

INFORMED CONSENT FORM

A Phase 4, Open-Label study to Evaluate Safety of Amivantamab in Combination With Chemotherapy in Indian patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer With EGFR Exon 19del or Exon21 L858R Mutations After Progression on Osimertinib

Study ID: 61186372NSC4018

If you are eligible, you are invited to be in a research study sponsored by Johnson & Johnson Private Limited, a pharmaceutical company. Here are a few things to know:

- Taking part in a research study is voluntary and is not part of your regular health care.
- To understand this study, why it is being done, and what it involves, take your time to carefully read this informed consent form (ICF).
- Discuss taking part with your doctors, medical professionals, family, and friends.
- Ask questions to the clinical staff at the study site and request any additional information.
- You are free to decide whether or not to join in this study, and if you agree now, you can change your mind at any time. Whether or not you take part is up to you. Whatever choice you make, you will not lose access to the medical care you already receive, gain any penalty, or give up any of your existing rights or benefits.

Thank you for taking the time to consider joining in this study

The sponsor may share sensitive Company information with you to help you decide about joining in this study. We kindly ask you to consider this when discussing details about the study with people other than your healthcare provider(s), family, and friends, or when using social media.

YOUR CONTACTS

Study sponsor Johnson & Johnson Private Limited	Represented by Johnson & Johnson Private Limited HIGI House, LBS Marg Mulund (West), Mumbai - 400080
Investigator's name: Dr. Prashant Pandey Address: TATA Medical Center, 14, MAR (E -W) New Town, Rajarhat, Kolkata-700160 Contact Number: +91-9804290687	
Contact of the Independent Ethics Committee/Institutional Review Board (IEC/IRB): Dr. Indranil Mallick Clinician & Member Secretary Landline: 033 6605 7103/7447	

IRB/IEC Name: **Institutional Review Board**

TATA Medical Center, 14, MAR (E -W) New Town, Rajarhat, Kolkata - 700160

An independent ethics committee (IEC) or institutional review board (IRB) has approved this study.

As required by U.S. law, description of this clinical study will be available on www.clinicaltrials.gov. This website will not include information that identifies you, but it will include a summary of the results. You may search the website at any time.

In addition, it will also be available on <https://ctri.nic.in/Clinicaltrials/login.php>

STUDY OVERVIEW AND GENERAL INFORMATION

The purpose of this study is to help researchers understand more about the possible effectiveness and safety of Amivantamab in combination with in Indian patients with locally advanced or metastatic non-small cell lung cancer with EGFR Exon 19del or Exon21 L858R mutations after progression on Osimertinib with locally advanced or metastatic non-small cell lung cancer.

All references to the words “**study drug**” means amivantamab.

All references to “**clinical staff**” includes the site doctor(s) and other site staff specifically involved in the study (e.g., nurses, scientists, healthcare professionals).

Depending on where the study is being conducted, “**site**” can refer to an institution or a hospital.

You can ask the clinical staff to forward any questions, concerns, or complaints you may have to the IEC/IRB, the sponsor, or the sponsor's authorized representatives. Independent Ethics Committees/Institutional Review Boards (IEC/IRB) are independent committees who review research studies to protect the rights and welfare of research participants.

We expect about 40 participants will take part in this study in India at approximately 12-15 sites. You will be in the study for about 8.5 months, and you will need to visit the site approximately 14 times.

Research has shown that certain diseases, treatments, and medications affect people differently based on their age, sex assigned at birth, gender identity, sexual orientation, race, ethnicity, access, and genetic background. You may be asked questions which may help ensure that various groups are included in the study. Your information will be included in your study record but does not change the care and treatment you receive during the study or in the future. To make sure that clinical trials are available to everyone, you may be asked about where you live and how easy it is to come to the clinical trial site. This ensures people are made aware of the available trials and how to access them.

WHAT HAPPENS DURING THE STUDY?

Clinical staff will check if you meet the requirements to be in this study. If you are eligible and agree, you will sign this informed consent form after reading and understanding the study requirements. **You should come to all of your study visits appointments. Please also tell the clinical staff about any health problems or concerns you have during the study, including side effects.**

The table below describes the procedures you can expect during this research study. Not all procedures will be done at every visit. The clinical staff will discuss this with you in more detail.

Visit	Examinations, Tests and Procedures
Screening [up to 28 days prior to treatment start]	The following will be reviewed/conducted by clinical staff: • Provide correct information about the following: your medical history (including lung cancer), any allergies, previous treatments, and all medications, including prescription medications, over-the-counter medications, as well as vitamins you have been taking. • Detailed physical exam (including measuring vital signs; height, and weight) • General health status - how you feel and how well you perform daily activities • Blood and urine samples will be collected to check your general health and if you are eligible to enter the study. The amount taken is approximately (4 to 5 teaspoons at screening visit); 1 CUP = ABOUT 250 MLS; 1 TABLESPOON = 15 MLS; 1 TEASPOON = 5 MLS]. The clinical staff will discuss all tests and risks with you. • If you can have children, a pregnancy test will be done. • An ECOG (Eastern Cooperative Oncology Group) performance status will be completed. You will be asked questions about your cancer symptoms and your ability to carry out daily life activities. • An ECG (electrocardiogram) will be done which involves placing sticky patches on your chest and connecting them to a machine that shows your heart's electrical activity. • An ECHO (echocardiogram) or MUGA (multigated acquisition scan) will be done to check the health of your heart. An ECHO is a test that uses high-frequency sound waves (ultrasound) to take pictures of the heart and its chambers and measure its pumping strength. MUGA is a test that creates video images of the heart chambers to check if they are pumping blood properly. • If there is no confirmed diagnosis or biopsy report at the time of screening, a Tumor biopsy will be collected at screening (a small portion of your cancer tissue would be taken). • A CT scan (computed tomography scan) or PET (positron emission tomography) will be done. Picture of the inside of your body can be taken by CT scan. To improve the scan pictures, you may receive a small injection of a contrast material. PET scan takes pictures of the function of your tissues and organs and uses a radioactive tracer to show this activity. It can often show signs of disease

	before other imaging tests, such as CT and MRI. A Brain MRI (or brain CT if MRI is contraindicated) will take a picture of the inside of your head. There is no radiation exposure from an MRI. You will receive the contrast material through intravenous infusion, unless your doctor confirms that this cannot be done. Clinical staff will discuss if you need to stop taking any of your current treatments before starting the study.
Study treatment period – Cycle 1 Day 1 THROUGH End of Treatment	• Receive the study drug/treatment, amivantamab, will be given via intravenous infusion (put into a vein in your arm through a small tube attached to a needle from a small bag). • You will receive amivantamab along with other background chemotherapy drugs – pemetrexed and carboplatin – for 8 cycles (21 days duration of each cycle). Your condition will be monitored at approximately 12 visits (including the treatment end visit, which is 1 month after the last dose), and assessed with clinical staff by: • Reviewing your health status, extent of your disease, any side effects, and how you are feeling • Reviewing your health status, extent of your disease, any side effects, and how you are feeling • If you can have children, pregnancy test will be done • General skin care recommendations, treatment, and education • Detailed physical exam (including, but not limited to: general appearance, vital signs, height and weight measurements) • An ECOG performance status will be completed. You will be asked questions about your cancer symptoms and your ability to carry out daily life activities. • Blood samples will be collected to check your general health and disease status (approximately 1 to 2 teaspoons every time). Urine sample will be collected as clinically indicated. • ECG and ECHO/MUGA as clinically indicated by your doctor (see description above). • A CT scan (computed tomography scan) or PET (Positron Emission Tomography) and brain MRI will be done as clinically indicated by your doctor – see description above. • For more information in "Information on study samples". • During the study, you should: • BEFORE taking any other drugs or treatment, tell the clinical staff. • Should not use any other experimental treatments nor enroll in the same study at a different site.

After treatment completion	Safety Follow up: After you discontinue the study treatment, you may enter the Safety Follow-up period, which will be 1 month after the end of treatment visit. Depending on what is being reviewed, the visits can be done by phone call.
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WHAT IS THE INVESTIGATIONAL STUDY TREATMENT?

The sponsor provides the investigational study treatment, which is called "amivantamab ". Amivantamab will be given as an intravenous infusion for approximately 6 months, as per treatment schedule (it will be put into a vein in your arm from a small bag through a small tube attached to a needle). Other background chemotherapy drugs – pemetrexed and carboplatin will be given intravenously along with amivantamab for 8 cycles (21 days duration of each cycle).

This treatment is for your use only and must not be shared.

Amivantamab has been approved by the Central Drugs Standard Control Organization (CDSCO) for various indications in patients with locally advanced or metastatic EGFR-mutated non-small cell lung cancer (NSCLC), either as a monotherapy or in combination with other compounds. Amivantamab is sold as RYBREVANT.

Amivantamab is approved by CDSCO in combination with carboplatin and pemetrexed for the treatment of patients with locally advanced or metastatic EGFR mutated non-small cell lung cancer (NSCLC). Pemetrexed and carboplatin are available under various brand names.

Amivantamab is also being studied to treat several other illnesses.

The drug being studied is called amivantamab or JNJ-61186372. Amivantamab is an antibody. Antibodies are proteins that specifically recognize and bind to other types of proteins called antigens. Antibodies and antigens can work together to help your immune system fight cancer cells. In test tubes and animals, amivantamab binds to two different types of antigens that can be found on cancer cells. One type of antigen is the epidermal growth factor receptor, also called EGFR. The other type of antigen is called mesenchymal-epithelial transition factor (MET).

Some drugs that bind EGFR have been approved by regulatory authorities in your country and are in use patients with several different types of cancer. These drugs include: erlotinib, gefitinib, afatinib, and osimertinib. When one of these drugs binds to EGFR on a cancer cell, the growth of the cell is decreased or completely stops.

Drugs that only bind to MET have been approved by regulatory authorities for the treatment of metastatic non-small cell lung cancer. When one of these types of drugs binds to MET on a cancer cell, the cell cannot get the signals it needs to grow.

Amivantamab is currently approved in multiple countries for various indications as monotherapy or in combination with other compounds in patients with locally advanced or metastatic EGFR-mutated non-small cell lung cancer (NSCLC). However, in countries where it has not been approved, it can only be used in a research study such as this one.

Pemetrexed is a form of chemotherapy that is used to treat Non-Small Cell Lung Cancer that is at an advanced stage. It is also used to treat other forms of cancer.

Carboplatin is an anticancer drug referred to as chemotherapy and is classified as an alkylating agent. It is used in the treatment of various types of cancer, such as lung and ovarian cancer. Carboplatin is usually given through an infusion into a vein.

What treatment will I receive?

All participants in this study will receive amivantamab. In addition, each participant will receive chemotherapy with pemetrexed and carboplatin along with amivantamab.

Both you and the clinical staff will know which treatment you are receiving. This is an open-label study.

If you miss a dose or vomit after taking the study medication, please inform the clinical staff.

SAFE STORAGE OF STUDY MEDICATION

The packaging of the investigational study treatment is not child-resistant; keep the study treatment out of the reach of children, as it may harm them. If you feel you cannot do this, you should not participate in this study.

WHAT ARE THE POSSIBLE RISKS AND SIDE EFFECTS OF THE STUDY?

There may be risks associated with the use of amivantamab that we are not aware of. If any new, important information about the risks or side effects of amivantamab becomes available, the clinical staff will inform you so that you can decide whether you want to continue in the study.

Potential Discomforts, Side Effects, and Risks Associated with Amivantamab

The possible discomforts, side effects, and risks associated with amivantamab treatment are not fully known. Most side effects are not serious. Some may be serious, life-threatening, or could lead to death, and may require treatment or additional testing. This section describes how frequently side effects occurred in subjects treated with amivantamab.

As of May 20, 2025, safety data are available for approximately 3,486 patients who have received amivantamab. Safety information related to amivantamab is still evolving, and there may be risks that are not yet known. Sometimes, during a study, the sponsor may learn new information about the study drug and its risks. It is possible that this new information could change your mind about being in the study. If new information is discovered, your study doctor will tell you about it at that time. During your participation in this study, if you experience any side effects or problems, you should tell your study doctor immediately.

The following side effects have been observed in patients who have already received amivantamab:

Very common (May affect more than 1 in 10 patients)	• Rash (see separate section below) • Infusion-related reactions (only for administration of amivantamab in the vein, see separate section below) • Infection or inflammation of the skin around the fingernail and other nail problems • Low levels of a blood protein called albumin (can cause generalized swelling) • Tiredness • Inflammation of the mouth or mouth sores • Swelling in the hands, feet, or limbs • Nausea • Increased levels of liver enzymes (alanine and aspartate aminotransferase) in the blood, which usually do not cause symptoms but may indicate liver damage • Constipation • Dry or cracked skin • Fever • Eye problems (such as dry eyes, itchy eyes) • Itching • Decreased appetite • Diarrhea • Decreased blood calcium level usually does not cause any symptoms, but if severe, they can lead to muscle twitching and/or contractions, abnormal heart beats or seizures • Dizziness • Vomiting • Decreased potassium levels in the blood usually does not cause symptoms but if severe, it can cause an abnormal heart rates which can be serious and life-threatening • Muscle aches or pain • Abdominal pain • Increased levels of alkaline phosphatase (ALP) in the blood, which usually does not cause symptoms, but may indicate liver damage or bone turnover • Decreased platelet count in the blood usually does not cause symptoms, but if severe, it can make it difficult for the blood to clot properly. (This applies only to Amivantamab in combination with Carboplatin and Pemetrexed) • Decreased neutrophil count in the blood usually does not cause symptoms but if severe, it can make individuals more vulnerable to infections. (This applies only to Amivantamab in combination with Carboplatin and Pemetrexed)
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Common (May affect up to 1 in 10 patients)	• Low magnesium levels in the blood (which can cause weakness and muscle cramping) • Vision problems • Hemorrhoids • Growth of eyelashes	• Inflammation of the lungs (which may cause sudden difficulty breathing, cough or fever, see separate section below) • Redness or darkening and swelling of the palms of the hands and/or soles of the feet • Skin ulcer
Uncommon (May affect up to 1 in 100 patients)	• Generalized inflammation of the skin with redness and scaling • Rash due to allergic reaction	• Inflammation of the cornea
Rare (May affect up to 1 in 1000 patients)	• Severe rash with blisters and peeling over much of the body (TEN) • Inflammation inside the eye	

Infusion-related reactions: Amivantamab is an antibody made from a protein and is designed to target and eliminate a specific harmful substance in your body, in this case, a cancer cell. One side effect of some antibody therapies, such as amivantamab, that can occur during or shortly after the infusion is completed (when the medication is given into a vein) is called an infusion-related reaction. Infusion-related reactions have been reported in slightly more than half of all patients treated with amivantamab. Infusion-related reactions are most common during the first infusion and are much less likely to occur during subsequent infusions. The most common symptoms of infusion-related reactions are chills, shortness of breath, nausea, flushing, chest discomfort, and vomiting. Less common symptoms include fever, cough, itching, rash, changes in blood pressure, fast heart rate and breathing rate, dizziness, and decreased oxygen levels in the blood. Most infusion-related reactions observed to date have been mild or moderate and have been managed by the study doctors and medical staff by temporarily stopping the infusion and administering medication to treat any side effects. For some patients, no treatment was needed. For most patients, the infusion-related reaction symptoms typically resolve within a short time, and the infusion can be restarted and completed on the same day. If you experience these types of symptoms, especially during the first infusion, you should tell your doctors or nurses so they can assess you and take any appropriate actions to treat any possible infusion-related reaction, including temporarily stopping the infusion.

To help prevent or reduce any symptoms, you will receive pre-medication before the infusion, including paracetamol/acetaminophen, an antihistamine, and a corticosteroid. If you experience any symptoms, the infusion may be temporarily stopped, you may be given additional medication, and the infusion rate may be changed to help resolve the infusion-related reaction and, if possible, allow you to receive the full dose of the study medication. If you do not experience any infusion-related reactions during your first and second infusions, you may not require corticosteroids before any future infusions, but you will still receive paracetamol/acetaminophen and an antihistamine.

If you have experienced an infusion-related reaction and your doctor thinks your symptoms may persist, you may also receive medications after the infusion, including paracetamol/acetaminophen, an antihistamine, an anti-nausea medication, a corticosteroid, and other medications as needed for your symptoms.

Rash: Your doctor will provide you with instructions on how to prevent and treat rashes. This will include avoiding unnecessary exposure to sunlight and using a sunscreen with an SPF of ≥ 30 when you need to be in the sun. It will also include using topical creams on dry or sun-exposed areas of the skin. If necessary, your doctor may also prescribe antibiotics or other medications.

In addition to instructions on preventing and treating rashes, you will also be given prescriptions for more specific treatments to prevent rashes from occurring or to begin treating them immediately if they do occur and to prevent them from reappearing.

Lung inflammation: Cases of lung inflammation have been reported in patients treated with amivantamab monotherapy as well as with the combination of amivantamab and lazertinib, including serious cases that resulted in death. Inform your doctor if you experience worsening symptoms of shortness of breath, cough, or difficulty breathing.

Venous Thromboembolic Event (VTE, blood clots in the veins): Patients with lung cancer are known to have an increased risk of developing blood clots in their veins. In participants receiving treatment with the combination of amivantamab and lazertinib, a higher risk of these blood clotting events has been observed compared to participants receiving amivantamab or lazertinib as a single therapy. Severe blood clotting events, including death, have been reported. Your study doctor will discuss this risk and the precautions you should take with you. You should tell your doctor if you experience swelling and/or pain in one or more of your arms or legs or worsening shortness of breath, as these may be signs of a blood clot.

Potential discomforts, side effects, and risks associated with pemetrexed

The possible discomforts, side effects, and risks associated with pemetrexed is not known. Most side effects are not serious. Some may be serious and may require treatment or additional testing. This section describes how often side effects occurred in subjects treated with pemetrexed.

There may be some risks associated with the use of pemetrexed that are not yet known. Sometimes, during a study, the sponsor may learn new information about the study drug and its risks. It is possible that this new information could change your mind about being in the study. If new information is discovered, your study doctor will tell you about it right away.

The following side effects have been observed in patients who have previously received pemetrexed.

Very common (May affect more than 1 in 10 patients)	• Low white blood cell count • Low red blood cell count (anemia) • Low platelet count • Diarrhea • Nausea • Loss of appetite • Feeling tired • Skin rash • Hair loss
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	• Vomiting • Pain, redness, swelling, or sores in the mouth	• Constipation • Loss of sensation • Abnormal kidney blood tests
Common (May affect up to 1 in 10 patients)	• Allergic reaction which may include skin rash/burning or prickling sensation • Infection including sepsis • Fever • Infection • Dehydration • Kidney failure • Irritation of the skin and itching • Chest pain	• Muscle weakness • Conjunctivitis (pink eye) • Upset stomach • Pain in the abdomen • Taste change • Liver abnormal blood tests • Watery eyes • Increased skin pigmentation
Uncommon (May affect up to 1 in 100 patients)	• Acute kidney failure • Fast heart rate • Inflammation of the lining of the esophagus post radiation therapy • Inflammation of the lining of the large bowel, which may be accompanied by intestinal or rectal bleeding • Scarring of the air sacs of the lung (Interstitial lung disease or pneumonitis)	• Excess fluid in body tissue, causing swelling • Combined decrease in the number of white blood cells, red blood cells, and platelets (Pancytopenia) • Scarring of the air sacs of the lung associated with radiation therapy may occur in patients who are also treated with radiation either before, during or after being treated with Pemetrexed • Extremity pain, low temperature and discoloration have been reported. • Blood clots in the lung (pulmonary embolism)
Rare (May affect up to 1 in 1000 patients)	• Skin that has previously been exposed to radiotherapy may develop severe skin rashes or burn from days to years after radiation exposure.	• Anemia due to the destruction of red blood cells. • Inflammation of the liver • Anaphylactic shock (a life-threatening allergic reaction such as difficulty breathing, low blood pressure, and/or organ failure) • Severe blistering skin diseases

Some additional side effects have also been observed in patients taking pemetrexed. Please ask your study doctor for information about these side effects.

Warnings and precautions for pemetrexed

Before starting treatment with pemetrexed, talk to your doctor if you have any of the following conditions:

- Kidney problems
- Prior radiation therapy
- Recently been vaccinated
- Heart disease
- Fluid accumulation around your lungs

Other Medicines and Pemetrexed: Medicines taken for pain or inflammation (swelling), such as “non-steroidal anti-inflammatory drugs” (NSAIDs), some of which can be bought without a prescription (i.e. ibuprofen), may affect the effectiveness of pemetrexed if taken at the same time and may increase the risk of kidney damage or failure. Your immune system may become compromised while taking pemetrexed. Therefore, live vaccines should be avoided. It is important that your doctor knows about all the medicines you are taking before you receive your first dose of pemetrexed so that your doctor can discuss appropriate treatment options with you.

Driving and using machines: Taking pemetrexed may make you feel tired. Be careful when driving a car or using machines.

Potential Discomforts, Side Effects, and Risks Associated with Carboplatin

The possible discomforts, side effects, and risks associated with carboplatin is not known. Most side effects are not serious. Some may be serious and may require treatment or additional testing. This section describes how often side effects occurred in subjects treated with carboplatin.

There may be some risks associated with the use of carboplatin that are not yet known. Sometimes during the study, Sponsor may receive new information about the study drug and its risks. It is possible that this new information could change your mind about being in the study. If new information is discovered, your study doctor will tell you about it right away.

The following side effects have been observed in patients who have received carboplatin.

Very common (May affect more than 1 in 10 patients)	• Tiredness • Shortness of breath • Low red blood cell count (anemia), rarely blood transfusion may be necessary • Nausea • Vomiting • Stomach pain and cramping • Low white blood cell count • Low platelet count • Abnormal liver blood tests
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	- Abnormal kidney blood tests - Abnormal blood electrolytes
Common (May affect up to 1 in 10 patients)	- Infections and signs of infection such as fever or sore throat - Flu-like symptoms - Bleeding that can lead to significant blood loss - Diarrhea - Constipation - Sore lips or mouth ulcers - Hair loss - Rash and/or itchy skin - Pain or discomfort in your bones, joints, or muscles - Extreme tiredness/weakness - Symptoms of allergic reactions, including severe reactions, (sudden wheezing or tightness of chest, swelling of the eyelids, face or lips, facial flushing, low blood pressure, rapid heartbeat, hives, shortness of breath and dizziness) - Tingling, burning, numbness or prickling sensations in your hands, feet, arms or legs - Slow tendon reflexes - Changes in taste or loss of taste - Temporary worsening of eyesight or changes to your vision - Ear disorders that may cause hearing loss, ringing in the ears, dizziness, and unsteadiness - Heart disorders - Tightness of the chest or wheezing - Inflammation of the lungs - Bladder and genital disorders
Uncommon side effects (may affect up to 1 in 100 patients)	Fever and chills without an infection
Rare (may affect up to 1 in 1,000 patients)	Loss of vision
Very Rare (may affect 1 in 10,000 patients)	- Acute promyelocytic leukemia (a type of white blood cell cancer) may occur years after treatment - Scarring of the lungs causing shortness of breath and/or cough (pulmonary fibrosis)

Some additional side effects have also been observed in patients who have received carboplatin. Please ask your study doctor for information about these side effects.

Warnings and precautions for Carboplatin: Talk to your doctor before using Carboplatin intravenous infusion

- If you are pregnant or if there is a chance you may be pregnant.
- If you are breastfeeding.
- If you have mild renal disease. Your doctor will want to monitor you more regularly.
- If you are elderly (over 65 years old).
- If you have previously been treated with cisplatin or similar anti-cancer medicines.
- Carboplatin can cause abnormalities in your nervous system, such as pins and needles or hearing and vision problems.
- If you experience headache, altered mental functioning, seizures, and abnormal vision
- If you develop extreme tiredness and shortness of breath, along with a decrease in red blood cells (haemolytic anemia), either alone or together with a decrease in platelet count, abnormal bruising (thrombocytopenia), and kidney disease where you pass little or no urine (symptoms of Haemolytic-uraemic syndrome).
- If you have a history of liver disease not related to lung cancer.
- If you have a fever (temperature greater than or equal to 38°C) or chills, as these may be signs of infection.

During treatment with Carboplatin, you will be given medicines that help reduce a potentially life-threatening complication called tumour lysis syndrome, which is caused by chemical disturbances in the blood due to the breakdown of dying cancer cells, releasing their contents into the bloodstream.

Contraindications for Carboplatin:

- Allergic reaction to the active substance or any of the excipients
- Pre-existing severe kidney disease (creatinine clearance < 30 ml/min), unless the potential benefits of treatment outweigh the risks in the judgment of the physician and patient.
- Severe myelosuppression (or severe reduction of blood cells in your bone marrow)
- Bleeding tumours
- Do not use live or live-attenuated vaccines
- Other medicines and carboplatin intravenous infusion

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, for example:

- Taking medicines that can lower the number of cells in your blood, at the same time as carboplatin, may require changes to the dose and frequency of carboplatin treatment.
- Taking certain antibiotics called aminoglycosides, vancomycin or capreomycin, at the same time as carboplatin, may increase the risk of kidney or hearing problems.
- Taking carboplatin along with certain water tablets (diuretics) may increase the risk of kidney or hearing problems.

- Live or live-attenuated vaccines (for yellow fever)
- Blood-thinning medicines, e.g. warfarin, at the same time as carboplatin, may require an increase in frequency of blood coagulation monitoring.
- Taking phenytoin and fosphenytoin (used to treat various types of convulsions and seizures) at the same time as carboplatin may increase the risk of seizures.
- Other medicines that suppress the activity of the immune system (for example, ciclosporin)

Other Potential Risks

From the time you start taking the study drug until at least 6 months after your last dose, you must use a condom when engaging any activity that could allow passage of ejaculate to another person. Detailed information about birth control, pregnancy, and sperm donation can be found in the section "What about birth control and pregnancy during the study?"

There may be risks associated with the use of amivantamab that we are not aware of. If any new, important information about amivantamab, its risks, or side effects becomes available, the clinical staff will inform you so that you can decide whether you want to continue in the study.

There may be risks related to procedures described under the section "What Happens During the Study". If you have any concern, please discuss with clinical staff.

- For example, you may get a bruise or irritation from a blood draw or feel faint.
- CT scan uses low amount of radiation (equivalent to background radiation of 1-5 years), that has a small potential to cause cancer and other defects.
- You will have to stay in a small enclosed space for MRI that can be noisy, so this can cause you some anxiety.
- For PET - bruising from injection; possible injection reaction, but you will be closely monitored during PET scan.
- ECG – there is generally no risk associated with undergoing an ECG Sticky patches can pull your skin or cause redness or itching. Your doctor will inform you about procedures and risks related to biopsy in detail, because these will depend on where tumor(s) are located in your body.
- Biopsy: Your doctor will inform you about procedures and risks related to biopsy in detail because these will depend on where tumor(s) are located in your body. Typical procedures include inserting a thin needle through the skin using images to guide precise location ("transthoracic needle biopsy") or inserting a scope through mouth into windpipe ("bronchoscopy") to get quite close to the tumor with a biopsy device. To make the procedure as comfortable as possible, you will be administered sedation and local anesthesia as needed.

WHAT ARE THE BENEFITS OF JOINING THE STUDY?

Your condition may improve by participation in the study, but there is no guarantee that this will happen. During the study, your condition may remain as it is or worsen and you may have side-effects. Your participation can help future patients, because researchers understand more about possible effectiveness and safety of amivantamab in lung cancer.

There is a possibility that the investigational product may fail to provide intended therapeutic effect.

WHAT ELSE DO I NEED TO KNOW?

What other treatments are there outside this study?

Instead of participation in the study, you may opt to take other treatments available, like other EGFR TKIs chemotherapy, immunotherapy, etc. There may also be other clinical studies available. Clinical staff will explain you benefits and risks of these other treatments or studies and discuss which will be most suitable for you.

Birth control and pregnancy during the study

Effects of amivantamab or pemetrexed and carboplatin on fertility, the human embryo, the fetus or breastfeeding infant are unknown. Depending on the way amivantamab functions, it can injure human embryo or fetus. It is not known whether amivantamab or pemetrexed and carboplatin will get into breast milk. If you are a participant who is pregnant (or get pregnant) while participation in the study, your unborn child or breastfeeding child can be injured. So, you must agree not to get pregnant or donate eggs for assisted reproduction while being in the study and up to at least 6 months after final dosing. Also, if you are pregnant or breastfeeding a child, you cannot participate in the study.

Participants who are not able to get pregnant do not need to use birth control. If you fulfill any of the following conditions, you will not need to use birth control:

- Have never had a menstrual period
- Are older than 45 years of age and have not had a menstrual period for at least 12 months
- Have had a bilateral tubal ligation
- Have had a hysterectomy (surgical removal of womb), bilateral salpingectomy (surgical removal of both fallopian tubes), or bilateral oophorectomy (surgical removal of both ovaries).

If you have any questions about your ability to get pregnant, please ask your study doctor.

If you are a participant who is able to get pregnant, your blood will be drawn to perform pregnancy testing. Your pregnancy test must be negative for you to be enrolled in the study. If your study doctor thinks you might be pregnant during the study, they can also test for pregnancy at any time using a sample of your blood or urine.

If you are able to get pregnant, you shall have to use suitable birth control during the study and up to [6] months after your final dose of the study drug.

Before you commence the study, you shall have to discuss with the study doctor type of birth control used by you. The study doctor shall have to approve the method used by you before you can enter the study.

If you are a participant who is able to get pregnant, your blood will be drawn to perform pregnancy testing. Your pregnancy test must be negative for you to be enrolled in the study. If your study doctor thinks you might be pregnant during the study, they can also test for pregnancy at any time using a sample of your blood or urine.

If you get pregnant during the study, you shall have to inform the study doctor immediately. You shall have to discontinue taking the study drug immediately. You must also tell the study doctor if you get pregnant within the first 6 months after you stop taking study drug. The study doctor will advise you about your medical care and ask you to allow to collect information about your pregnancy and your child's health.

If you are a participant and your partner is able to get pregnant, effect of the study drug on your sperms is unknown.

From when you start taking the study drug until 6 months after your last dose, you must use a condom when you have sex with a partner who is able to get pregnant.

You will not have to donate sperm during the study and up to 6 months after your final dose of the study drug.

You shall have to discuss with the study doctor type of birth control used by you and your partner before starting the study. The study doctor shall have to approve the method used by you before you can enter the study.

If your partner becomes pregnant in the time between when you start taking the study drug until 6 months after your final dose, you must tell the study doctor immediately. Sponsor may ask you and your partner to allow them to collect information about her pregnancy and child's health.

Due to possible risk of birth defects, female patients with child bearing potential must adopt contraceptive measures before and during treatment, and up to 6 months after final dose. Males treated with the drug are advised not to father a child during treatment and up to 6 months after treatment. Advice on conservation of sperm should be sought prior to treatment because of the possibility of irreversible infertility. You may want to seek counselling on sperm storage before starting your therapy.

Treatment with carboplatin can reduce fertility in males and females temporarily or permanently. If you have concerns, inform your doctor.

If you are breastfeeding, inform your doctor. Breastfeeding will have to be discontinued during treatment.

You may use these birth control methods while being in the study: Implantable progestogen-only hormonal contraception; intrauterine device (IUD); Intrauterine hormone releasing system (IUS); Tubal closure (for example, bilateral tubal occlusion, bilateral tubal ligation); Azoospermic (absence of sperms) partner (vasectomized or due to medical reasons); combined hormonal contraception; progestogen-only hormonal contraception and sexual abstinence. Please make sure that you follow these instructions, if you are unable to do so, discuss with clinical staff. Please inform your clinical staff on changing your birth control methods during the study.

If you get pregnant during the study, you shall have to inform clinical staff immediately. They will advise you about continuing the study treatment, medical care and collection of information about pregnancy and child. By signing the consent, you agree to share relevant medical information related to your pregnancy. You are free to change your mind at any time.

If your partner becomes pregnant by you during the study, they will be asked to sign a separate consent to collect information about pregnancy and child's health. This is optional for your pregnant partner, and they may change their mind at any time. When you sign this main consent as the study participant, you agree to collection of the information.

The study may involve risks to your embryo or fetus that are currently unexpected.

Will I be paid?

You will not be for participating in the study. You will be reimbursed for expenses directly related to study visits, such as local travel and meals.

You and your caregiver will be reimbursed reasonable expenses directly related to study visits, such as local travel and meals, if any.

You will receive up to **Rs. 2000** per visit to help cover your expenses for attending study visits, e.g., travel.

Your caregiver will get up to **Rs. 2000** per visit to help cover your expenses for attending study visits as applicable for you, per study, e.g., travel.

Please discuss with clinical staff the reimbursement allowed by the sponsor for you and the caregiver.

Who pays for the study tests and procedures?

The sponsor will provide all investigational study treatments amivantamab and reimbursement for pemetrexed, carboplatin, dermatological prophylaxis, pre and post infusion medication and VTE prophylaxis, and pay "the institution" for visits, tests and procedures that are part of the study.

Sponsor will not pay for doctor visits, tests and procedures that are not a part of the study. Their payment will be made by you or your insurance company or government health plan. If you have any concern, discuss with the clinical staff.

Investigator 'has no' financial relationship or interest related to the study.

Can I change my mind about participation?

You may change your mind at any time for any reason, but we encourage you to discuss with clinical staff before taking this decision. You may be asked to confirm your decision in writing, but it is not mandatory. Please see the section "Withdrawal of Consent".

Can I be removed from the study?

Yes, but this will be fully discussed with you, along with alternative treatments or research options. Reasons may include:

- It is in your best medical interests to stop.
- You do not follow instructions of clinical staff.
- Before you are enrolled, the study is cancelled or acceptance of new participants is

discontinued.

- You no longer fulfill eligibility criteria.
- Commencement of subsequent therapy

Can I take the study drug after end of the study?

If you complete the study and clinical staff determine that it will be beneficial for you to continue amivantamab, you will be given this option upon approval of independent ethics committee / institutional review board.

FINANCIAL COMPENSATION AND MEDICAL MANAGEMENT

Regulations governing the conduct of clinical trials in India require that medical management be provided to you and financial compensation be paid in case of study-related injury or death.

(a) If you have an injury during the study, you will be provided medical management free of cost as long as needed or unless it is established that the injury has no relationship with the clinical trial, whichever is earlier.

(b) In case of a trial related injury or death, sponsor or his representative or investigator or centre, as the case may be, will provide financial compensation for injury or death according to Rule 39 of New Drugs and Clinical Trials Rules, 2019.

Above statement does not limit your legal rights.

HOW IS MY CONFIDENTIALITY PROTECTED?

Study staff and sponsor will manage your personal data (information about you) in compliance with applicable Indian data protection and confidentiality laws, and as described in the consent form.

The “Privacy Appendix” in the document describes your rights related to use and protection of your personal data.

INFORMATION ON STUDY SAMPLES

Clinical staff will collect biological samples from you for the purpose of the study and provide them to a laboratory or any authorized representative designated by the site as described in the consent form. Clinical staff will inform you if there is any change in testing of your samples during the study.

How are my samples kept confidential?

To protect your privacy, clinical staff will label your samples and any test results with the study number and your coded participant number. No direct personal identifiers are used and only clinical staff will be able to match the sample to your name.

How long will my samples be stored?

Your samples will be stored as per the operating procedures of the sites appointed local laboratory for testing or until you ask for them to be destroyed.

Will genetic testing be performed on my samples?

No genetic research will be performed on your samples.

What are risks of the Genetic Analysis?

No genetic research will be performed on your samples.

Will I receive results of Genetic Analysis?

No genetic research will be performed on your samples.

USE OF STUDY RECORD AND SAMPLES

This section describes how your study records and samples may be used, how they may be shared, and what measures are available to protect confidentiality of the participant.

Coded Data and Samples

Sponsor and other authorized parties may use and share your coded study record (without personal identifiers) for study and compatible research purposes, to advance clinical science and medical knowledge, as described below:

- To evaluate and understand amivantamab and locally advanced or metastatic non-small cell lung cancer and related health problems.
- To support development and approval of amivantamab
- To apply learnings from past studies to new ones or improve scientific analysis methods
- To make sure that the sponsor follows decisions and/or approvals of Regulatory authorities for study drug availability and reimbursement (where applicable)
- To fulfill legal and regulatory obligations, in relation to clinical studies and product safety requirements
- To publish the results of the research described above in scientific journals or use them for educational purposes

Anonymous Data

The sponsor may generate anonymous data for purposes of scientific research. Research conducted using anonymous data may have a scientific purpose beyond compatible research described above. To generate anonymous data, your coded participant number and other information that may identify you indirectly, such as exact dates of your treatment, will be removed from your data. The sponsor may share anonymous data with others for scientific research purposes, as allowed by applicable laws.

You will not receive details or results of the research study for any scientific research that may be conducted that is not a part of the study and you are not expected to receive any financial or direct benefit from the research study.

WITHDRAWAL OF CONSENT

You may withdraw your consent to participate in the study or change your mind at any time. This means that you may either discontinue study treatment, or you may discontinue study treatment and stop coming to any further study visit. If you withdraw from the study, the data, tests or test results and samples already collected will continue to be shared and used for the study purposes to protect the scientific validity and integrity of the study. If you discontinue coming at study visits, no further study-related tests will be performed. If you are not willing to come to further study visits, clinical staff will discuss with you how your health will be managed. Clinical staff may also discuss how they will follow-up on your health condition, as described in the table below.

You can also withdraw consent for your samples to be used for compatible uses as described above in the “Use of Study Record and Samples” section, once the study is completed.

Please review the health status follow-up options below if you stop coming to study visits:

Clinical staff may directly contact you by means described below.	If you are not willing to be contacted directly, clinical staff may use following sources:	If you do not agree to direct or indirect contact described previously, and this is allowed in your country, clinical staff may use the following:
Telephone/video call, text/email message, standard mail.	Family members; other doctors / medical professionals involved in your standard care; Medical records (including standard care results);	<u>Publicly available</u> registries/sources

WHAT HAPPENS AFTER THE STUDY?

A summary of study results written in plain language will be made available to you sometime after all study participants have completed the study. Please ask clinical staff if such a summary will be made available to you.

By signing this consent, you agree that you may be contacted by clinical staff after you have finished the study to be offered the results summary.

Johnson & Johnson Private Limited will use information collected about you for purposes of the study and scientific research, such as study of your disease and genetic research [if applicable]. Johnson & Johnson Private Limited may also use the information to apply for permission to sell the drug in some countries. The information will be stored both on paper and on computer. To protect your confidentiality, information will be labeled in a way that will not identify you. If the study results are published your identity is kept confidential. By signing the form, you allow for such use of your information.

Your study doctor will keep your personal medical record and a list for at least 15 years that links each participant’s name to his or her code number.

Regulatory authorities, ethics committee/institutional review board members, study site staff and representatives of Johnson & Johnson Private Limited will have access to the list and they will be able to compare and check the study information collected about you with information in your medical record. Your medical records will not be made public to the extent allowed by laws. By signing the form, you allow direct access to your medical records by those who have a valid reason to view them.

The information collected may be sent to other members of the Johnson & Johnson group of companies, to contractors working for them, and to regulatory authorities.

You may ask the study doctor to view information collected about you, and to correct any mistakes. Johnson & Johnson Private Limited may postpone your access to your information if it would interfere with the study itself. If you decide to leave the study at any time, Johnson & Johnson Private Limited may still use your information collected up to that point, if the law allows.

PRIVACY APPENDIX TO MAIN INFORMED CONSENT

Medical record - Information and data including personal details, that is recorded by clinical staff; remains at the site only.

Study record – Medical record data (without personal details) that are documented by clinical staff and shared with the sponsor.

1. What personal data will the clinical staff collect?

If you participate in the study, clinical staff collect and share your personal data for research purposes. **Personal data** may include:

- Information about your health that is found in current or past medical records or collected during the study. This may include medical images, written details (including records of telephone calls, visits and examinations) and other formats like health questionnaires.
- Information collected from analysis of your biological samples
- Information related to adverse reaction or side-effect
- Direct personal identifiers such as your name, initials, date of birth, address
- Other sensitive data such as racial or ethnic origin, gender determined at the time of birth, gender identity, lifestyle, religious or philosophical beliefs, sexual behavior or sexual orientation, that are collected only when needed to evaluate study results.

2. Who will have access to my medical record?

Your personal data will be recorded in your **Medical Record**, that may be stored in paper files and electronic database, including databases that can be accessed remotely (if approved in your country). Clinical staff will have access to your **Medical Record**. Apart from this, persons below may have direct access to your medical record to make sure that the research study is being conducted properly.

- Monitors and auditors from the sponsor or the sponsor's representatives.

- The Institutional Review Board (IRB) or Independent Ethics Committee (IEC) (a group of people who review research studies to protect the rights and welfare of people participating in research).
- Regulatory authorities; local and outside your country.
- Other persons or groups, as required by law, who may be located outside of your country. Laws in other countries have a different protection level for your information.

3. How will my personal data be protected?

Clinical staff will also record information from your medical record in your **Study Record**. These data are provided to the sponsor for study purposes. This will only be identified by study number and your coded participant number. Direct personal identifiers such as your name, initials, date of birth will not be included in your **Study Record**. Clinical staff may match the study record with your name, but the information will be kept confidential and will not be shared with the sponsor or anyone else except as required by law.

4. How will my study record be used and shared?

Sponsor and other authorized parties described in the consent form will use and share your coded **Study Record** for scientific research purposes and compatible research described and authorized in the consent form. See the section on “Use of study record and samples”. Authorized parties may include organizations providing services for the sponsor (such as laboratories), researchers, collaborators, and companies who may share an interest in the study drug or disease. The sponsor, other authorized parties, and Regulatory Authorities may be located outside of your country, where the laws may provide a different level of protection.

5. Data transfer

Measures are available to protect your personal data when transferred outside your country as required by applicable laws. This also applicable to persons who have remote access to your data, as well as when it is shared in the manner described above.

6. Will my personal identifiers be shared with service providers?

Clinical staff may share certain personal identifiers, such as your name, home address, email address or telephone number, with service provider for the applicable service, e.g., taxi, patient transport, locator agency or DCT capability. Clinical staff will discuss details with you. These identifiers will not be a part of your study record and will not be used or retained by the service provider except for the purposes of this service for the study.

7. How long will my personal data be kept?

Clinical staff will keep your **Medical Record** at the site according to local laws and requirements. The sponsor may keep your **Study Record** as long as needed according to applicable laws.

8. What rights do I have concerning my personal data?

If you would like to review, correct, delete, or make other requests regarding your personal data in accordance with your country's laws, you should contact the clinical staff.

Name: **Dr. Prashant Pandey**

Contact number: **+91-9804290687**

You may not be able to review your data until after the end of the study. A request to delete your personal data may not be allowed, depending on regulations and laws that require clinical research and personal data to be retained.

Study Information

Study Title: A phase 4, Open-Label Study to Evaluate Safety of Amivantamab in combination with Chemotherapy in Indian patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer With EGFR Exon 19del or Exon21 L858R Mutations After Progression on Osimertinib

Study Number: 61186372NSC4018

As required by US laws, details of the clinical trial will be available at www.clinicaltrials.gov. Apart from this, it will also be available at www.clinicaltrialsregister.eu and <http://ctri.nic.in/Clinicaltrials/login.php>. These website[s] will not contain any information that may identify you. At most, a summary of results will be included on the website. You may search the website at any time.

An independent ethics committee or institutional review board has approved this study.

Initials of the Participant: _____

Participant Name: _____

Participant's Date of Birth/Age: _____

Participant's Address: _____

Participant's Qualification: _____

Participant's occupation (*please tick as appropriate*)

☐ Student ☐ Self-Employed ☐ Service ☐ Housewife ☐ Others

Participant's Annual Income: Rs. _____

Name and address of nominee(s) and relationship with the participant (for the purpose of compensation in case of a trial related death).: _____

YOUR CONSENT TO PARTICIPATE

If you agree to all of the following statements and choose to participate in the study, please sign below. You will receive a copy of the signed Informed Consent Form.

HIV (Human immunodeficiency virus) Test (LTM to keep this section, if the study requires HIV test or obtaining history related to HIV, as part of eligibility check, otherwise delete it)

I understand that to determine my eligibility to participate in the study, the HIV status will be checked either via history or a blood test. The significance, relevant information and pre-test counselling has been provided to me by the study doctor. All details related to HIV, its transmission, prevention, testing procedures, its limitations and interpretation of results have been explained to me by the study doctor in the language best understood by me.

Depending on the information provided, I provide my consent to provide any history or conduct an HIV test. Check Yes or No:

☐ Yes ☐ No

I understand that if I do not agree to provide history or HIV test, or if I am found to be positive, I will not be eligible to participate in the study. Check Yes or No:

☐ Yes ☐ No

I understand that my HIV test result will be kept confidential. Check Yes or No:

☐ Yes ☐ No

I understand that if my HIV test is positive, Post-test counselling shall be done by the study doctor or a qualified person assigned by him/her or the study site. Check Yes or No:

☐ Yes ☐ No

Clinical staff and I have discussed the study and my responsibilities in detail. I understand what is expected of me as a research participant.

- I agree that clinical staff may inform my other doctors that I am in the study and about any side-effect.
- I agree for my doctors, other health professionals, institutions and hospitals, or laboratories to release my disease and treatment information to clinical staff for the purposes of this study.
- I understand that I shall have to keep confidential (a) “Confidential Information” defined in the information sheet above and (b) information received by me during the study and return all study products (used or unused, even empty tubes or boxes as the case may be) and diary sheets (used and unused) to the Principal Investigator.
- It is written in a language that I can read and understand
- I understand that a copy of signed ICF will be provided to me

Signature Page

S.No.	Declaration	Subject's Initials
(i)	I confirm that I have read and understood Information Sheet Version 2.1.0 dated 17-June-2026 for the study above, I have had an opportunity to ask questions and I have received satisfactory answers and information.	[]
(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 a third party or published.	[]
(iv)	I agree not to restrict the use of data or results arising from the study provided such a use is for scientific purpose(s) only.	[]
(v)	I agree to participate in the study above on terms determined in the information sheet above.	[]

Signature (or Thumb impression) of the subject / Legally Acceptable Representative:

Date: ____/ ____/ ____ (DD-MON-YYYY)

Name of signatory: _____

Investigator's signature: _____

Date: ____/ ____/ ____ (DD-MON-YYYY)

Study Investigator's Name: ____

Statement of an impartial witness: I confirm that the information in the consent form was accurately explained to, and apparently understood by, the patient and/or the patient's legally acceptable representative, and that consent was freely given by the patient and/or the patient's legally acceptable representative

Signature of the witness _____

Date: ____/ ____/ ____ (DD-MON-YYYY)

Name of the Witness: _____

Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the participant his or her attendant.