mature with events in 199 of 718 patients.

Mismatch repair (MMR) status was determined centrally using an MMR immunohistochemistry panel assay. Of a total of 718 patients randomised in the study, 575 (80%) patients had MMR-proficient (pMMR) tumour status and 143 (20%) patients had MMR-deficient (dMMR) tumour status.

Patients with MMR-deficient (dMMR) endometrial cancer

Among patients with dMMR tumour status, demographic and baseline characteristics were generally well balanced between the treatment arms. Baseline demographics across all three arms were as follows: median age of 62 years (range: 34 to 85), 41% age 65 or older, 1.5% age 75 or older, 62% White, 29% Asian, and 2% Black or African American. Disease characteristics were as follows: ECOG PS of 0 (58%) or 1 (42%), 46% newly diagnosed and 54% recurrent disease. The histologic subtypes were endometrioid (83%), mixed epithelial (5%), serous (3%), carcinosarcoma (3%), undifferentiated (2%), and other (3%).

In patients with dMMR tumour status, the results are summarised in Table 20 and Figure 11. The median follow-up time for PFS in censored patients with dMMR tumour status was 15.5 months in the platinum-based chemotherapy + IMFINZI arm and 10.2 months in the platinum-based chemotherapy arm. At the time of PFS analysis, interim OS data were 26% mature with events in 25 of 95 patients treated with platinum-based chemotherapy + IMFINZI and platinum-based chemotherapy.

Table 20. Efficacy results for the DUO-E Study (Patients with dMMR tumour status)

	Platinum-based chemotherapy + IMFINZI N=46	Platinum-based chemotherapy N=49
PFS^{a,b}		
Number of events (%)	15 (32.6)	25 (51.0)
Median PFS (months) (95% CI)^c	NR (NR, NR)	7.0 (6.7, 14.8)
HR (95% CI)	0.42 (0.22, 0.80)	-
OS^b		
Number of events (%)	7 (15.2)	18 (36.7)
Median OS (months) (95% CI)^c	NR (NR, NR)	23.7 (16.9, NR)
HR (95% CI)	0.34 (0.13, 0.79)	-

ORR ^b		
ORR ^d n (%)	30 (71.4)	17 (40.5)
DoR ^b		
Median DoR (months) (95% CI) ^c	NR (NR, NR)	10.5 (4.3, NR)

^a Investigator assessed.

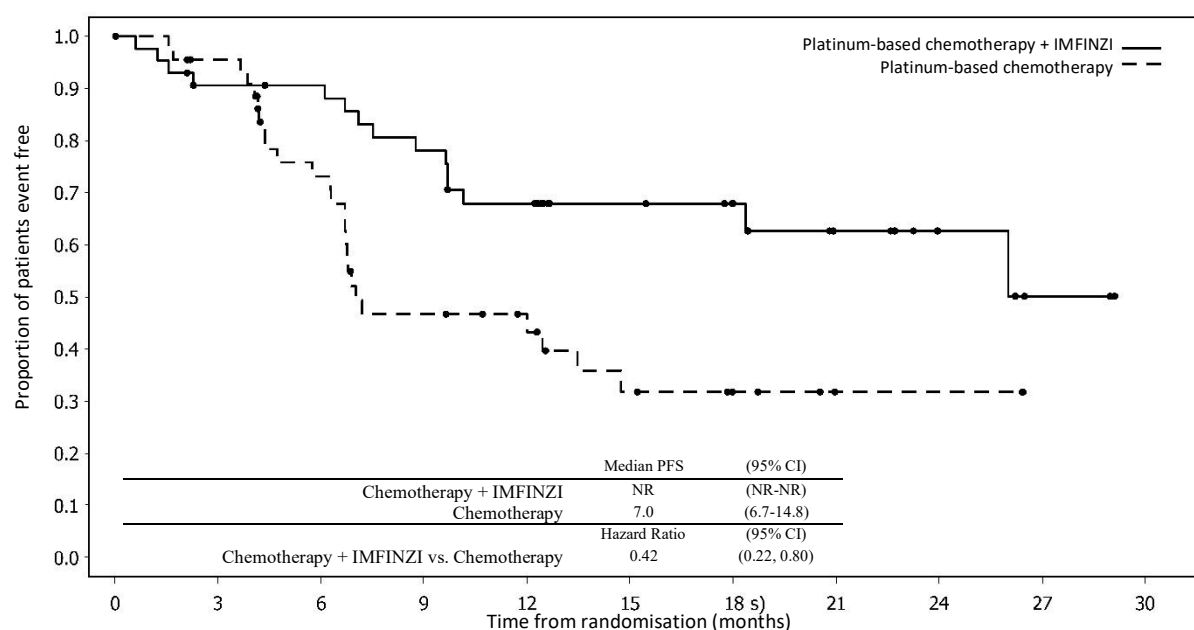
^b Results are based on the first interim analysis (DCO: 12 April 2023).

^c Calculated using the Kaplan-Meier technique.

^d Response: Best objective response as confirmed complete response or partial response. Based on number of patients in treatment group with measurable disease at baseline (N=42 in platinum-based chemotherapy + IMFINZI arm, N=42 in platinum-based chemotherapy arm).

CI=Confidence Interval, HR=Hazard Ratio, NR=Not Reached

Figure 11. Kaplan-Meier curve of PFS in DUO-E (Patients with dMMR tumour status)



Number of patients at risk:

Platinum-based chemotherapy + IMFINZI										
46	37	36	31	26	19	14	9	5	2	0
Platinum-based chemotherapy										
49	41	28	17	13	8	5	2	2	0	0

Patients with MMR-proficient (pMMR) endometrial cancer

Among patients with pMMR tumour status, demographic and baseline characteristics were generally well balanced between the treatment arms. Baseline demographics across all three arms were as follows: median age of 64 years (range: 22 to 86), 48% age 65 or older, 8.1% age 75 or older, 56% White, 30% Asian, and 6% Black or African American. Disease characteristics were as follows: ECOG PS of 0 (69%) or 1 (31%), 47% newly diagnosed and 53% recurrent disease. The histologic subtypes were endometrioid (54%), serous (26%), carcinosarcoma (8%), mixed epithelial (4%), clear cell (3%), undifferentiated (2%), mucinous (< 1%), and other (3%).

Results in patients with pMMR tumour status are summarised in Table 21 and Figure 12. The median follow-up time in censored patients with pMMR tumour status was 15.2 months in the platinum-based chemotherapy + IMFINZI + olaparib arm, and 12.8 months in the platinum-based chemotherapy arm.

At the time of PFS analysis, interim OS data were 29% mature with events in 110 of 383 patients treated with platinum-based chemotherapy + IMFINZI + olaparib and platinum-based chemotherapy.

Table 21. Efficacy results for the DUO-E Study (Patients with pMMR tumour status)

Platinum-based chemotherapy + IMFINZI + olaparib N=191		Platinum-based chemotherapy N=192
PFS^{a,b}		
Number of events (%)	108 (56.5)	148 (77.1)
Median PFS (months) (95% CI)^c	15.0 (12.4, 18.0)	9.7 (9.2, 10.1)
HR (95% CI)	0.57 (0.44, 0.73)	-
OS^b		
Number of events (%)	46 (24.1)	64 (33.3)
Median OS (months) (95% CI)^c	NR (NR, NR)	25.9 (25.1, NR)
HR (95% CI)	0.69 (0.47, 1.00)	-
ORR^b		
ORR ^d n (%)	90 (61.2)	92 (59.0)
DoR^b		
Median DoR (months) (95% CI)^c	18.7 (10.5, NR)	7.6 (7.1, 10.2)

^a Investigator assessed.

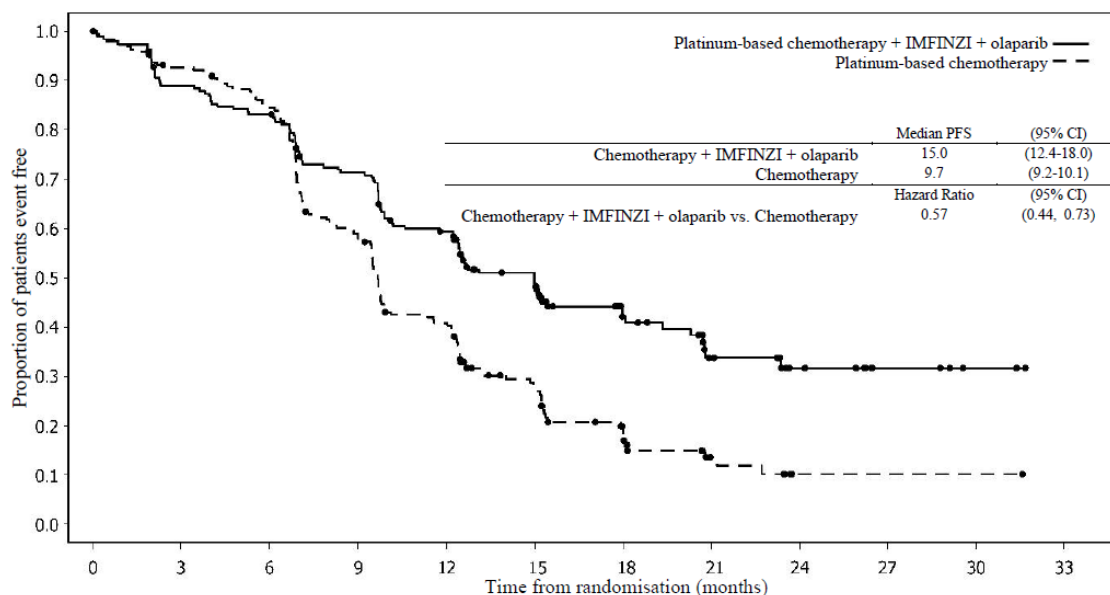
^b Results are based on the first interim analysis (DCO: 12 April 2023).

^c Calculated using the Kaplan-Meier technique.

^d Response: Best objective response as confirmed complete response or partial response. Based on number of patients in treatment group with measurable disease at baseline (N=147 in platinum-based chemotherapy + IMFINZI + olaparib arm, N=156 in platinum-based chemotherapy arm).

CI=Confidence Interval, HR=Hazard Ratio, NR=Not Reached

Figure 12. Kaplan-Meier curve of PFS in Duo-E (Patients with pMMR tumour status)



Number of patients at risk:

Platinum-based chemotherapy + IMFINZI + olaparib											
191	168	157	132	107	72	35	20	12	5	2	0
Platinum-based chemotherapy											
192	172	156	108	73	37	21	8	1	1	1	0

Among patients with pMMR tumour status, the PFS HRs were 0.44 (95% CI: 0.31, 0.61) in patients with PD-L1 expression positive status (236/383; 62%) and 0.87 (95% CI: 0.59, 1.28) in patients with PD-L1 expression negative status (140/383; 37%), for the platinum-based chemotherapy + IMFINZI + olaparib arm compared to the platinum-based chemotherapy arm. PD-L1 expression positive was defined as tumour area positive (TAP) $\geq$ 1%

Muscle invasive bladder cancer (MIBC)

MIBC – NIAGARA Study

The efficacy of neoadjuvant IMFINZI in combination with gemcitabine and cisplatin followed by adjuvant IMFINZI as a single agent in patients with MIBC was evaluated in NIAGARA (NCT03732677), a randomized, open-label, multicenter study. The study randomized (1:1) 1,063 patients who were candidates for radical cystectomy and who had not received prior systemic chemotherapy or immune-mediated therapy for the treatment of NMIBC or MIBC. The study excluded patients with pure non-urothelial histology, any small cell histology and primary non-bladder (i.e., ureter, urethral, or renal pelvis) cancer of the urothelium.

Randomization was stratified by clinical tumor stage T2N0 vs. > T2N0 (including T2N1, T3, and T4a), renal function (creatinine clearance [CrCl] $\geq$ 60 mL/min vs. CrCl $\geq$ 40 mL/min to < 60 mL/min), and PD-L1 expression (high vs. low/negative). Patients received:

- Neoadjuvant IMFINZI 1,500 mg plus gemcitabine 1,000 mg/m² and cisplatin 70 mg/m² every 3 weeks for 4 cycles prior to surgery, followed by IMFINZI 1,500 mg every 4 weeks as a single agent adjuvant treatment for up to 8 cycles after surgery, or
- Neoadjuvant gemcitabine 1,000 mg/m² and cisplatin 70 mg/m² every 3 weeks for 4 cycles prior to surgery, without adjuvant treatment.

Patients with CrCl $\geq$ 40 mL/min to < 60 mL/min in both arms received split-dose cisplatin of 35 mg/m² on days 1 and 8 of each cycle.

A RECIST 1.1 tumor assessment was performed at baseline and upon completion of neoadjuvant therapy (prior to surgery). After surgery, tumor assessments were performed every 12 weeks for the first 24 months, then every 24 weeks for 36 months, and then every 52 weeks thereafter until progression, the end of study, or death.

The major efficacy outcome measure was EFS by BICR assessment. OS was an additional efficacy outcome measure.

Baseline demographics were: male (82%), median age 65 years (range: 32 to 84), age $\geq$ 65 years (53%), White (67%), Asian (28%), Black or African American (0.9%), other (0.8%), Hispanic or Latino (8%), and ECOG PS 0 (78%) vs. PS 1 (22%). Disease characteristics were: tumor stage T2N0 (40%) and >T2N0 (60%), regional lymph nodes N0 (95%) and N1 (5%), adequate renal function (81%) and borderline renal function (19%). The histologic subtypes included urothelial carcinoma (85%) and urothelial carcinoma with variant histology (15%).

In the overall population, 469 (88%) patients in the IMFINZI plus gemcitabine and cisplatin arm and 441 (83%) patients in the gemcitabine and cisplatin arm underwent radical cystectomy.

At a pre-specified interim analysis, the study demonstrated a statistically significant improvement in EFS and OS in the IMFINZI plus gemcitabine and cisplatin arm compared to the gemcitabine and cisplatin arm. The trial was not designed to isolate the effect of IMFINZI in each phase (neoadjuvant or adjuvant) of treatment. See Table 18 and Figures 13 and 13.

Table 22. Efficacy Results for the NIAGARA Study

	IMFINZI plus gemcitabine and cisplatin (N=533)	Gemcitabine and cisplatin (N = 530)
EFS*		
Number of events (%)	187 (35.1)	246 (46.4)
Median EFS (months) (95% CI)	NR (NR, NR)	46.1 (32.2, NR)
HR (95% CI) [†]	0.68 (0.56, 0.82)	
2-sided p-value ^{§,#}	<0.0001	
Overall Survival (OS)		

	IMFINZI plus gemcitabine and cisplatin (N=533)	Gemcitabine and cisplatin (N = 530)
Number of events (%)	136 (25.5)	169 (31.9)
Median OS (months) (95% CI)	NR (NR, NR)	NR (NR, NR)
HR (95% CI) [†]	0.75 (0.59, 0.93)	
2-sided p-value ^{§, #}	0.0106	

*EFS is defined as the time from randomization to the first recurrence of disease after radical cystectomy, the time of first documented progression in patients who are medically precluded from a radical cystectomy, or time of expected surgery in patients who refuse to undergo a radical cystectomy or failure to undergo a radical cystectomy in participants with residual disease, or the time of death due to any cause, whichever occurs first.

[†] Based on stratified Cox proportional hazard model.

[§] Based on stratified log-rank test.

[#] Alpha allocated at the interim analysis was 0.0412 for EFS and 0.0154 for OS.

CI = Confidence Interval, HR = Hazard Ratio, NR = Not Reached

Figure 13. Kaplan-Meier Curve of EFS

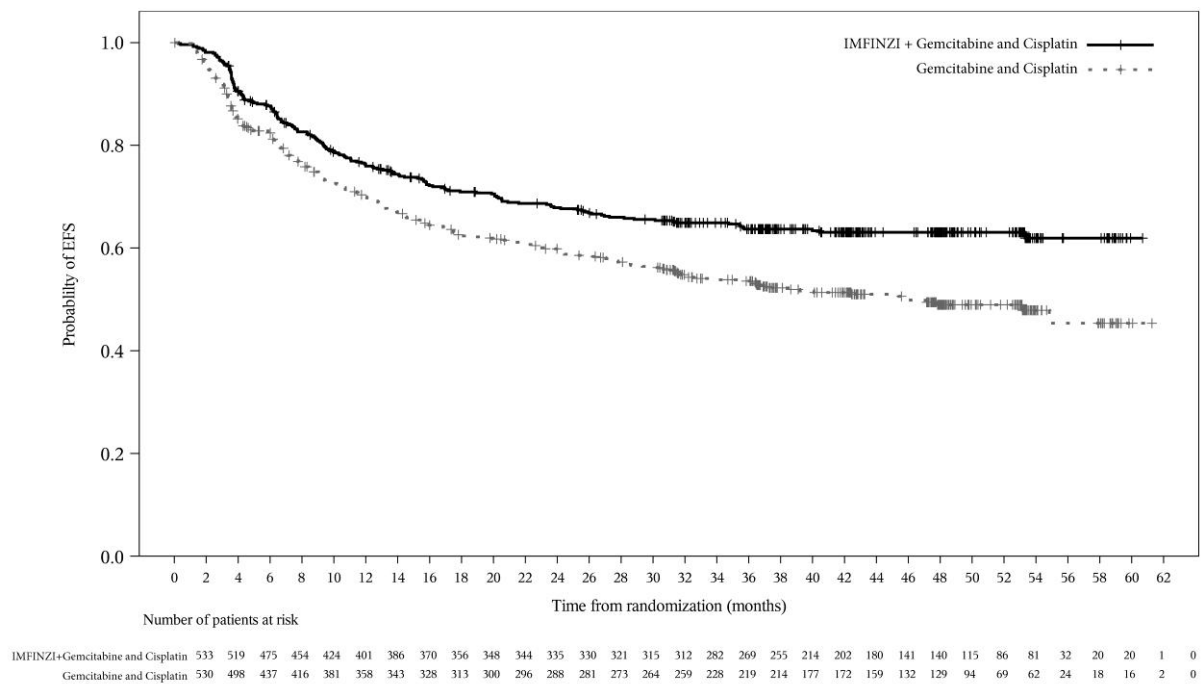
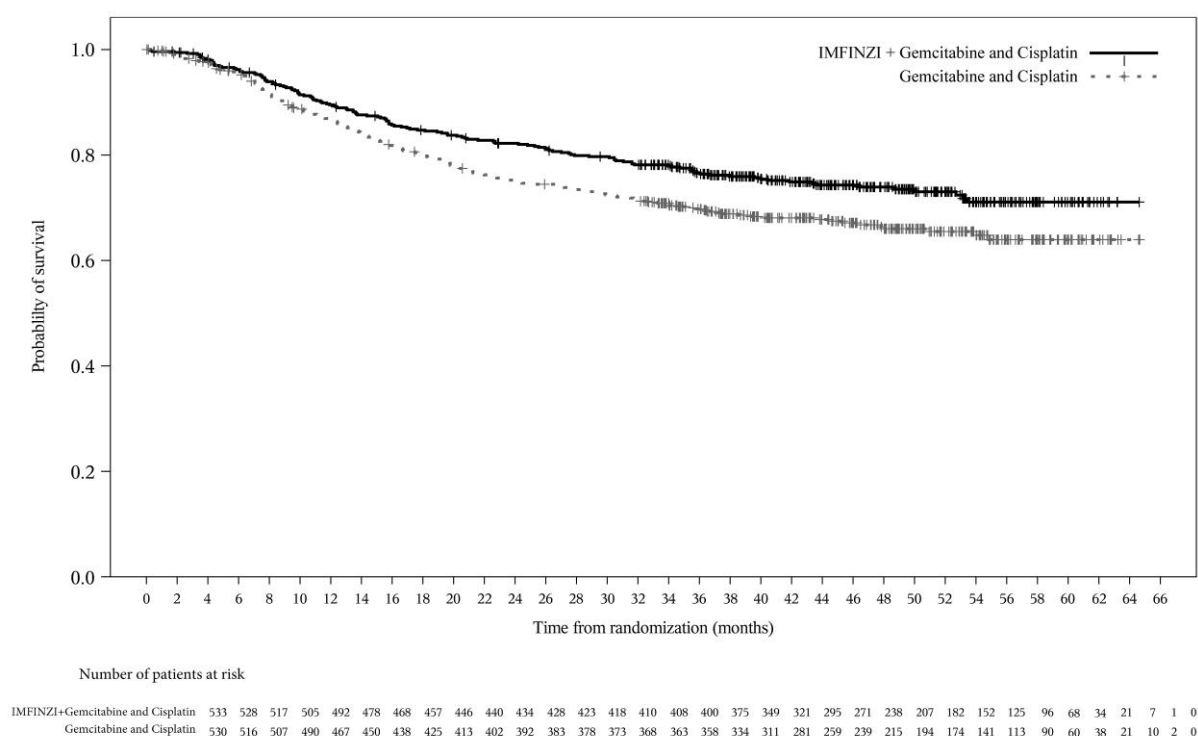


Figure 14. Kaplan-Meier Curve of OS



Gastric or gastroesophageal junction adenocarcinoma (GC/GEJC)

Neoadjuvant and Adjuvant Treatment of Resectable GC/GEJC – MATTERHORN Study

The efficacy of IMFINZI with FLOT as neoadjuvant and adjuvant treatment, followed by IMFINZI as a single agent, was investigated in MATTERHORN (NCT04592913), a randomized, double-blind, placebo-controlled, multicenter study conducted in 948 patients with previously untreated and resectable GC/GEJC (Stage II to Stage IVA [AJCC, 8th edition]). Eligible patients had no prior exposure to immune-mediated therapy and a WHO/ECOG performance status of 0 or 1. Patients with active or prior documented autoimmune or inflammatory disorders, or use of immunosuppressive medication within 14 days of the first dose of durvalumab were ineligible.

Randomization was stratified by geographic region (Asia vs. non-Asia), clinical lymph node status (positive vs. negative), and PD-L1 expression status (TAP < 1% vs. TAP ≥ 1%).

Patients were randomized in a 1:1 ratio to one of the following treatment arms. Crossover between the study arms was not permitted.

- IMFINZI 1,500 mg on Day 1 + FLOT on Days 1 and 15 of every 4-week cycle for 2 cycles in the neoadjuvant phase and 2 cycles in the adjuvant phase followed by IMFINZI 1,500 mg on Day 1 every 4 weeks for up to 10 additional cycles for a total of 12 cycles (1 dose per cycle)
- Placebo on Day 1 + FLOT on Days 1 and 15 of every 4-week cycle for 2 cycles in the neoadjuvant phase and 2 cycles in the adjuvant phase followed by placebo on Day 1 every 4 weeks for up to 10 additional cycles for a total of 12 cycles (1 dose per cycle)

Tumor assessment per RECIST was performed prior to the start of neoadjuvant therapy, prior to surgery, before starting adjuvant treatment and then every 12 weeks for 2 years and every 24 weeks until RECIST 1.1 defined radiological progression, consent withdrawal, or death.

The major efficacy outcome measure of the study was EFS by BICR assessment. EFS was defined as the earliest of one of the following: disease progression according to RECIST 1.1 that precluded

surgery or that required non-protocol therapy during the neoadjuvant treatment period; progression (after R1/R2 resection) or recurrence (after R0 resection), according to RECIST 1.1, during the adjuvant treatment period; non-RECIST progression (according to investigator assessment or confirmed by local pathology testing) that precluded surgery or that required non-protocol therapy during the neoadjuvant treatment period, or that was discovered during surgery; progression or recurrence confirmed by local pathology testing after surgery; or death.

Additional efficacy outcome measures were OS and pCR rate by blinded central pathology review. The trial was not designed to isolate the effect of IMFINZI in each phase (neoadjuvant or adjuvant) of treatment.

The demographics were as follows: median age 62 years (range: 26 to 84), age ≥ 65 years (41%), male (72%), White (68%), Asian (20%), American Indian or Alaska Native (4%), Black or African American (1.1%), other race (1.7%), Hispanic or Latino (20%), and WHO/ECOG PS 0 (74%). Disease characteristics were as follows: Stage II (29%), Stage III (62%), Stage IVA (9%), gastric (68%), gastroesophageal junction (32%), Siewert type 1 (10%), Siewert type 2 (15%), Siewert type 3 (7%), intestinal type (51%), diffuse type (26%), indeterminate type (23%), clinical lymph node status positive (70%), clinical lymph node status negative (29%), PD-L1 expression status TAP $\geq 1\%$ (90%), and PD-L1 expression status TAP $< 1\%$ (10%).

There were 412 (87%) patients in the IMFINZI arm who completed curative intent surgery compared to 400 (84%) patients in the placebo arm. Surgery was delayed (defined as surgery attempt > 8 weeks from last dose of neoadjuvant therapy) in 48 (10%) patients in the IMFINZI arm and 51 (11%) patients in the placebo arm. In the IMFINZI arm, 248 (52%) and 291 (61%) patients completed the two cycles of adjuvant IMFINZI and two cycles of adjuvant FLOT, respectively. In the placebo arm, 245 (52%) and 303 (64%) patients completed the two cycles of adjuvant placebo and two cycles of adjuvant FLOT, respectively. There were 344 (73%) patients in the IMFINZI arm who initiated adjuvant IMFINZI monotherapy compared to 332 (70%) patients in the placebo arm.

The study demonstrated a statistically significant improvement in EFS in the IMFINZI arm compared to the placebo arm. See Table 23, Figure 15, and Figure 16.

Table 23. Efficacy Results for the MATTERHORN Study

	IMFINZI + FLOT chemotherapy (N = 474)	Placebo + FLOT chemotherapy (N = 474)
Event Free Survival (EFS) [*]		
Number of events, n (%)	167 (35)	218 (46)
Median EFS (months) (95% CI) [‡]	NR (40.7, NE)	32.8 (27.9, NE)
HR (95% CI) [†]	0.71 (0.58, 0.86)	
p-value [¶]	<0.001	
Overall Survival (OS) [*]		
Number of events (%)	160 (33.8)	192 (40.5)
Median OS (months) (95% CI) [‡]	NR (NE, NE)	NR (NE, NE)
HR (95% CI) [†]	0.78 (0.63, 0.96)	
p-value [§]	0.021	
pCR [*]		

	IMFINZI + FLOT chemotherapy (N = 474)	Placebo + FLOT chemotherapy (N = 474)
Number of patients with response	91	34
Response rate, (%) (95% CI) [#]	19.2 (15.7, 23.0)	7.2 (5.0, 9.9)
p-value [‡]	<0.001	

* Results for EFS are based on a pre-specified interim analysis (DCO: 20 December 2024), results for OS are based on a pre-specified final analysis (DCO: 01 September 2025), and results for pCR are based on a pre-specified final analysis (DCO: 01 February 2023).

[‡] Calculated using the Kaplan-Meier method.

[†] Based on stratified Cox proportional hazards model stratified by geographic region, clinical lymph node status and PD-L1 expression status at randomization. CI calculated using the profile likelihood approach.

[¶] Based on stratified log-rank test adjusting for geographic region, clinical lymph node status, and PD-L1 expression status using an O'Brien-Fleming boundary of 0.0239 (2-sided).

[§] Based on stratified log-rank test adjusting for geographic region, clinical lymph node status, and PD-L1 expression status using a pre-specified boundary of 0.0499 (2-sided).

[#] CI was calculated using the Clopper Pearson method.

[‡] Based on a stratified Cochran-Mantel-Haenszel test adjusting for geographic region, clinical lymph node status, and PD-L1 expression status using a pre-specified boundary of 0.001 (2-sided).

CI=Confidence Interval, HR=Hazard Ratio, NE=Not estimable, NR=Not reached

Figure 15. Kaplan-Meier Curve of EFS

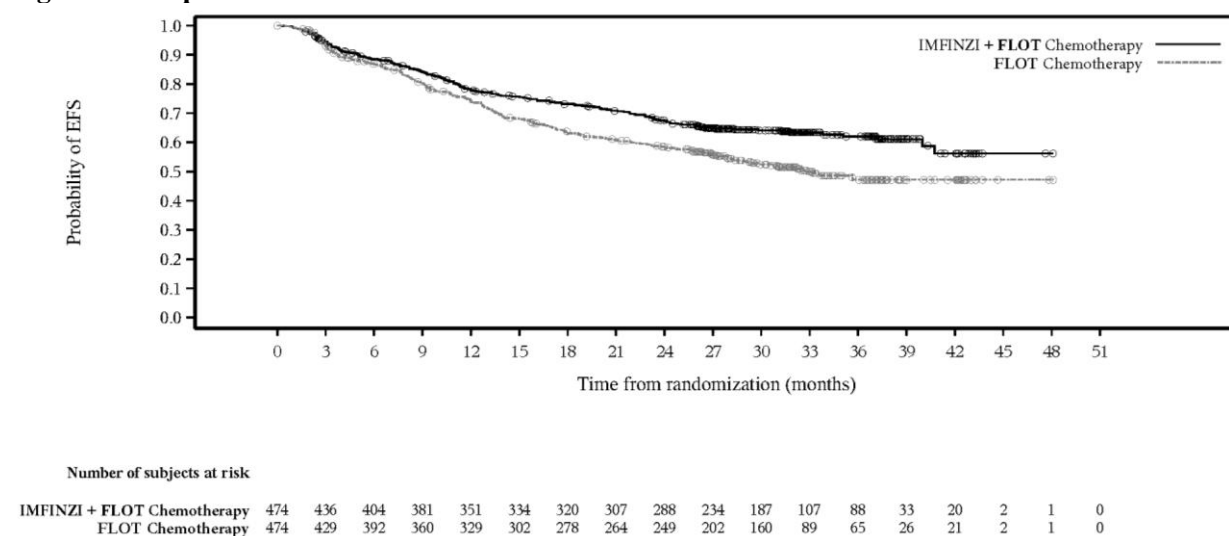
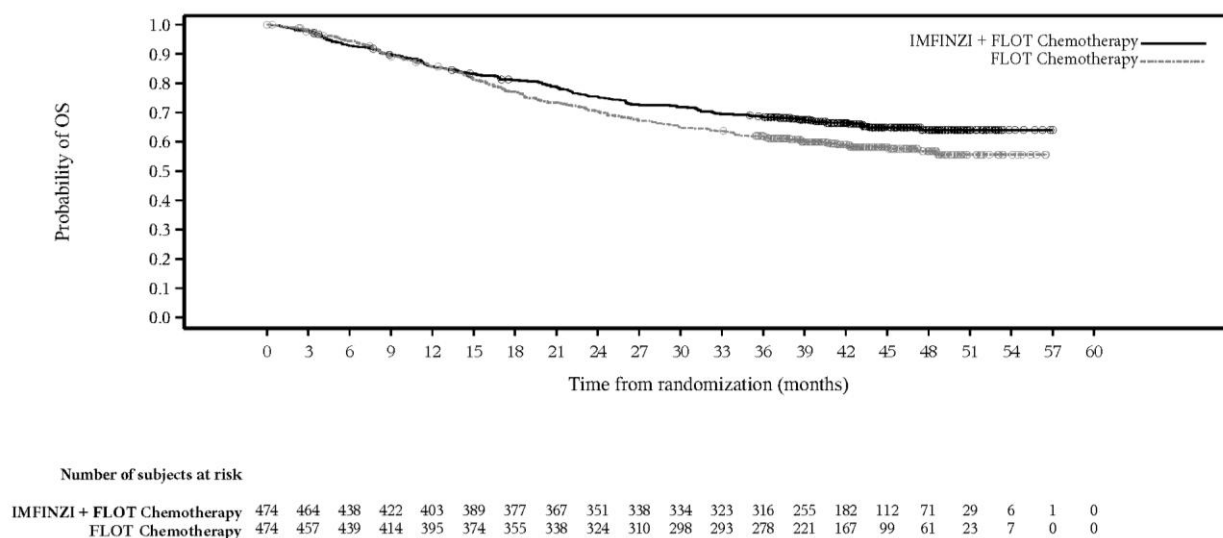


Figure 16. Kaplan-Meier Curve of OS



5.2 Pharmacokinetic properties

The PK of durvalumab was assessed for both IMFINZI as a single agent and in combination with chemotherapy, in combination with tremelimumab and platinum-based chemotherapy in combination with tremelimumab and in combination with platinum-based chemotherapy followed by IMFINZI in combination with olaparib.

The pharmacokinetics of durvalumab was studied in 2903 patients with solid tumours with doses ranging from 0.1 to 20 mg/kg administered once every two, three or four weeks. PK exposure increased more than dose-proportionally (non-linear PK) at doses < 3 mg/kg and dose proportionally (linear PK) at doses ≥ 3 mg/kg. Steady state was achieved at approximately 16 weeks. Based on population PK analysis that included 1878 patients in the dose range of ≥ 10 mg/kg Q2W, Q2W, 15 mg/kg Q3W and 20 mg/kg Q4W, the geometric mean, steady state volume of distribution (V_{ss}) was 5.64 L. Durvalumab clearance (CL) decreased over time resulting in a geometric mean steady state clearance (CL_{ss}) of 8.16 mL/h at Day 365; the decrease in CL_{ss} was not considered clinically relevant. The terminal half-life ($t_{1/2}$), based on baseline CL, was approximately 18 days. There was no clinically meaningful difference between the PK of durvalumab as a single agent and in combination with chemotherapy, in combination with tremelimumab and platinum-based chemotherapy, in combination with tremelimumab and in combination with platinum-based chemotherapy followed by IMFINZI in combination with olaparib. The primary elimination pathways of durvalumab are protein catabolism via reticuloendothelial system or target mediated disposition.

Special populations

Age (19–96 years), body weight (31–149 kg), gender, positive anti-drug antibody (ADA) status, albumin levels, LDH levels, creatinine levels, soluble PD-L1, tumour type, race, mild renal impairment (creatinine clearance (CRCL) 60 to 89 mL/min), moderate renal impairment (creatinine clearance (CRCL) 30 to 59 mL/min), mild hepatic impairment (bilirubin $\leq$ ULN and AST > ULN or bilirubin > 1.0 to 1.5 $\times$ ULN and any AST), moderate hepatic impairment (bilirubin > 1.5 to 3 $\times$ ULN

and any AST) or ECOG/WHO status had no clinically significant effect on the pharmacokinetics of durvalumab.

The effect of severe renal impairment (CRCL 15 to 29 mL/min) or severe hepatic impairment (bilirubin > 3.0 x ULN and any AST) on the pharmacokinetics of durvalumab is unknown.

Elderly

Of the 476 patients with locally advanced, unresectable NSCLC (primary efficacy population) treated with IMFINZI, 215 patients were 65 years or older. No overall clinically meaningful differences in safety were reported between patients $\geq$ 65 years of age and younger patients.

Of the 401 patients with resectable NSCLC treated with IMFINZI in combination with chemotherapy in the AEGEAN study, 209 (52%) patients were 65 years or older and 49 (12%) patients were 75 years or older. There were no overall clinically meaningful differences in safety or effectiveness between patients $\geq$ 65 years of age and younger patients.

Of the 265 patients with ES-SCLC treated with IMFINZI in combination with chemotherapy, 101 (38%) patients were 65 years or older. There were no overall clinically meaningful differences in safety or effectiveness between patients $\geq$ 65 years of age and younger patients.

Of the 262 patients with LS-SCLC treated with IMFINZI, 103 (39.3%) patients were 65 years or older. There were no overall clinically meaningful differences in safety or effectiveness between patients $\geq$ 65 years of age and younger patients.

Of the 338 patients with BTC treated with IMFINZI in combination with chemotherapy, 158 (46.7%) patients were 65 years or older. There were no overall clinically meaningful differences in safety or effectiveness between patients $\geq$ 65 years of age and younger patients.

Of the 462 patients with uHCC treated with STRIDE, 173 (37.4%) patients were 65 years or older and 63 (13.6%) patients were 75 years or older. There were no clinically meaningful differences in safety or efficacy between patients 65 years or older and younger patients.

Of the 530 patients with MIBC treated with IMFINZI in combination with gemcitabine and cisplatin in the NIAGARA study, 272 (51%) patients were 65 years or older, and 57 (11%) patients were 75 years or older. No overall differences in safety or effectiveness of IMFINZI have been observed between patients 65 years of age and older and younger adult patients.

Of the 475 patients with resectable GC/GEJC treated with IMFINZI in combination with FLOT chemotherapy in the MATTERHORN study, 184 (39%) patients were 65 years or older and 37 (8%) patients were 75 years or older. No overall differences in safety or effectiveness were observed between patients $\geq$ 65 years of age and younger adult patients.

Drug interaction studies

PK drug-drug interaction between durvalumab and chemotherapy was assessed in the CASPIAN study and no clinically meaningful PK drug-drug interaction was identified.

Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. Immunogenicity of IMFINZI as monotherapy is based on pooled data in 2280 patients who were treated with IMFINZI 10 mg/kg every 2 weeks or 20 mg/kg every 4 weeks as a single-agent and evaluable for the presence of anti-drug antibodies (ADA). Sixty-nine patients (3.0%) tested positive for treatment emergent ADA. Neutralising

antibodies against durvalumab were detected in 0.5% (12/2280) patients. The presence of ADAs did not have a clinically relevant effect on pharmacokinetics, pharmacodynamics or safety.

In the ADRIATIC study, of the 206 patients who were treated with IMFINZI monotherapy and evaluable for the presence of ADAs, 7 (3.4%) patients tested positive for treatment-emergent ADAs. Neutralising antibodies against durvalumab were detected in 1% (2/206) patients. The presence of ADAs did not have an apparent effect on the pharmacokinetics or safety.

In the AEGEAN study, of the 375 patients who were treated with IMFINZI 1500 mg in combination with chemotherapy every 3 weeks prior to surgery, followed by IMFINZI 1500 mg every 4 weeks following surgery, and were evaluable for the presence of ADAs, 25 (6.7%) patients tested positive for treatment emergent ADAs. Neutralising antibodies against durvalumab were detected in 2 patients (0.5%). The presence of ADAs did not have an apparent effect on the pharmacokinetics or safety of IMFINZI.

In the CASPIAN study, of the 201 patients who were treated with IMFINZI 1500 mg every 3 weeks in combination with chemotherapy and evaluable for the presence of ADAs, 0 (0%) patients tested positive for treatment-emergent ADAs. The impact of treatment-emergent ADA on pharmacokinetics and clinical safety of durvalumab was not evaluable as no patient samples tested positive for treatment-emergent durvalumab ADA.

In the TOPAZ-1 study, of the 240 patients who were treated with IMFINZI 1500 mg every 3 weeks in combination with chemotherapy, followed by IMFINZI 1500 mg every 4 weeks and evaluable for the presence of ADAs, 2 (0.8%) patients tested positive for treatment-emergent ADAs. There were insufficient numbers of patients with treatment emergent ADAs or neutralising antibodies (2 patients each) to determine whether ADAs have an impact on pharmacokinetics and clinical safety of durvalumab.

In the HIMALAYA study, of the 294 patients who were treated with STRIDE and evaluable for the presence of ADAs, 9 (3.1%) patients tested positive for treatment-emergent ADAs. Neutralising antibodies against durvalumab were detected in 1.7% (5/294) patients. The presence of ADAs did not have an apparent effect on pharmacokinetics or safety.

Immunogenicity assay results are highly dependent on several factors, including assay sensitivity and specificity, assay methodology, sample handling, timing of sample collection, concomitant medications and underlying disease.

For these reasons, comparison of incidence of antibodies to IMFINZI with the incidence of antibodies to other products may be misleading.

In clinical trials of patients who received IMFINZI for 10 to 48 weeks at dosages of 1,500 mg every 4 weeks, 10 mg/kg every 2 weeks, 20 mg/kg every 4 weeks as a single agent or 1,120 mg every 3 weeks, or 1,500 mg every 3 weeks in the combination therapies, 3.5% (209/6,000) of evaluable patients tested positive for treatment-emergent anti-durvalumab antibodies, and 9% (18/209) of treatment-emergent ADA positive patients had neutralizing antibodies against durvalumab. There were no identified clinically significant effects of ADAs on durvalumab pharmacokinetics or safety; however, the effect of these ADAs on the effectiveness of IMFINZI is unknown.

5.3

Preclinical safety data

Carcinogenicity and mutagenicity

The carcinogenic and genotoxic potential of durvalumab has not been evaluated.

Reproductive toxicology

As reported in the literature, the PD-1/PD-L1 pathway plays a central role in preserving pregnancy by maintaining maternal immune tolerance to the fetus, and in mouse allogeneic pregnancy models disruption of PD-L1 signalling was shown to result in an increase in fetal loss. In reproduction studies in cynomolgus monkeys, administration of durvalumab from the confirmation of pregnancy through delivery at exposure levels approximately 22 times higher than those observed at the clinical dose of 10 mg/kg of durvalumab (based on AUC) was not associated with maternal toxicity or effects on embryofetal development, pregnancy outcome or postnatal development.

Animal toxicology and/or pharmacology

Repeat dose toxicity studies in sexually mature cynomolgus monkeys with durvalumab of up to 3 months duration were not associated with any adverse effects that were considered of relevance to humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L-histidine

L-histidine hydrochloride monohydrate

α,α -Trehalose dihydrate

Polysorbate 80

Water for Injection

6.2 Incompatibilities

Durvalumab

No incompatibilities between IMFINZI and 9 g/L (0.9%) sodium chloride or 50 g/L (5%) dextrose in polyvinylchloride or polyolefin IV bags have been observed.

This drug product must not be mixed with other drug products except those mentioned in section 6.6.

Do not co-administer other drugs through the same intravenous line.

6.3 Shelf-life

Unopened Vial

3 years at 2° C—8° C.

There are no sources in the current document.

After preparation of infusion solution

IMFINZI does not contain a preservative. Administer infusion solution immediately once prepared. If infusion solution is not administered immediately and it needs to be stored, the total time from vial puncture to the start of administration should not exceed:

- 28 days at 2°C to 8°C (36°F to 46°F).
- 12 hours at room temperature.

6.4 Special precautions for storage

Unopened vial

Store vials under refrigeration at 2°C to 8°C (36°F to 46°F) in original carton to protect from light.

Do not freeze.

Do not shake.

Diluted Solution

For storage conditions after preparation of the infusion, see section 6.3.

6.5 Nature and contents of container

Two pack sizes of IMFINZI are available:

10 mL (a total of 500 mg durvalumab) concentrate in a Type 1 glass vial with an elastomeric stopper and a white flip-off aluminium seal . Pack size of 1 vial.

2.4 mL (a total of 120 mg durvalumab) concentrate in a Type 1 glass vial with an elastomeric stopper and a gray flip-off aluminium seal . Pack size of 1 vial.

Not all pack sizes may be marketed.

6.6 Instructions for use, handling and disposal

Preparation of solution

IMFINZI is supplied as a single-dose vial and does not contain any preservatives, aseptic technique must be observed.

- Visually inspect drug product for particulate matter and discolouration. IMFINZI is clear to opalescent, colourless to slightly yellow solution. Discard the vial if the solution is cloudy, discoloured or visible particles are observed. Do not shake the vial.
- Withdraw the required volume from the vial(s) of IMFINZI and transfer into an intravenous (IV) bag containing 0.9% Sodium Chloride Injection, or 5% Dextrose Injection. Mix diluted solution by gentle inversion. The final concentration of the diluted solution should be between 1 mg/mL and 15 mg/mL. Do not freeze or shake the solution.
- Care must be taken to ensure the sterility of prepared solutions.
- Do not re-enter the vial after withdrawal of drug; only administer one dose per vial.
- Discard any unused portion left in the vial.

Administration

- Administer infusion solution intravenously over 1 hour through an intravenous line containing a sterile, low-protein binding 0.2 or 0.22 micron in-line filter.
- Do not co-administer other drugs through the same infusion line.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Import and market permission No: BIO/IMP/18/000001 dated 01-Jun-2018
Additional Indication File No: BIO/IMP/19/000056 dated 13-Jul-2020
Additional Indication File No: BIO/IMP/22/000071 dated 13-Feb-2023
Additional Indication File No: BIO/IMP/24/000004 dated 23-Sep-2024
Additional Indication File No: BIO/IMP/23/000104 dated 28-Feb-2025
Additional Indication File No: BIO/IMP/24/000091 dated 07-Mar-2025
Additional Indication File No: BIO/IMP/25/000021 dated 01-Jul-2025
Additional Indication File No: BIO/IMP/24/000132 dated 14-Jul-2025
Additional Indication File No: BIO/IMP/25/000128 dated 30-Jan-2026
Additional Indication File No: BIO/IMP/25/000132 dated 09-Feb-2026

IMFINZI is a registered trademark of the AstraZeneca group of companies.

Manufactured By:

AstraZeneca AB, Gartnavagen, SE-152 57, Sodertalje, Sweden

Imported & Marketed By:

AstraZeneca Pharma India Limited,
Global Complex, Shed D1, Part-A, Unit 6-17,
Village at Chinchavali Tarfe Sonale,
Grampanchayat Chinchavali Khandpe,
Maharashtra, Bhiwandi, Thane- 421302 (India)

PI dated 04-Sep-2025 (updated on 09-Feb-2026)

Reference: CDS v.33 dated 08-Jun-2024, EMA SmPC v.35 & USPI v.28.0 dated Nov-2025.

Patient Information Leaflet

Rx

Durvalumab Solution for Infusion

IMFINZI[®], 500 mg (500mg/10mL) for intravenous infusion

IMFINZI[®], 120 mg (120mg/2.4mL) for intravenous infusion

Read this entire leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor, pharmacist or nurse.

This medicine has been prescribed for you only.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet

1. WHAT IMFINZI IS AND WHAT IT IS USED FOR
2. BEFORE YOU RECEIVE IMFINZI
3. HOW IMFINZI WILL BE GIVEN
4. POSSIBLE SIDE EFFECTS
5. STORING IMFINZI
6. FURTHER INFORMATION

1. What IMFINZI is and what it is used for

What IMFINZI is

IMFINZI is a medicine used to treat cancer. It contains the active substance durvalumab which belongs to the monoclonal antibody class of anticancer medicines. IMFINZI works by helping your immune system fight your cancer.

What IMFINZI is used for

IMFINZI is used to treat a type of lung cancer called non-small cell lung cancer (NSCLC). It may be used in combination with chemotherapy prior to surgery (neoadjuvant treatment) and alone after surgery (adjuvant treatment) when your NSCLC:

- has spread within your lung and is able to be removed by surgery.

IMFINZI is used to treat a type of lung cancer called non-small cell lung cancer (NSCLC). It is used alone when your NSCLC:

- has spread within your lung and cannot be removed by surgery, and
- has responded or stabilised after initial treatment with chemotherapy and radiotherapy.

IMFINZI in combination with chemotherapy is used to treat a type of lung cancer called extensive-stage small cell lung cancer (ES-SCLC). It is used when your SCLC:

- has spread within your lungs (or to other parts of the body) and
- has not previously been treated.

IMFINZI is used to treat a type of cancer called biliary tract cancer (BTC), such as cancer of the bile ducts (cholangiocarcinoma) and gallbladder. It is used when your BTC:

- has spread within these regions (or to other parts of the body).

When IMFINZI is given in combination with other medicines, it is important that you also read the package leaflet for the specific anti-cancer medicines you may be receiving. If you have any questions about these medicines, ask your doctor.

IMFINZI in combination with tremelimumab is used to treat a type of liver cancer, called unresectable hepatocellular carcinoma (uHCC). It is used when your uHCC:

- cannot be removed by surgery (unresectable) and
- may have spread within your liver or to other parts of the body.

When IMFINZI is given in combination, it is important that you also read the package leaflet for the specific anti-cancer medicines you may be receiving. If you have any questions about these medicines, ask your doctor.

IMFINZI is used to treat a type of lung cancer called limited-stage small cell lung cancer (LS-SCLC). It is used when your LS-SCLC:

- has not been removed by surgery, and
- has responded or stabilised after initial treatment with chemotherapy and radiotherapy.

IMFINZI is a prescription medicine used to treat adults with:

a type of bladder cancer called muscle invasive bladder cancer (MIBC) that has spread into the muscle layer of the bladder but not to other parts of the body. IMFINZI may be used in combination with gemcitabine and cisplatin (neoadjuvant treatment) prior to the surgical removal of your bladder followed by IMFINZI alone after surgery (adjuvant treatment).

Durvalumab is used to treat a type of stomach cancer called gastric cancer (GC) or gastro-oesophageal junction adenocarcinoma (GEJC) that can be removed by surgery. It is used in combination with chemotherapy prior to and after surgery, followed by Durvalumab alone.

Durvalumab is used to treat a type of uterine cancer (endometrial cancer) that has spread beyond the original tumour or come back (recurred) in adults. It is used in combination with chemotherapy (carboplatin and paclitaxel), followed by:

- Durvalumab alone when your tumour is MMR-deficient, or
- Durvalumab in combination with olaparib when your tumour is MMR-proficient.

A test is used to find out the MMR status of your endometrial cancer.

How IMFINZI works

IMFINZI is a monoclonal antibody, which is a type of protein designed to recognise and attach to a specific target substance in the body. IMFINZI is a medicine that may treat your NSCLC, SCLC, uHCC or BTC by working with your immune system. IMFINZI can cause your immune system to attack normal organs and tissues in many areas of your body and can affect the way they work.

IMFINZI will only be prescribed to you by a doctor with experience in the use of medicines for cancer.

If you have any questions about how IMFINZI works or why this medicine has been prescribed for you, ask your doctor.

2. BEFORE YOU RECEIVE IMFINZI

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking IMFINZI.

Before you get IMFINZI tell your doctor if you:

- have immune system problems such as Crohn's disease, ulcerative colitis or lupus.
- have had an organ transplant.
- have lung or breathing problems.
- have liver problems.
- are pregnant or plan to become pregnant. IMFINZI can harm your unborn baby. If you are able to become pregnant, you should use an effective method of birth control during your treatment and for at least 3 months after the last dose of IMFINZI.
- are breastfeeding or plan to breastfeed. It is not known if IMFINZI passes into your breast milk. Do not breastfeed during treatment and for at least 3 months after the last dose of IMFINZI.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before receiving IMFINZI.

When you receive IMFINZI, you can have some serious side effects.

If you have any of the following, call or see your doctor right away. Your doctor may give you other medicines in order to prevent more severe complications and reduce your symptoms. Your doctor may withhold the next dose of IMFINZI or stop your treatment with IMFINZI.

- inflammation of the lungs: Signs and symptoms may include new or worsening cough, shortness of breath or chest pain.
- inflammation of the liver: Signs and symptoms may include nausea or vomiting, feeling less hungry, pain on the right side of stomach, yellowing of skin or whites of eyes, drowsiness, dark urine or bleeding or bruising more easily than normal.
- inflammation of the intestines: Signs and symptoms may include diarrhoea or more bowel movements than usual, black, tarry, sticky stools or stools with blood or mucous, severe stomach pain, tenderness or may lead to a hole in intestinal wall.

- inflammation of hormone glands (especially the thyroid, adrenals, pituitary and pancreas): Signs and symptoms may include headaches that will not go away or unusual headaches, extreme tiredness, weight gain or weight loss, dizziness or fainting, feeling more hungry or thirsty than usual, hair loss, feeling cold, constipation, changes to your voice, urinating more often than usual, nausea or vomiting, stomach area (abdomen) pain, changes in mood or behaviour, such as decreased sex drive, irritability or forgetfulness, fast and deep breathing, confusion, a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine or sweat.
- inflammation of the kidneys: Signs and symptoms may include changes in the amount or colour of your urine, swelling in your ankles or loss of appetite.
- inflammation of the skin or mouth: Signs and symptoms may include rash, itching, skin blistering or ulcers in mouth or other mucous membranes.
- inflammation of the heart: Signs and symptoms may include chest pain, shortness of breath or irregular heartbeat.
- inflammation or problems of the muscles: Signs and symptoms may include muscle weakness, tiredness and/or pain, and/or rapid fatigue of the muscles, in one or more areas of your body.
- inflammation of the brain: Signs and symptoms may include seizure, headache, fever, chills, comitting, confusion and sleepiness.
- low number of platelets: Signs and symptoms may include bleeding (e.g. nose or gum bleeding) and/or bruising.
- inflammation of the nerves: Signs and symptoms may include pain, weakness and paralysis in the hands, feet or arms.
- inflammation of the joints: Signs and symptoms include joint pain, swelling, and/or stiffness.
- inflammation of the eye: Signs and symptoms include eye redness, eye pain, light sensitivity, and/or changes in vision.
- infusion-related reactions: Signs and symptoms may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, fever, feeling like passing out, back or neck pain or facial swelling.
- **low number of red blood cell counts on testing:** symptoms may include shortness of breath, fatigue, pale skin and/or fast heartbeat. When IMFINZI is used in combination with another anti-cancer medicine (olaparib), low red blood cell counts could be a sign of ‘pure red cell aplasia’ (PRCA), a condition in which no red blood cells are produced, or ‘auto-immune haemolytic anaemia’ (AIHA), an excessive breakdown of red blood cells.

Children and adolescents

IMFINZI has not been studied in children or adolescents. Do not give this medicine to children or adolescents aged less than 18 years.

Other medicines and IMFINZI

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines and medicines obtained without a prescription.

Pregnancy

- If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor.
- If you are a woman who could become pregnant, you must use adequate birth control while you are being treated with IMFINZI and for at least 3 months after your last dose.

Breast-feeding

If you are breast-feeding, tell your doctor.

Do not breast-feed while taking IMFINZI and for at least 3 months after last dose.

It is not known if IMFINZI passes into your breast milk.

Driving and using machines

IMFINZI is unlikely to affect the ability to drive and use machines.

However, if you experience adverse reactions affecting your ability to concentrate and react, you should use caution when driving or operating machinery.

3. HOW IMFINZI WILL BE GIVEN

IMFINZI will be given to you in a hospital or clinic under the supervision of an experienced doctor.

The recommended dose of IMFINZI is 10 mg per of your body weight every 2 weeks 1 120 mg every 3 weeks or 1,500 mg every 3 or 4 weeks. Your doctor will give you IMFINZI through an infusion (drip) into your vein (IV) for about 1 hour. Depending on your type of cancer, IMFINZI may be given in combination with other anti-cancer medicines. Your doctor will decide how many treatments you need.

When IMFINZI is given in combination with chemotherapy for your lung cancer, you will first be given IMFINZI followed by chemotherapy.

When IMFINZI is given in combination with tremelimumab for your liver cancer, you will first be given tremelimumab followed by IMFINZI.

Please refer to the package leaflet of the other anti-cancer medicines in order to understand the use of these other medicines. If you have questions about these medicines, ask your doctor.

If you miss an appointment to get IMFINZI

Call your doctor right away to reschedule your appointment.

It is very important that you do not miss a dose of this medicine.

If you have any further questions about your treatment, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

When you get IMFINZI, you can have some serious side effects. See section 2.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

The following side effects have been reported in clinical trials with patients receiving IMFINZI alone:

Most frequent serious side effects

- inflammation of the lungs (pneumonitis)
- stomach pain
- fever
- lung infection (pneumonia)

Most common side effects

- cough
- diarrhoea
- stomach pain
- skin rash or itchiness
- fever
- swelling of the legs (oedema peripheral)
- upper respiratory tract infection
- underactive thyroid gland that can cause tiredness or weight gain

Tell your doctor straight away if you notice the side effects listed above.

The most common side effects of IMFINZI when used with gemcitabine and cisplatin in adults with MIBC include:

- | | |
|--|--|
| • low red blood cells (anemia) | • decreased lymphocyte counts |
| • low white blood cells | • constipation |
| • increased level of creatinine in the blood | • decreased level of magnesium in the blood |
| • decreased level of sodium in the blood | • decreased appetite |
| • nausea | • increased level of alkaline phosphatase in the blood |
| • increased liver function tests | • rash |
| • decreased level of calcium in the blood | • fever |
| • decreased blood platelet counts | • diarrhea |
| • feeling tired | • vomiting |
| • increased level of potassium in the blood | • stomach (abdominal) pain |

The most common side effects of Durvalumab when used with FLOT in adults with GC or GEJC include:

- | | |
|--|-------------------------------|
| • diarrhea | • decreased appetite |
| • nausea | • rash |
| • inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs | • stomach (abdominal) pain |
| • feeling tired | • vomiting |
| • hair loss | • muscle and joint pain |
| | • fever |
| | • pain and sores in the mouth |

5. HOW TO STORE IMFINZI

- Do not use this medicine after the expiry date (EXP) which is stated on the carton and vial label. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C to 8°C).
- Do not freeze. Do not shake.
- Store in the original package in order to protect from light.
- Any unused medicine or waste material should be disposed of in accordance with local requirements.

6. FURTHER INFORMATION

What IMFINZI contains?

- The active ingredient is durvalumab.
- The other ingredients are: L-histidine, L-histidine hydrochloride monohydrate, α,α -trehalose dihydrate, polysorbate 80, water for injection.

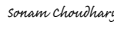
What IMFINZI looks like and contents of the pack

- IMFINZI injection (US) or concentrate for solution for infusion (EU)
- Sterile, preservative-free, clear to opalescent, colourless to slightly yellow solution, free from visible particles.

It is available in packs containing either 1 vial of 2.4 mL or 1 vial of 10 mL.

Case Report Form

Document Title:	Document ID:	AD03-01
Signature Page	Version Number:	8.0
	Effective Date:	29-Apr-2024

CASE REPORT FORM				
Protocol Number:	D9106R00007			
Sponsor Name:	AstraZeneca Pharma India Ltd.			
Version Number and Date:	Version 2.0, dated: 13-Feb-2026	Supersedes, if any:	Version 1.0, dated: 02-Feb-2026	
Function Name:	Clinical Data Management			
Signatories:	Name	Role in the Study/ Designation	Organization Name	Dated Signature
Prepared By (Author):	Akhila Kardas	CRF Designer	Tech Observer	Electronically signed by: Akhila Kardas Reason: By electronically signing this document using Adobe e-Sign, I am agreeing that I have authored the document(s). Date: Feb 13, 2026 18:03:28 GMT+5.5 
Reviewed By:	Dr. Prathap Reddy P	Project Manager	Tech Observer	Electronically signed by: Prathap Reddy Reason: By electronically signing this document using Adobe e-Sign, I'm agreeing that I have completed review of this document(s). Date: Feb 13, 2026 18:47:35 GMT+5.5 
Reviewed & Approved By:	Sonam Choudhary	Project Manager	AstraZeneca Pharma India Ltd.	Electronically signed by: Sonam Choudhary Reason: By electronically signing this document using Adobe e-Sign, I'm agreeing to provide my approval on document(s). Date: Feb 13, 2026 20:34:04 GMT+5.5 

CASE REPORT FORM

A prospective, observational, multicenter, post marketing surveillance study to assess safety of Durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC)

Protocol Number : D9106R00007

Protocol Version : 1.0

Protocol Date : 22-Dec-2024

Site Number :

Patient Number :

Sponsor:

AstraZeneca



Contract Research Organization:

Tech Observer



Confidentiality Information: This Clinical Study Protocol has been subject to a peer review according to AstraZeneca Standard procedures. The Clinical Study Protocol is publicly registered and the results are disclosed and/or published according to the AstraZeneca Global Policy on Bioethics and in compliance with prevailing laws and regulations.

Protocol Number: D9106R00007

Site No.

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Patient No.

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Visit Schedule

Baseline/ Screening visit:	V1 = Visit 1
Neoadjuvant therapy period:	C1 = Cycle 1 C2 = Cycle 2 C3 = Cycle 3 C4 = Cycle 4
Pre-Surgery	
Surgery	
Post Surgery	
Adjuvant therapy period:	C5 = Cycle 5 C6 = Cycle 6 C7 = Cycle 7 C8 = Cycle 8 C9 = Cycle 9 C10 = Cycle 10 C11 = Cycle 11 C12 = Cycle 12 C13 = Cycle 13 C14 = Cycle 14 C15 = Cycle 15 C16 = Cycle 16
Follow-up period:	EOS = End of Study
Unscheduled visit	

Protocol Number: D9106R00007

Site No.

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Patient No.

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DATE OF VISIT

(Applicable for visit days: V1, C1, C2, C3, C4, Pre-Surgery, Surgery, Post- Surgery, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16 and EOS)

Date of Visit:

D	D	-	M	M	M	-	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---	---

INFORMED CONSENT

(Applicable for visit days: V1)

Informed consent taken?

☐ Yes
☐ No

Is the subject vulnerable?

☐ Yes
☐ No

If vulnerable, was Audio-visual consent taken?

☐ Yes
☐ No

Date of Informed Consent Obtained:

D	D	-	M	M	M	-	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---	---

Time of Informed Consent Obtained:

H	H	:	M	M
---	---	---	---	---

INCLUSION CRITERIA

(Applicable for visit days: V1, Pre-surgery)

S.No	Criteria	Yes	*No
1.	Patients with newly diagnosed previously untreated resectable NSCLC (tumors $\geq$ 4 cm and/or node positive) and no known EGFR mutations or ALK rearrangements prescribed with durvalumab as per local prescriber information.	☐	☐
2.	Provision of signed, written and dated informed consent	☐	☐
3.	Male or female patients aged 18 years or older	☐	☐

***If No, patient is ineligible**

Protocol Number: D9106R00007

Site No.

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Patient No.

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EXCLUSION CRITERIA

(Applicable for visit days: V1, Pre-surgery)

S.No	Criteria	*Yes	No
1.	Presence of unresectable or metastatic disease	☐	☐
2.	Prior treatment with durvalumab for any other indications	☐	☐
3.	Requires concurrent treatment for cancers other than resectable NSCLC	☐	☐
4.	Concurrently participating in any other clinical trial	☐	☐
5.	Patients with active or prior autoimmune disease or with medical conditions that required systemic corticosteroids or immunosuppressants	☐	☐
6.	Any condition that, in the opinion of the investigator, would interfere with the patient's participation in the study	☐	☐

***If Yes, patient is ineligible**

DEMOGRAPHICS

(Applicable for visit days: V1, Post- surgery)

Date of Birth:	<table border="1"><tr><td>D</td><td>D</td><td>-</td><td>M</td><td>M</td><td>M</td><td>-</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	-	M	M	M	-	Y	Y	Y	Y
D	D	-	M	M	M	-	Y	Y	Y	Y		
Age (in years): (Autocalculated)	<table border="1"><tr><td>X</td><td>X</td></tr></table> Completed years	X	X									
X	X											
Gender:	☐ Male ☐ Female											
Race:	☐ Indian ☐ Other, specify _____											
Height (cm)	<table border="1"><tr><td>X</td><td>X</td><td>X</td></tr></table>	X	X	X								
X	X	X										
Weight (kg)	<table border="1"><tr><td>X</td><td>X</td><td>X</td></tr></table>	X	X	X								
X	X	X										

Protocol Number: D9106R00007

Site No.

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Patient No.

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BMI (derived):

X	X	.	X	X
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kg/m2

MEDICAL/SURGICAL HISTORY

(Applicable for visit days: V1, Post- surgery)

Does the Subject have any significant medical/surgical history?

☐ Yes, complete the following

☐ No

(Radiation Treatment Details will be recorded on Radiation Treatment page under Visit 1.)

Seq. No.	Medical/ Surgical History	Type of Condition	Start Date	Treatment Required*	Ongoing*																						
			End Date																								
	-----	☐ Medical ☐ Surgery/ Procedure	<table border="1"> <tr> <td>D</td><td>D</td><td>-</td> <td>M</td><td>M</td><td>M</td><td>-</td> <td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> <tr> <td>D</td><td>D</td><td>-</td> <td>M</td><td>M</td><td>M</td><td>-</td> <td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>	D	D	-	M	M	M	-	Y	Y	Y	Y	D	D	-	M	M	M	-	Y	Y	Y	Y	☐	☐
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	-----	☐ Medical ☐ Surgery/ Procedure	<table border="1"> <tr> <td>D</td><td>D</td><td>-</td> <td>M</td><td>M</td><td>M</td><td>-</td> <td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> <tr> <td>D</td><td>D</td><td>-</td> <td>M</td><td>M</td><td>M</td><td>-</td> <td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>	D	D	-	M	M	M	-	Y	Y	Y	Y	D	D	-	M	M	M	-	Y	Y	Y	Y	☐	☐
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D	D	-	M	M	M	-	Y	Y	Y	Y																	
	-----	☐ Medical ☐ Surgery/ Procedure	<table border="1"> <tr> <td>D</td><td>D</td><td>-</td> <td>M</td><td>M</td><td>M</td><td>-</td> <td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> <tr> <td>D</td><td>D</td><td>-</td> <td>M</td><td>M</td><td>M</td><td>-</td> <td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>	D	D	-	M	M	M	-	Y	Y	Y	Y	D	D	-	M	M	M	-	Y	Y	Y	Y	☐	☐
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	-----	☐ Medical ☐ Surgery/ Procedure	<table border="1"> <tr> <td>D</td><td>D</td><td>-</td> <td>M</td><td>M</td><td>M</td><td>-</td> <td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> <tr> <td>D</td><td>D</td><td>-</td> <td>M</td><td>M</td><td>M</td><td>-</td> <td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>	D	D	-	M	M	M	-	Y	Y	Y	Y	D	D	-	M	M	M	-	Y	Y	Y	Y	☐	☐
D	D	-	M	M	M	-	Y	Y	Y	Y																	
D	D	-	M	M	M	-	Y	Y	Y	Y																	

* Treatment Required and Ongoing: 1= Yes, 2= No

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	Site No.	Patient No.

EGFR/ ALK STATUS	
(Applicable for visit days: V1 and EOS)	
Was EGFR mutation status checked?	☐ Yes, specify the result: ☐ Positive ☐ Negative ☐ No, specify reason _____
Was ALK status checked?	☐ Yes, specify the result: ☐ Positive ☐ Negative ☐ No, specify reason _____

PHYSICAL EXAMINATION						
(Applicable for visit days: V1,C1, C2, C3, C4, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS and Unscheduled Visit)						
Assessment done?			☐ Yes, fill the details below ☐ No, specify reason _____			
Date of Assessment:			D D - M M M - Y Y Y Y			
Time of Assessment:			H H : M M (24 hours format)			
Seq. No.	System	Not Done	Normal	Abnormal (check one)*		If Abnormal CS, please describe the abnormality
1	General Appearance	☐	☐	☐ CS	☐ NCS	_____
2	Respiratory	☐	☐	☐ CS	☐ NCS	_____
3	Cardiovascular System	☐	☐	☐ CS	☐ NCS	_____

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4	Abdomen	☐	☐	☐ CS	☐ NCS	_____
5	Skin	☐	☐	☐ CS	☐ NCS	_____
6	@HEENT	☐	☐	☐ CS	☐ NCS	_____
7	Neck	☐	☐	☐ CS	☐ NCS	_____
8	Lymph nodes	☐	☐	☐ CS	☐ NCS	_____
9	Thyroid	☐	☐	☐ CS	☐ NCS	_____
10	Musculoskeletal	☐	☐	☐ CS	☐ NCS	_____
11	Genital/ Rectal	☐	☐	☐ CS	☐ NCS	_____
12	Neurological System	☐	☐	☐ CS	☐ NCS	_____
13	Other, specify_____		☐	☐ CS	☐ NCS	_____

@HEENT = Head, Eyes, Ears, Nose, Throat.

*CS = Clinically Significant, NCS = Not Clinically Significant

Please record abnormal clinically significant finding(s) in Adverse Event form.

VITAL SIGNS

(Applicable for visit days: V1,C1, C2, C3, C4, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS and Unscheduled Visit)

Assessment done?			☐ Yes, fill the details below ☐ No, specify reason_____		
Date of Assessment:			D D - M M M - Y Y Y Y		
Time of Assessment:			H H : M M (24 hours format)		
Parameters	Results	Normal	Abnormal (check one)*		If Abnormal CS, please describe
Systolic blood pressure (Sitting)	mmHg	☐	☐ CS	☐ NCS	_____
Diastolic blood pressure (Sitting)	mmHg	☐	☐ CS	☐ NCS	_____

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Pulse rate	beats/min		CS	NCS	_____
Respiratory rate	breaths/min		CS	NCS	_____
Temperature	. °F		CS	NCS	_____
Oxygen Saturation	percentage		CS	NCS	_____
Weight	kg				

*CS = Clinically Significant, NCS = Not Clinically Significant

Please record abnormal clinically significant finding(s) in Adverse Event form.

ECOG PERFORMANCE STATUS

(Applicable for visit days: V1, Post-Surgery and Unscheduled Visit)

Was ECOG performance status performed?

☐ Yes, fill the below details

☐ No, specify reason _____

Date of assessment:

D	D	-	M	M	M	-	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---	---

Performance Status:

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Performance Status:

0= active, able to carry on all pre-disease performance without restriction

1= Restricted in physically strenuous activity but ambulatory and able to carry outwork of a light or sedentary nature (eg light housework, office work)

2= Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours

3=Capable of only limited self-care, confined to bed or chair more than 50% of waking hours

4=Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair

5=Dead

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	Site No. 	Patient No.

RADIOLOGICAL TUMOR ASSESSMENT (Applicable for visit days: V1,C1, C2,C3,C4, Pre-surgery, Post- surgery, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS)	
Was Radiological Tumor Assessment performed?	☐ Yes ☐ No, specify reason_____
Was RECIST 1.1 criteria used for Radiological Tumor Assesment?	☐ Yes* ☐ No
If No, provide the details of Radiological Tumor assessment performed:	_____
<i>*If Yes, kindly complete ‘Baseline Radiological Tumor Assessment- Primary Tumor Assesment (Recist 1.1)’ and ‘Radiological Tumor Assessment- Primary Tumor Assesment (Recist 1.1)’ form.</i>	

Protocol Number: D9106R00007

Site No.

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Patient No.

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BASELINE RADIOLOGICAL TUMOR ASSESSMENT- Primary Tumor Assesment (RECIST 1.1)

(Applicable for visit days: V1)

Does the Subject have at least one measurable Target lesion at baseline visit?

☐ Yes, fill the below details

☐ No, specify reason _____

Seq number	Lesion location	Was imaging performed?*	Imaging Date	Method of Assessment*	Other Assessment	Primary Tumor Assessment Result*	Long/ Short axis Diameter	Not Evaluable*											
	_____	☐	<table border="1"><tr><td>D</td><td>D</td><td>-</td><td>M</td><td>M</td><td>M</td><td>-</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	-	M	M	M	-	Y	Y	Y	Y	☐	_____	☐	_____	☐
D	D	-	M	M	M	-	Y	Y	Y	Y									
	_____	☐	<table border="1"><tr><td>D</td><td>D</td><td>-</td><td>M</td><td>M</td><td>M</td><td>-</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	-	M	M	M	-	Y	Y	Y	Y	☐	_____	☐	_____	☐
D	D	-	M	M	M	-	Y	Y	Y	Y									
		* Imaging performed 1=Yes 2=No		*Method of assessment = 1. CT scan 2. PET scan 3. Other		*Primary Tumor Assessment Result = 1. Present 2. Not Evaluable		*Not Evaluable= 1. Not Assessed 2. Obscured, cannot be evaluated 3. Coalesced											

Protocol Number: D9106R00007

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Patient No.

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RADIOLOGICAL TUMOR ASSESSMENT- Primary Tumor Assessment (RECIST 1.1)

(Applicable for visit days: Pre-surgery, Post- surgery, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS)

Does the Subject have at least one measurable Target lesion?

☐ Yes, fill the below details

☐ No, specify reason_____

Seq number	Lesion location	Was imaging performed?*	Imaging Date	Method of Assessment*	Other Assessment	Primary Tumor Assessment Result*	Long/ Short axis Diameter	Not Evaluable*											
	_____	☐	<table border="1"><tr><td>D</td><td>D</td><td>-</td><td>M</td><td>M</td><td>M</td><td>-</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	-	M	M	M	-	Y	Y	Y	Y	☐	_____	☐	_____	☐
D	D	-	M	M	M	-	Y	Y	Y	Y									
	_____	☐	<table border="1"><tr><td>D</td><td>D</td><td>-</td><td>M</td><td>M</td><td>M</td><td>-</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	-	M	M	M	-	Y	Y	Y	Y	☐	_____	☐	_____	☐
D	D	-	M	M	M	-	Y	Y	Y	Y									
		* Imaging performed 1=Yes 2=No		*Method of assessment = 1.CT scan 2. PET scan 3.Other		*Primary Tumor Assessment Result = 1. Present 2. Not Evaluable		*Not Evaluable= 1. Not Assessed 2. Obscured, cannot be evaluated 3. Coalesced											

Protocol Number: D9106R00007		
	Site No. 	Patient No.

LABORATORY TESTS ASSESSMENT	
(Applicable for visit days: V1,C1, C2, C3, C4, Pre-Surgery, Post-Surgery, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS and Unscheduled Visit)	
Were any laboratory test performed?	☐ Yes, fill the below details ☐ No, specify reason_____
Lab Tests performed at the visit:	☐ 12-lead Electrocardiogram (ECG) ☐ Biochemistry ☐ Hematology ☐ Urinalysis ☐ Serology

Protocol Number: D9106R00007

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12-LEAD ELECTROCARDIOGRAM (ECG)

(Applicable for visit days: V1, C1, C2, C3, C4, Pre-Surgery, Post-Surgery, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS and Unscheduled Visit)

Was ECG performed?

☐ Yes, fill the below details

☐ No, specify reason _____

Date of ECG Assessment:

D	D	-	M	M	M	-	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---	---

Time of ECG Assessment:

H	H	:	M	M
---	---	---	---	---

 (24 hours format)

Parameters	Result	Unit	Interpretation*	If Abnormal (check one) [#]	If Abnormal CS, please describe the abnormality
Heart rate	_____	beats/ min	☐	☐ CS ☐ NCS	_____
QRS	_____	Ms	☐	☐ CS ☐ NCS	_____
PR	_____	Ms	☐	☐ CS ☐ NCS	_____
RR	_____	Ms	☐	☐ CS ☐ NCS	_____
QT	_____	Ms	☐	☐ CS ☐ NCS	_____
QTcF	_____	Ms	☐	☐ CS ☐ NCS	_____

*Interpretation: 1= Normal; 2= Abnormal

[#]CS = Clinically Significant

NCS = Not Clinically Significant

Please record Clinically Significant abnormal finding(s) in the Adverse Event Log.

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Patient No.

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BIOCHEMISTRY

(Applicable for visit days: V1,C1, C2, C3, C4, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS and Unscheduled Visit)

Was the sample collected?

☐ Yes, fill the below details

☐ No, specify reason_____

Date of Sample collection:

D	D	-	M	M	M	-	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---	---

Time of Sample collection

H	H	:	M	M
---	---	---	---	---

(24 hours format)

Lab Parameters	Result	Unit	Interpretation*	If Abnormal (check one)#	If Abnormal CS, please describe the abnormality
Albumin	_____	g/dL	☐	☐ CS ☐ NCS	_____
Glucose	_____	mg/dL	☐	☐ CS ☐ NCS	_____
Alkaline phosphatase	_____	U/L	☐	☐ CS ☐ NCS	_____
Lactate dehydrogenase	_____	U/L	☐	☐ CS ☐ NCS	_____
Alanine amino-transferase	_____	U/L	☐	☐ CS ☐ NCS	_____
Lipase	_____	U/L	☐	☐ CS ☐ NCS	_____
Aspartate Aminotransferase (AST)	_____	U/L	☐	☐ CS ☐ NCS	_____
Magnesium	_____	mg/dL	☐	☐ CS ☐ NCS	_____
Amylase	_____	U/L	☐	☐ CS ☐ NCS	_____
Potassium	_____	mmol/L	☐	☐ CS ☐ NCS	_____
Bicarbonate	_____	mEq/L	☐	☐ CS ☐ NCS	_____
Sodium	_____	mEq/L	☐	☐ CS ☐ NCS	_____
Calcium	_____	mg/dL	☐	☐ CS ☐ NCS	_____
Total Bilirubin	_____	mg/dL	☐	☐ CS ☐ NCS	_____

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Chloride	_____	mEq/L	☐	☐ CS ☐ NCS	_____
Total Protein	_____	g/dL	☐	☐ CS ☐ NCS	_____
Creatinine Clearance	_____	mg/dL	☐	☐ CS ☐ NCS	_____
Urea	_____	mg/dL	☐	☐ CS ☐ NCS	_____
Blood Urea Nitrogen	_____	mg/dL	☐	☐ CS ☐ NCS	_____
Gamma glutamyltransfe rase	_____	IU/L	☐	☐ CS ☐ NCS	_____
Uric acid	_____	mg/dL	☐	☐ CS ☐ NCS	_____
APTT	_____	sec	☐	☐ CS ☐ NCS	_____
INR	_____		☐	☐ CS ☐ NCS	_____

*Interpretation: 1= Normal; 2= Abnormal

#CS = Clinically Significant

NCS = Not Clinically Significant

Please record Clinically Significant abnormal finding(s) in the Adverse Event Log.

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HEMATOLOGY					
(Applicable for visit days: V1,C1, C2, C3, C4, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS and Unscheduled Visit)					
Was sample collected?			☐ Yes, fill the below details ☐ No, specify reason_____		
Date of Sample collection:			D D - M M M - Y Y Y Y		
Time of Sample collection			H H : M M (24 hours format)		
Lab Parameters	Result	Unit	Interpretation*	If Abnormal (check one)#	If Abnormal CS, please describe the abnormality
Hematocrit	_____	%	☐	☐ CS ☐ NCS	_____
Red blood cell count	_____	/uL	☐	☐ CS ☐ NCS	_____
Hemoglobin	_____	g/dL	☐	☐ CS ☐ NCS	_____
Basophils	_____	/mm3	☐	☐ CS ☐ NCS	_____
Eosinophils	_____	/mm3	☐	☐ CS ☐ NCS	_____
Monocytes	_____	/mm3	☐	☐ CS ☐ NCS	_____
Absolute Neutrophil Count	_____	/mm3	☐	☐ CS ☐ NCS	_____
Platelet Count	_____	x10^3/uL	☐	☐ CS ☐ NCS	_____
Total Lymphocyte Count	_____	/mm3	☐	☐ CS ☐ NCS	_____
Differential Lymphocyte Count	_____	/mm3	☐	☐ CS ☐ NCS	_____
*Interpretation: 1= Normal; 2= Abnormal #CS = Clinically Significant NCS = Not Clinically Significant Please record Clinically Significant abnormal finding(s) in the Adverse Event Log.					

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Patient No.

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URINALYSIS

(Applicable for visit days: V1,C1, C2, C3, C4, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS and
Unscheduled Visit)

Was sample collected?

☐ Yes, fill the below details

☐ No, specify reason _____

Date of Sample collection:

D	D	-	M	M	M	-	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---	---

Time of Sample collection

H	H	:	M	M
---	---	---	---	---

(24 hours format)

Lab Parameters	Result	Unit	Interpretation*	If Abnormal (check one)#	If Abnormal CS, please describe the abnormality
Specific gravity	_____		☐	☐ CS ☐ NCS	_____
pH	_____		☐	☐ CS ☐ NCS	_____
Glucose	_____		☐	☐ CS ☐ NCS	_____
Ketones	_____		☐	☐ CS ☐ NCS	_____
Bilirubin	_____		☐	☐ CS ☐ NCS	_____
Urobilinogen	_____		☐	☐ CS ☐ NCS	_____
RBC	_____	/hpf	☐	☐ CS ☐ NCS	_____
Dysmorphic Red Blood Cells	_____	/hpf	☐	☐ CS ☐ NCS	_____
Pus cells (WBC)	_____	/hpf	☐	☐ CS ☐ NCS	_____
Crystals	_____		☐	☐ CS ☐ NCS	_____
Casts	_____	/lpf	☐	☐ CS ☐ NCS	_____
Epithelial cells	_____	/hpf	☐	☐ CS ☐ NCS	_____
Protein (Albumin)	_____		☐	☐ CS ☐ NCS	_____

*Interpretation: 1= Normal; 2= Abnormal

#CS = Clinically Significant, NCS = Not Clinically Significant

Please record Clinically Significant abnormal finding(s) in the Adverse Event Log.

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SEROLOGY

(Applicable for visit days: V1,C1, C2, C3, C4, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS and Unscheduled Visit)

Was blood sample collected?	☐ Yes, fill the below details ☐ No, specify reason_____
Date of blood sample:	D D - M M M - Y Y Y Y
Parameters	Results
Human immunodeficiency virus (HIV)	☐ Reactive ☐ Non-Reactive
Hepatitis BsAG (HBsAG)	☐ Reactive ☐ Non-Reactive
Hepatitis C virus (HCV)	☐ Reactive ☐ Non-Reactive

URINE PREGNANCY TEST

(Applicable for visit days: V1 and Unscheduled Visit)

Urine Pregnancy Test performed?	☐ Yes, fill the below details ☐ No, specify reason_____
	☐ NA
Date of Sample collection:	D D - M M M - Y Y Y Y
Result:	☐ Positive* ☐ Negative
*If Positive, patient should be excluded from study	
Note: If Serum Pregnancy Test is recorded then Urine Pregnancy Test is not required and mark as NA.	

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Site No.

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Patient No.

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SERUM PREGNANCY TEST

(Applicable for visit days: V1 and Unscheduled Visit)

Serum Pregnancy Test performed?

- ☐ Yes, fill the below details
- ☐ No, specify reason_____
- ☐ NA

Date of Sample collection:

D	D	-	M	M	M	-	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---	---

Time of Sample collection

H	H	:	M	M
---	---	---	---	---

 (24 hours format)

Result:

- ☐ Positive
- ☐ Negative

FSH Test Performed?

(For women of non-child bearing potential only females. 54 years old with amenorrhea. 12 months with no other cause)

- ☐ No, specify reason_____
- ☐ Yes, complete the following.

FSH Result:

_____ mIU/mL

Note: If Urine Pregnancy Test is recorded then Serum Pregnancy Test is not required and mark as NA.

THYROID FUNCTION TEST

(Applicable for visit days: V1,C1, C2, C3, C4, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS and Unscheduled Visit)

Was sample collected?

- ☐ Yes, please fill the below details
- ☐ No, specify reason_____

Date of Sample collection:

D	D	-	M	M	M	-	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---	---

Time of Sample collection

H	H	:	M	M
---	---	---	---	---

 (24 hours format)

Lab Parameters	Result	Unit	Interpretation*	If Abnormal (check one)#	If Abnormal CS, please describe the abnormality
TSH	_____	mU/L	☐	☐ CS ☐ NCS	_____
Tri iodothyronine (T3) NA	_____	ng/dL	☐	☐ CS ☐ NCS	_____

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Tetraiodothyronine (T4) NA	_____	ng/dL	☐	☐ CS ☐ NCS	_____
*Interpretation: 1= Normal; 2= Abnormal #CS = Clinically Significant NCS = Not Clinically Significant Please record Clinically Significant abnormal finding(s) in the Adverse Event Log.					

NSCLC TREATMENT

(Applicable for visit days: C1, C2, C3, C4, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS)

Gross Examination:

Specimen integrity:	☐ Lobectomy ☐ Segmentectomy ☐ wedge ☐ Others, specify_____
Dimensions (cm):	_____
Tumor location (lobe/segment):	_____
Tumor size (3D in cm):	_____
Distance from margins:	
Bronchial	☐ Involved ☐ Free
Vascular	☐ Involved ☐ Free
Parenchymal	☐ Involved ☐ Free
Chest wall	☐ Involved ☐ Free
Pleural involvement:	☐ Visceral

Protocol Number: D9106R00007

Site No.

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Patient No.

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☐ Parietal

☐ Chest wall

Satellite nodules number:

Satellite nodules site:

Lymph nodes submitted (station-wise count):

Block key:

Microscopic – Primary Tumor:

Histologic Type (WHO 2021):

☐ Adenocarcinoma

☐ Squamous cell carcinoma

☐ Large cell carcinoma

☐ Adenosquamous

☐ Other, specify _____

Predominant pattern (%):

Tumor size (total cm):

Invasive component size (cm):

Histologic Grade:

Spread Through Air Spaces (STAS):

☐ Present

☐ Absent

☐ Not Assessed / Not known

Visceral Pleural Invasion:

☐ PL0

☐ PL1

☐ PL2

Lymphovascular Invasion:

☐ Present

☐ Absent

Perineural Invasion:

☐ Present

☐ Absent

Protocol Number: D9106R00007

Site No.

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Patient No.

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Necrosis (% estimate):

Tumor to Margins (distance mm / involved):

Overall margin status:

☐ R0

☐ R1

☐ R2

Treatment Effect (if neoadjuvant; % viable tumor):

Additional tumor nodules site:

Additional tumor nodules number:

Lymph Nodes (IASLC Map):

Stations examined:

Total nodes examined:

Total nodes positive:

Positive stations:

Extranodal Extension (ENE):

☐ Present

☐ Absent

Pathologic Stage (pTNM) Edition used (8th / 9th):

pT:

pN:

pM:

Final Stage Group:

Ancillary Studies:

Immunohistochemistry:

☐ TTF-1

☐ Napsin A

☐ p40

☐ CK7

☐ Others, specify _____

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	Site No. 	Patient No.

PD-L1 IHC:	☐ % TPS/CPS ☐ Clone ☐ platform
Molecular Results:	☐ EGFR ☐ ALK ☐ ROS1 ☐ BRAF ☐ KRAS ☐ MET ☐ RET ☐ NTRK ☐ HER2
Other, specify	_____
Final Diagnosis (Synoptic Summary):	
Procedure	_____
Site	_____
Histologic Type	_____
Predominant Pattern:	_____
Tumor Size (total & invasive):	_____
Grade:	_____
STAS:	_____
VPI:	_____
LVI:	_____
PNI:	_____
Margin status:	☐ Bronchial ☐ Vascular ☐ Parenchymal

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	Site No. 	Patient No.

	☐ Chest wall ☐ Overall R
Nodes:	☐ Examined ☐ Positive ☐ Stations ☐ ENE
Additional nodules:	_____
Treatment effect:	_____
pTNM & Stage group:	_____
PD-L1 result:	_____
Biomarker result:	_____
Block selected for future testing:	_____
Pathologist's comment:	_____

Protocol Number: D9106R00007		
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NEO ADJUVANT THERAPY DETAILS (Applicable for visit days: C1, C2, C3 and C4)	
Please provide Neo adjuvant drug details:	
Total Dose:	_____
Total duration of the treatment:	_____
Ongoing Treatment	☐ Yes ☐ No
Discontinuation of treatment:	☐ Yes ☐ No
Reason for discontinuation of treatment:	_____
Change of dose treatment:	☐ Yes ☐ No
Reason for change of dose treatment:	_____

Protocol Number: D9106R00007		
	Site No. 	Patient No.

DRUG ADMINISTRATION (INFUSION)

(Applicable for visit days: C1, C2, C3, C4, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS)

Was drug infused?	☐ Yes, complete the following ☐ No, specify reason _____
Date of Sample collection:	D D - M M M - Y Y Y Y
Start Time of infusion of IP:	H H : M M (24 hours format)
Stop Time of infusion of IP:	H H : M M (24 hours format)
Total Dose calculated by Investigator	_____ (mg/ml)
Was Dose interrupted during infusion?	☐ No ☐ Yes*
If *yes, provide the reason	_____
Interruption time	H H : M M (24 hours format)
Was Dose Restarted?	☐ No* ☐ Yes
If *No, Provide the reason	_____
If Yes, provide the re-start time:	H H : M M (24 hours format)
Please record Clinically Significant abnormal finding(s) in the Adverse Event Log.	

Protocol Number: D9106R00007		
	Site No.	Patient No.

ADJUVANT THERAPY DETAILS

(Applicable for visit days: C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS)

Please provide Adjuvant drug details:

Total Dose:	_____
Total duration of the treatment:	_____
Ongoing Treatment	☐ Yes ☐ No
Discontinuation of treatment:	☐ Yes ☐ No
Reason for discontinuation of treatment:	_____
Change of dose treatment:	☐ Yes ☐ No
Reason for change of dose treatment:	_____

ADDITIONAL THERAPY DETAILS

(Applicable for visit days: C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS)

Was any additional therapy given?	☐ Yes* ☐ No
*If Yes, provide brief description of the therapy.	_____

Protocol Number: D9106R00007		
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CONCOMITANT MEDICATIONS (Applicable for visit days: V1,C1, C2, C3, C4, Pre-surgery, Surgery, Post- surgery, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS)	
Has the subject taken any medication other than the study drug?	☐ *Yes ☐ No
*If Yes, please fill details in Concomitant Medication Form.	

ADVERSE EVENT (Applicable for visit days: V1,C1, C2, C3, C4, Pre-surgery, Surgery, Post- surgery, C5, C6, C7, C8, C9, C10, C11, C12, C13, C14, C15, C16, EOS)	
Has the subject experienced any adverse event since last visit?	☐ *Yes ☐ No
*If Yes, please fill details in Adverse Event Form.	

Protocol Number: D9106R00007		
Study Completion	Site No.	Patient No.

STUDY COMPLETION/DISCONTINUATION	
Subject completed the study?	☐ Yes ☐ No
Date of completion	D D - M M M - Y Y Y Y
Date of withdrawal/Discontinuation	D D - M M M - Y Y Y Y
Primary reason for withdrawal/discontinuation	☐ Adverse Event, that in the opinion of the investigator or the sponsor, contraindicates further dosing, please specify AE No____ ☐ Patient decision. The patient is at any time free to discontinue treatment, without prejudice to further treatment ☐ Severe non-compliance to study protocol that, in the opinion of the investigator or sponsor, warrants withdrawal; e.g. refusal to adhere to scheduled visits ☐ Any AE that meets criteria for discontinuation ☐ Initiation of alternative anticancer therapy including another investigational agent ☐ Disease progression as per investigator’s clinical and imaging assessment ☐ Pregnancy or intent to become pregnant ☐ Use of prohibited concomitant medication ☐ Study terminated by sponsor ☐ Death (Record Date, if death): D D - M M M - Y Y Y Y ☐ Screen Failure ☐ Other, please specify:_____
Investigator’s Statement:_____	

Protocol Number: D9106R00007		
Unscheduled Visit	Site No.	Patient No.

UNSCHEDULED VISIT	
Unscheduled visit occurred?	☐ Yes ☐ No
Date of Visit:	D D - M M M - Y Y Y Y
Reason for Unscheduled Visit:	☐ Adverse Event/Serious Adverse Event ☐ Concomitant Illness ☐ Clarification on study procedures ☐ Other, specify_____
Please tick the forms for procedures performed at Unscheduled Visit:	
Physical Examination	☐
Vital Signs	☐
Hematology	☐
Biochemistry	☐
Coagulation Panel *	☐
Urine Pregnancy Test	☐
Urinalysis	☐
Thyroid function test	☐
12-Lead ECG	☐
Serology	☐
ECOG Performance status	☐
Adverse Event	☐
Concomitant Medication	☐

* As per protocol "Coagulation Panel" is not applicable for the study, kindly avoid selecting the Coagulation panel.

Protocol Number: D9106R00007

General Form

Site No.

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Patient No.

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PRIOR AND CONCOMITANT MEDICATION FORM

Did subject consume any medication?

☐ Yes

☐ No

Seq. No.	Medication Name	Start Date	Ongoing	Indication	Dosage Form*	Dose	Unit [#]	Route [^]	Frequency ^{\$}											
		Stop Date																		
	-----	<table border="1"> <tr> <td>D</td><td>D</td><td>-</td> <td>M</td><td>M</td><td>M</td><td>-</td> <td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>	D	D	-	M	M	M	-	Y	Y	Y	Y	☐	-----	☐ Other---	-----	☐ Other--	☐ Other---	☐ Other-----
D	D	-	M	M	M	-	Y	Y	Y	Y										
	-----	<table border="1"> <tr> <td>D</td><td>D</td><td>-</td> <td>M</td><td>M</td><td>M</td><td>-</td> <td>Y</td><td>Y</td><td>Y</td><td>Y</td> </tr> </table>	D	D	-	M	M	M	-	Y	Y	Y	Y	☐	-----	☐ Other---	-----	☐ Other--	☐ Other---	☐ Other-----
D	D	-	M	M	M	-	Y	Y	Y	Y										

***Dosage Form**
 1 = Tablet
 2 = Capsule
 3 = Syrup
 4 = Cream
 5 = Suppository
 6 = Spray
 7 = Liquid
 8 = Elixir
 9 = Parenterals
 10 = Ointment
 11 = Other, specify

#Unit
 1 = mg
 2 = gm
 3 = mcg
 4 = ml
 5 = IU
 6 = Other, specify

^Route
 1 = Oral (PO)
 2 = Intramuscular
 3 = Intravenous
 4 = Topical
 5 = Subcutaneous
 6 = Other, specify

\$Frequency
 1 = Once daily
 2 = Twice daily
 3 = Thrice daily
 4 = Four times daily
 5 = As and When Required
 6 = Oher, specify

Protocol Number: D9106R00007														
General Forms					Site No.					Patient No.				

ADVERSE EVENT FORM														
Any adverse event reported?										☐ Yes ☐ No				
Seq. No.	AE Term	Start Date	Time of Onset (HH:MM) (24 hrs format)	Ong oing	Intensi ty ^{&}	Severity as per CTCAE Grade*	Action taken on the study drug (with regard to medicinal product) [#]	Treatment / Medicatio n received? @	Investigator causality rating against the medicinal product [%]	Relationship with study drug ^{\$}	Outco me [^]	SAE (AE is serious or not)	Therapy Discontin ued (AE caused participant 's withdrawa l from the study)	
		Stop Date	Time of Resolution (HH:MM) (24 hrs format)											
	-----	D D - M M M - Y H H : M M		☐	☐	☐	☐ Specify-- --	☐	☐	☐	☐	☐	☐	
		D D - M M M - Y Y Y Y Y M M												
	-----	D D - M M M - Y H H : M M		☐	☐	☐	☐ Specify-- --	☐	☐	☐	☐	☐	☐	
		D D - M M M - Y Y Y Y Y												

Protocol Number: D9106R00007

General Forms

Site No.

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Patient No.

--	--	--	--	--

			HH : MM										
	-----	DD - MM - YY	HH : MM				☐	☐	☐	☐	☐	☐	☐
		DD - MM - YY	HH : MM				☐	☐	☐	☐	☐	☐	☐
			HH : MM										
& Intensity: 1 = Mild 2 = Moderate 3 = Severe	*CTCAE grade: 1 = Mild 2 = Moderate 3 = Severe 4 = Life-threatening 5 = Death	#Action taken: 1 = No change in IP 2 = IP temporarily Interrupted 3 = IP permanently discontinued 4 = Other, specify	@Treatment received: 1 = Yes* 2 = No	%Investigator causality rating against the medicinal product: 1 = Yes 2 = No	\$Relationship with drug: 1 = Certain 2 = Probable/ Likely 3 = Possible 4 = Unlikely 5 = Conditional/ Unclassified 6 = Unassessable/ Unclassifiable	^Outcome: 1 = Resolved 2 = Recovered/ Resolved with sequelae 3 = Recovering/ Resolving 4 = Not recovered/ Not resolved 5 = Fatal/ Result in death 6 = Unknown		SAE: 1 = Yes# 2 = No	Therapy discontinued: 1 = Yes# 2 = No				

*If treatment taken, please provide details in the prior and Concomitant Medication Form.

#If SAE, complete Serious Adverse Event Form

Protocol Number: D9106R00007

General Forms

Site No.

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Patient No.

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PROTOCOL DEVIATION

Has the subject undergone any Protocol Deviation?

☐ Yes, complete the following

☐ No

Seq. No.	Deviation*	Deviation Date	Deviation Description	Deviation codes [#]	Action taken (if any)^											
	☐	<table><tr><td>D</td><td>D</td><td>-</td><td>M</td><td>M</td><td>M</td><td>-</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	-	M	M	M	-	Y	Y	Y	Y	-----	☐ -----	☐ -----
D	D	-	M	M	M	-	Y	Y	Y	Y						
	☐	<table><tr><td>D</td><td>D</td><td>-</td><td>M</td><td>M</td><td>M</td><td>-</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	-	M	M	M	-	Y	Y	Y	Y	-----	☐ -----	☐ -----
D	D	-	M	M	M	-	Y	Y	Y	Y						
	☐	<table><tr><td>D</td><td>D</td><td>-</td><td>M</td><td>M</td><td>M</td><td>-</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	-	M	M	M	-	Y	Y	Y	Y	-----	☐ -----	☐ -----
D	D	-	M	M	M	-	Y	Y	Y	Y						
	☐	<table><tr><td>D</td><td>D</td><td>-</td><td>M</td><td>M</td><td>M</td><td>-</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	-	M	M	M	-	Y	Y	Y	Y	-----	☐ -----	☐ -----
D	D	-	M	M	M	-	Y	Y	Y	Y						
	☐	<table><tr><td>D</td><td>D</td><td>-</td><td>M</td><td>M</td><td>M</td><td>-</td><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr></table>	D	D	-	M	M	M	-	Y	Y	Y	Y	-----	☐ -----	☐ -----
D	D	-	M	M	M	-	Y	Y	Y	Y						

* Deviation: 1= Visit 1, 2= Cycle 1, 3= Cycle 2, 4= Cycle 3, 5= Cycle 4, 6= Cycle 5, 7= Cycle 6, 8= Cycle 7, 9= Cycle 8, 10= Cycle 9, 11= Cycle 10, 12= Cycle 11, 13= Cycle 12, 14= Cycle 13, 15= Cycle 14, 16= Cycle 15, 17= Cycle 16, 18= End of Study

[#]Protocol Deviation Codes: 1 = Restrictions, 2 = Enrolment/IE Criteria, 3 = Out of visit window, 4 = IP Administration, 5 = Drug Accountability, 6= Noncompliance, 7= Use of prohibited medication, 8= Safety assessment, 9 = Other, specify

[^]Action Taken: 1=Patient continued in the study, 2=Patient Discontinued in the study, 3=Retraining 4=Other, specify

Protocol Number: D9106R00007		
General Forms	Site No.	Patient No.

SERIOUS ADVERSE EVENT

Date of Birth (derived from Demography page):	D D - M M M - Y Y Y Y
Age (derived from Demography page):	X X Years
Gender (derived from Demography page):	☐ Male ☐ Female
Body Weight:	X X X . X kg
Related AE sequence number	_____
SAE term:	-----
Date of AE met criteria for SAE	D D - M M M - Y Y Y Y
Date Investigator became aware of serious AE	D D - M M M - Y Y Y Y
Was patient hospitalised due to SAE	☐ No ☐ Yes, complete the following Date of Hospitalisation D D - M M M - Y Y Y Y Date of Discharge D D - M M M - Y Y Y Y
Seriousness Criteria: (select all that apply)	☐ Death ☐ Life-threatening ☐ Inpatient hospitalisation or Prolonged of existing hospitalisation ☐ Persistent or significant disability/incapacity ☐ Congenital anomaly/Birth defect ☐ Important medical event_____
Date of event onset:	D D - M M M - Y Y Y Y

Protocol Number: D9106R00007

General Forms

Site No.

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Patient No.

--	--	--	--	--

Time of event onset

H	H	:	M	M
---	---	---	---	---

 (24 hours format)

Causality assessment in relation to study procedure(s)

☐ Yes
☐ No

Causality assessment in relation with other medications

☐ Yes
☐ No

Date and time of site awareness of SAE:

Date of SAE Awareness:

D	D	-	M	M	M	-	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---	---

Time of SAE Awareness:

H	H	:	M	M
---	---	---	---	---

 (24 hours format)

Outcome:

☐ Fatal/ Result in Death
Probable cause of Death_____

Date of Death

D	D	-	M	M	M	-	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---	---

Time of Death

H	H	:	M	M
---	---	---	---	---

 (24 hours format)

Was Autopsy performed

☐ No
☐ Yes,

Date of Autopsy

D	D	-	M	M	M	-	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---	---

☐ Recovered/Resolved

Date of Resolution

D	D	-	M	M	M	-	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---	---

Stop Time of Event

Protocol Number: D9106R00007

General Forms

Site No.

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Patient No.

--	--	--	--	--

H	H	:	M	M
---	---	---	---	---

(24 hours
format)

☐

Recovered/Resolved with sequelae

☐

Recovering/Resolving

☐

Not Recovered/ Not Resolved

☐

Unknown

Comments: _____

Principal Investigator Documents

CURRICULUM VITAE

Personal Details					
Name (In capitals)		DR. SOMNATH ROY			
Address		Tata Medical Center,			
		14 MAR(E-W) Newtown, Rajarhat, Kolkata-700160			
State	WEST BENGAL	City	KOLKATA	Pin code	700160
Mobile Number		Email Id: somnath.roy1@tmckolkata.com			

Institutional / Hospital Affiliations (Professional Experience)			
Name of the Institute / Hospital	Designation	Start Year	End Year
Dept. Of Radio-Therapy, IPGMER, Kolkata	Senior Resident	2014	2016
Dept. Of Medical Oncology, Tata Memorial Hospital, Mumbai	Senior Resident	2016	2020

Educational Qualification		
Degree	University	Year of passing
DM (Medical Oncology)	Tata Memorial Hospital, Mumbai	2019
MD (Radio-Therapy)	W.B. University of Health Sciences(IPGMER)	2014
DMRT (Radio-Therapy)	W.B. University of Health Sciences(IPGMER)	2009
MBBS	North Bengal Medical College	2005

Medical Registration Number	WB-61923	Year of Registration	
ICH GCP Trained	YES ☒ NO ☐		
Relevant Trainings and Certifications (If any) (Present data in reverse chronological order)			

Clinical Research Experience				
Diagnosis/Indication	Phase	Role	Start Year	End Year
Head Neck Cancer	III	Sub Investigator	2022	
Lung Cancer	III	Principal Investigator	2021	
Prostate Cancer	III	Principal Investigator	2021	
Breast Cancer	III	Principal Investigator	2022	

CURRICULUM VITAE

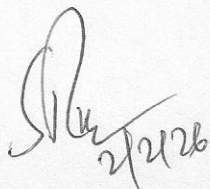
Ovarian Cancer	III	Sub Investigator	2021	
NSCLC	III	Principal Investigator	2021	
Urothelial Cancer	IV	Principal Investigator	2021	

Total no of studies completed till date , Total no of studies ongoing

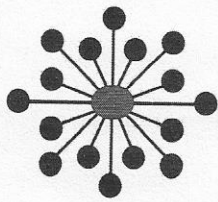
16 studies ongoing, 10 studies completed.

Declaration

I hereby declare that the information given in this CV is true, complete and accurate to the best of my knowledge and belief.



Signature and Date



NIDA Clinical Trials Network

Certificate of Completion

is hereby granted to
Somnath Roy
to certify your completion of the six-hour required course on:

GOOD CLINICAL PRACTICE

MODULE:

Introduction
Institutional Review Boards
Informed Consent
Confidentiality & Privacy
Participant Safety & Adverse Events
Quality Assurance
The Research Protocol
Documentation & Record-Keeping
Research Misconduct
Roles & Responsibilities
Recruitment & Retention
Investigational New Drugs

STATUS:

N/A
Passed
Passed
Passed
Passed
Passed
Passed
Passed
Passed
Passed
Passed
Passed

Course Completion Date: 22 April 2024

CTN Expiration Date: 22 April 2027

Eve Jelstrom

Eve Jelstrom, Principal Investigator
NDAT CTN Clinical Coordinating Center

Good Clinical Practice, Version 5, effective 03-Mar-2017

This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN27201201000024C.

Shy
25/4/25



WEST BENGAL MEDICAL COUNCIL

Constituted by the Govt. of West Bengal under Bengal Medical Act, 1914
IB - 196, Sector - III, Salt Lake, Kolkata - 700 106, West Bengal

Updated Registration Certificate - 2022

Registration No. : 61923 dated 17-07-2006

Name : ROY
DR. SOMNATH

Father's Name : LATE BISWANATH ROY

Sex : MALE

Address : Permanent : BEHIND NAKASHIPARA POLICE STATION, PO : BETHUADAHARI
NADIA 741126 WEST BENGAL INDIA

Present : DB 22/A, SAHAPARA,
DESHBANDHUNAGAR, PO : BAGUIATI
KOLKATA 700059 WEST BENGAL INDIA

Qualification : Basic : M B B S (North Bengal University), 2008

Additional : ● D M R T (West Bengal University of Health Sciences) , 2011
[Regd. on 17-07-2012]
● M D (Radio Therapy) (West Bengal University of Health Sciences) , 2014
[Regd. on 28-07-2014]
● D M (Medical Oncology) (Homi Bhabha National Institute) , 2019
[Regd. on 22-03-2022]
● Diplomate N B (Med. Oncology) (N B Exam., New Delhi) , 2019
[Regd. on 22-03-2022]



Signature of Applicant Full : *Somnath Roy*

Specimen : *S.Roy*

[Signature of Registrar]

Registrar, WBMC

VALID TILL 31.12.2026



2022

[Handwritten signature]
25/4/25

CO-Investigator Documents

Curriculum Vitae

Dr. PRASHANT PANDEY

**MBBS, MD, DrNB (Medical Oncology), MRCP (UK, SCE Medical Oncology),
ECMO**

West Bengal Medical Council Reg. No: 60535

Mobile: +91-9804290687 | Email: prashantpandeydr@gmail.com

- **Current Position**
- **Consultant medical oncologist**
- **Tata medical centre , kolkata**
- **1/07/25–**

EDUCATION :

MBBS(1999–2005)

NRS Medical College, Kolkata

MD (Radiotherapy - Clinical Oncology) (2008–2011)

SSKM & IPGMER, Kolkata

DrNB (Medical Oncology) (2019–2022)

Tata Medical Centre, Kolkata

MRCP (UK, SCE Medical Oncology) (2022)

Federation of Royal Colleges of Physicians, UK

ECMO (Medical Oncology) (October 2023)

European Society for Medical Oncology (ESMO)

PREVIOUS POSITION

Clinical director oncology service and Consultant Hemato-Medical Oncologist

B P Poddar Hospital & Medical Research Ltd, Kolkata

Since: 01 September 2022 –20/06/25

Consultant Clinical Oncologist

Narayana Multispeciality Hospital, Barasat, WB

Visiting Radiation Oncologist

Narayana Superspeciality Hospital, Howrah, WB

Consultant Clinical Oncologist

Sanjiban Hospital, Howrah, WB

Clinical Tutor (WBMES)

Department of Clinical Oncology

May 2013 – March 2018

Senior Resident

Dept. of Medical Oncology, Chittaranjan National Cancer Research

Institute, Kolkata , May 2011 – April 2013

Junior Resident

Dept. of Chest Medicine, Medical College

July 2007 – April 2008

Junior resident

ICU , Shree jain hospital howrah , 2005-2007

CLINICAL STUDY PARTICIPATION

Principal Investigator:

1. **C2A03229** – A double-blind, multicenter, randomized bioequivalence study of Olaparib Tablets (Natco Pharma) vs. Lynparza Tablets (AstraZeneca) in ovarian, breast, or prostate cancer patients.
2. **C2A03014** – Bioequivalence study of Olaparib Tablets (Natco Pharma) vs. Lynparza Tablets (AstraZeneca) under fasting conditions in cancer patients.
3. **CA-170-302A** – Phase IIb/III randomized, double-blind study of CA-170 with chemotherapy in Stage IV non-squamous non-small cell lung cancer.
4. **BIO-PERTUZ-301** – Phase III randomized study comparing biosimilar PERT-IJS with EU-Perjeta® in HER2-positive early-stage or locally advanced breast cancer.

5. **61186372COR3002** : A Randomized, Open-label Phase 3 Study of Amivantamab + FOLFIRI Versus Cetuximab/Bevacizumab + FOLFIRI in Participants With KRAS/NRAS and BRAF Wildtype Recurrent, Unresectable or Metastatic Colorectal Cancer Who Have Received Prior Chemotherapy
PUBLICATION

Early Metabolic Syndrome in Testicular Germ Cell Tumors: A Prospective Study from India

Journal of Clinical Oncology, June 2022

[DOI:10.1200/JCO.2022.40.16_suppl.e17010](https://doi.org/10.1200/JCO.2022.40.16_suppl.e17010)

High-sensitivity C-reactive Protein as Prognostic and Predictive Marker in Metastatic Non-small Cell Lung Carcinoma

Journal of Clinical Oncology, June 2022

[DOI:10.1200/JCO.2022.40.16_suppl.e21101](https://doi.org/10.1200/JCO.2022.40.16_suppl.e21101)

Perspective of Oncology Patients During COVID-19 Pandemic: A Prospective Observational Study from India

Journal of Global Oncology, June 2020

[DOI: 10.1200/GO.20.00172](https://doi.org/10.1200/GO.20.00172)

An Audit of Gastrointestinal Stromal Tumors from a Tertiary Medical College Hospital in Eastern India

Asian Journal of Oncology, January 2018

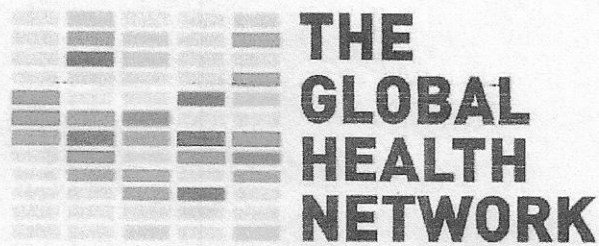
[DOI:10.4103/ASJO.ASJO_17_18](https://doi.org/10.4103/ASJO.ASJO_17_18)

Certifications and Training

ICH-GCP Certification (01-Jun-2024)

Completed training in ICH-Good Clinical Practice (ICH-GCP) under the NIDA Clinical Trials Network.

[Handwritten signature]
3/12/24



Enabling research by sharing knowledge

Hereby Certifies that
PRASHANT PANDEY

has completed the e-learning course
**ICH GOOD CLINICAL
PRACTICE E6 (R2)**

with a score of

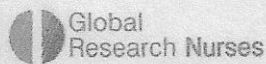
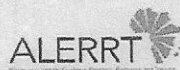
98%

on

24/03/2023

This e-learning course has been formally recognised for its quality and content by
the following organisations and institutions

This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.



Global Health Training Centre
globalhealthtrainingcentre.org/elearning

Certificate Number 88as2zer-mk0q-239l-w268-g5w214u2h22l Version number 0

Prashant
31/12/23



WEST BENGAL MEDICAL COUNCIL

Constituted by the Govt. of West Bengal under Bengal Medical Act, 1914
IB - 196, Sector - III, Salt Lake, Kolkata - 700 106, West Bengal

Updated Registration Certificate - 2022

Registration No. : 60535 dated 05-05-2005
Name : PANDEY
DR. PRASHANT
Father's Name : LATE HARI RAM PANDEY
Sex : MALE
Address : Permanent : 44, CHINTAMONY DEY ROAD, PO : HOWRAH MAIDAN
HOWRAH 711101 WEST BENGAL INDIA
Present : 52 LOWER ANDUL ROAD,
LEMON BOTANY COMPLEX, PO : PODRA
HOWRAH 711109 WEST BENGAL INDIA
Qualification : Basic : M B B S (Calcutta University), 2005
Additional : ● MD (Radio-Therapy) (West Bengal University of Health Sciences), 2011
(Regd. on 05-12-2023)
● DrNB (Medical Oncology) (NB Exam., New Delhi), 2022
(Regd. on 05-12-2023)



Prashant Pandey
3/12/22

Signature of Applicant Full : *Prashant Pandey*

Specimen : *Prashant Pandey*

[Signature]

Registrar, WBMC

VALID TILL 31.12.2026

