

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

You are invited to be in a research study, if you are eligible, 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.
- Take your time to read this Informed Consent form (ICF) carefully to understand the study, why it is being done, and what it involves.
- Discuss taking part with your doctors, medical professionals, family, and friends.
- Ask questions and request any additional information from the clinical staff at the study site.
- You are free to decide to join this study or not and, if you agree now, you can change your mind 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 this study

The sponsor may share sensitive Company information with you to help you decide about joining 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

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Clinician & Member Secretary

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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.

A description of this clinical study will be available on www.clinicaltrials.gov as required by U.S. law. This website will not include information that can identify you, but will include a summary of the results. You can search this 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 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 with locally advanced or metastatic non-small cell lung cancer.

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

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

“**Site**” can refer to an institution or hospital depending on where the study is being conducted.

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. The Independent Ethics Committee/Institutional Review Board (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 depending 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 various groups are included in the study. Your information will be included in your study record but does not change the care and treatments you receive during the study or in the future. To make sure 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 available trials and how to access them.

WHAT HAPPENS DURING THE STUDY?

The 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 when you have read and understood the study requirements. **You should come to all your study visit 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 the clinical staff: • Provide correct information about the following: your medical history (including lung cancer), any allergies, previous treatments, and all medications, including prescriptions, over-the-counter medicines as well as vitamins you have been taking. • Detailed physical exam (including vital signs; height and weight measurements) • 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 symptoms of your cancer and your ability to carry out activities of daily living. • An ECG (electrocardiogram) will be done where sticky patches are placed on your chest and connected to a machine that shows the electrical activity of your heart. • An ECHO (echocardiogram) or MUGA (multigated acquisition scan) will be

	done to check your heart health. ECHO is a test that uses high frequency sound waves (ultrasound) to take pictures of the heart and its chambers and measures its pumping strength. MUGA is test that creates video images of the chambers of the heart to check they are pumping blood properly. • Tumor biopsy (small portion of your cancer tissue would be taken) will be collected at screening, if there is no confirmed diagnosis or biopsy report at the time of screening. • 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. You may receive a small injection of a contrast material to improve the scan pictures. 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 contrast material through intravenous infusion, unless your doctor confirms 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 intravenous as an infusion (put into a vein in your arm from a small bag through a small tube attached to a needle). • You will receive other background chemotherapy drugs -pemetrexed and carboplatin along with amivantamab for 8 cycles (21 days duration of each cycle). Your condition will be monitored at approximately 12 visits (which includes end of treatment visit which is 1 month after 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 symptoms of your cancer and your ability to carry out activities of daily living. • 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 (see description above) as clinically indicated by your doctor. • 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 • Find more information in “Information on study samples”. • During the study, you should: • tell the clinical staff about any other drugs or treatments BEFORE you take them. • not use any other experimental treatments nor enroll in the same study at a different site
After Study 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 end of treatment visit. The visits can be done by a phone call depending on what is being reviewed.

WHAT IS THE INVESTIGATIONAL STUDY TREATMENT?

The sponsor provides the investigational study treatment, called “amivantamab. Amivantamab will be given intravenous as an infusion as per treatment schedule for approximately 6 months (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 only for your use and must not be shared.

Amivantamab is approved by Central Drugs Standard Control Organization (CDSCO) as a monotherapy or in combination with other compounds for various indications in patients with locally advanced or metastatic EGFR mutated non-small cell lung cancer (NSCLC). 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 to EGFR have been approved by regulatory authorities in your country and are in use in 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 can't get the signals it needs to grow.

Amivantamab is currently approved in multiple countries as a monotherapy or in combination with other compounds for various indications in patients with locally advanced or metastatic EGFR mutated non-small cell lung cancer (NSCLC). However, in countries where it is not 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 anti-cancer drug referred to as chemotherapy that is classified as an alkylating agent. It is used to treat different types of cancer such as lung and ovarian cancer. Carboplatin is usually given by infusion into a vein.

What treatment will I receive?

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

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

If you miss a dose or vomit after taking the study drug, please let the clinical staff know.

SAFE STORAGE OF STUDY MEDICATION

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

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

There may be risks to using amivantamab that we do not know about. The clinical staff will tell you if new, significant information is discovered about amivantamab, risks or its side effects so 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 related to amivantamab treatment are not all 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 who were treated with amivantamab.

As of May 20, 2025, safety data are available for approximately 3,486 patients who have received amivantamab. The safety information regarding amivantamab is still developing 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 the risks. It is possible that this new information might make you change your mind about being in the study. If new information is discovered, your study doctor will tell you about it right away. If you have any side effects or problems during your participation in this study, you should let your study doctor know right away.

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	• Itching • Decreased appetite • Diarrhea • Decreased blood calcium level that usually does not cause symptoms but when severe, can cause muscle twitching and/or contractions, abnormal heart beats or seizures • Dizziness • Vomiting • Decreased levels of potassium in the blood that usually does not cause symptoms but when severe, can cause abnormal heart rates that could be serious and life threatening • Muscle aches or pain • Abdominal pain • Increased levels of alkaline phosphatase (ALP) in the blood that usually does not cause symptoms, but can indicate liver damage or bone turnover
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	- Increased levels of liver enzymes (alanine and aspartate aminotransferase) in the blood that usually does not cause symptoms, but can indicate liver damage - Constipation - Dry or cracked skin - Fever - Eye problems (such as dry eye, itchy eyes)	- Decreased number of platelets in the blood that usually does not cause symptoms but when severe, can make it difficult for the blood to clot properly. (Applicable to only Amivantamab in combination with Carboplatin and Pemetrexed) - Decreased number of neutrophils in the blood that usually does not cause symptoms but when severe, can make individuals more vulnerable to infections. (Applicable to only Amivantamab in combination with Carboplatin and Pemetrexed)
Common (May affect up to 1 in 10 patients)	- Low levels of magnesium in the blood (can cause weakness and muscle cramping) - Vision problems - Hemorrhoids - Growth of eyelashes	- Inflammation of the lung (can cause sudden difficulty in 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 object in your body, in this case, a cancer cell. A side effect of some antibody therapies like amivantamab that may occur during or shortly after an infusion is completed (when the medicine is given into a vein) is called an infusion related reaction. Infusion related reactions have been reported in a little more than half of all patients treated with amivantamab. Infusion related reactions are most common during the first infusion and are far less likely to occur during the following 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 level in the blood. Most of the observed infusion related reactions so far have been mild or moderate and have been managed by the study doctors and medical staff by temporarily stopping the infusion and

giving medication to treat any side effects. For some patients, no treatment was required. For most patients, infusion related reaction, symptoms typically resolve within a short time and the infusion can be restarted and completed on the same day. You should let your doctors or nurses know if you experience these types of symptoms, particularly during the first infusion, so that they can evaluate you and take any appropriate actions to treat a possible infusion related reaction, including temporarily interrupting the infusion.

You will receive premedication, including paracetamol/acetaminophen, an antihistamine, and a corticosteroid before the infusion to help prevent or decrease any symptoms. If you experience any symptoms, the infusion may be temporarily paused, you may be given additional medication, and the infusion rate may be changed, to help resolve the infusion related reaction and allow you to receive the full dose of study drug if possible. If you don't have an infusion related reaction during your first and second infusion, you may not need the corticosteroid before any future infusions, but you will still receive the paracetamol/acetaminophen and antihistamine.

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

Rash: Your doctor will provide you with instructions on how to prevent and treat rash. This will include not being in the sun unnecessarily and using SPF ≥ 30 sun protector when you do need to be in the sun. It will also include using topical creams on areas of dry or sun-exposed skin. Your doctor also may prescribe antibiotics or other medications if necessary.

In addition to the instructions on how to prevent and treat rash, you will also be provided with prescriptions for more specific treatments to prevent rashes from appearing or start treating rashes quickly when they appear and attempt to prevent them from reappearing.**Lung Inflammation:** In patients treated with amivantamab monotherapy as well as the combination of amivantamab and lazertinib, there have been cases of lung inflammation, including severe cases resulting in death. Inform your physician if you experience increased symptoms of shortness of breath, cough, or difficulty breathing.

Venous Thromboembolic Event (VTE, blood clots in the veins): It is known that patients with lung cancer are at increased risk of developing blood clots in their veins. An increased risk of these blood clotting events has been observed in participants receiving the combination of amivantamab and lazertinib as compared to amivantamab or lazertinib as a single therapy. Severe blood clotting events, including death, have been reported. Your study doctor will discuss this risk with you, and precautions you should take. 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 related to pemetrexed

The possible discomforts, side effects, and risks related to pemetrexed are not all known. Most side effects are not serious. Some may be serious and may require treatment or additional testing. This section describes how frequently side effects occurred in subjects who were treated with Pemetrexed.

There may be risks 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 the risks. It is possible that this new information might make you 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 already 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 • Vomiting • Pain, redness, swelling or sores in your mouth	• Nausea • Loss of appetite • Feeling tired • Skin rash • Hair loss • 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 low counts of white cells, red 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)	• Severe skin rash or burn can occur on skin that has previously been exposed to radiotherapy, from days to years after the radiation.	• 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

There are additional side effects that have been seen in patients that have taken pemetrexed. Please ask your study doctor for information regarding these side effects.

Warnings and Precautions for pemetrexed

Talk to your doctor if you have any of the following conditions prior to starting treatment with Pemetrexed:

- Kidney problems
- Prior radiation therapy

- Recently been vaccinated
- Heart disease
- Fluid accumulation around your lungs

Other Medicines and Pemetrexed: Medication for pain or inflammation (swelling), such as “nonsteroidal anti-inflammatory drugs” (NSAIDs), some of which can be purchased over the counter (ie. ibuprofen) may affect the efficacy of pemetrexed and increase your risk of kidney injury or failure if taken at the same time. Your immune system may become compromised while taking pemetrexed. As a result, live vaccines should be avoided. It is important that your doctor is aware of all the medications you are taking prior to receiving your first dose of pemetrexed so that your doctor can discuss appropriate treatment options with you.

Driving and Using Machines: 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 related to carboplatin are not all known. Most side effects are not serious. Some may be serious and may require treatment or additional testing. This section describes how frequently side effects occurred in subjects who were treated with Carboplatin. There may be risks with the use of carboplatin that are not yet known. Sometimes during a study. The sponsor may learn new information about the study drug and the risks. It is possible that this new information might make you 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 already 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 • Abnormal kidney blood tests • Nausea • Vomiting • Stomach pain and cramping • Low white blood cell count • Low platelet count • Abnormal liver blood tests • Abnormal blood electrolytes
Common (may affect up to 1 in 10 patients)	• Infection and signs of infection such as fever or sore throat • Flu-like symptoms • Bleeding that can cause significant blood loss • Diarrhea • Constipation • Sore lips or mouth ulcers • Hair loss • Rash and/or itchy skin • Pain or discomfort in your bones, joints, 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 • Change 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 1000 patients)	• Loss of vision
Very Rare (may affect 1 in 10,000 patients)	• Acute Promyelocytic Leukemia (cancer of white blood cells) may occur years after treatment • Scarring of the lungs which causes shortness of breath and/or cough (pulmonary fibrosis)

There are additional side effects that have been seen in patients that have taken carboplatin. Please ask your study doctor for information regarding 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 breast-feeding.
- 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 been treated with cisplatin or similar anti-cancer medicines in the past,
- carboplatin may cause abnormalities in your nervous system, such as pins and needles or hearing and vision problems.
- if you have headache, altered mental functioning, seizures and abnormal vision
- if you develop extreme tiredness and shortness of breath with decreased number of red blood cells, (haemolytic anaemia), alone or combined with low 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 the lung cancer
- if you have fever (temperature greater than or equal to 38oC), or chills, which could be signs of infection.

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

Contraindications for carboplatin:

- Allergic reactions to the active substance or to any of the excipients
- Pre-existing severe kidney disease (creatinine clearance < 30 ml/min), unless in the judgement of the physician and patient the possible benefits of treatment outweigh the risks
- 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:

- medicines which can reduce the number of cells in your blood, at the same time as carboplatin, may require changes to the dosage and frequency of your carboplatin treatment
- some antibiotics called aminoglycosides, vancomycin or capreomycin, at the same time as carboplatin, may increase the risk of kidney or hearing problems
- some water tablets (diuretics), at the same time as carboplatin, 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
- phenytoin and fosphenytoin (used to treat various types of convulsions and seizures), at the same time as carboplatin, may increase the risk of a seizure
- other medicines which decrease the activity of the immune system (e.g. ciclosporin)

Other Potential Risk

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

There may be risks to using amivantamab that we do not know about. The clinical staff will tell you if new, significant information is discovered about amivantamab, risks or its side effects so you can decide whether you want to continue in the study.

There may be risks associated with the procedures described under “What Happens During the Study”. Please discuss with the clinical staff if you have any concerns.

- For example, you may get a bruise or irritation from a blood draw or feel faint.
- CT scans do use low levels of radiation (equivalent to 1-5 years background radiation) which has a small potential to cause cancer and other defects.
- For MRI, you will be in a small enclosure which can be noisy, so this may cause some anxiety.
- For PET - bruising from injection; possible reaction to the injection but you will be closely monitored during PET scans.
- ECG- there is generally no risk with having an ECG. The sticky patches may pull your skin or cause redness or itching. Your doctor will inform you in detail about the procedures and risks associated with the biopsy since these will depend upon where your tumor(s) are located in your body.
- Biopsy- Your doctor will inform you in detail about the procedures and risks associated with the biopsy since these will depend upon where your tumor(s) are located in your body. Typical procedures involve inserting a thin needle through the skin using images to guide exact placement (“transthoracic needle biopsy”), or passing a scope through the mouth into the windpipe, to get close enough to the tumor to reach it with a biopsy tool (“bronchoscopy”). You will be given sedation and local anesthesia as needed to make the procedure as comfortable as possible.

WHAT ARE THE BENEFITS OF JOINING THE STUDY?

Taking part in this study may improve your condition, but this is not guaranteed to happen. During the study, your condition may stay the same or get worse and you may experience side effects. Your participation may help future patients as researchers understand more about the possible effectiveness and safety of amivantamab in lung cancer.

There is a possibility of failure of investigational product to provide intended therapeutic effect.

WHAT ELSE DO I NEED TO KNOW?

What other treatments are there outside this study?

Instead of taking part in this study, you may choose to take other available treatments, such as other EGFR TKIs, chemotherapy, immunotherapy etc. There may also be other clinical studies available. The clinical staff will explain to you the benefits and risks of these other treatments or studies and discuss which would be best for you.

Birth control and pregnancy during the study

The effects of amivantamab or pemetrexed and carboplatin on fertility, the human embryo, the fetus, or the breast-fed infant are unknown. Based on the way that amivantamab works, it may cause harm to a human embryo or fetus. It is not known if amivantamab or pemetrexed and carboplatin will get into breast milk. If you are a participant who is pregnant (or gets pregnant) or breast feeding, while taking part in the study, your unborn child or breast-fed baby may be harmed. Therefore, you must agree not to become pregnant or donate eggs for assisted reproduction while you are in this study and for at least 6 months after last dose. Also, you cannot take part in this study if you are pregnant or breast-feeding a child.

Participants who are not able to get pregnant do not need to use birth control. If you meet any of these conditions, you will not be required 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 the womb), bilateral salpingectomy (surgical removal of both fallopian tubes), or a bilateral oophorectomy (surgical removal of both ovaries)

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

If you are a participant who is able to get pregnant, blood will be taken to test you for pregnancy. 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 must use appropriate birth control during the study and for [6] months after your last dose of study drug.

The type of birth control you use must be discussed with the study doctor before you begin the study. The study doctor must approve the method you use before you can enter the study.

If you are a participant who is able to get pregnant, blood will be taken to test you for pregnancy. 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 must tell the study doctor immediately. You will have to stop 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 will ask you to allow them to collect information about your pregnancy and the health of your baby.

If you are a participant and your partner is able to get pregnant, the effect of the study drug on your sperm 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 must not donate sperm during the study and for 6 months after your last dose of study drug.

The type of birth control you and your partner use must be discussed with the study doctor before you begin the study. The study doctor must approve the methods you use 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 last dose, you must tell the study doctor immediately. The sponsor may ask you and your partner to allow them to collect information about her pregnancy and the health of the baby.

Due to the possible risk of birth defects, female patients of childbearing potential should take contraceptive measures before and during treatment and for 6 months after the last dose. Men treated with this medicine are advised not to father a child during, 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 may temporarily or permanently reduce fertility in men and women. Tell your doctor if you have concerns.

If you are breast-feeding, tell your doctor. Breast-feeding must be discontinued during treatment.

You can use these birth control methods while in this study: Implantable progestogen-only hormone contraception; Intrauterine device (IUD); Intrauterine hormone-releasing system (IUS); Tubal closure (eg, bilateral tubal occlusion, bilateral tubal ligation); Azoospermic (absence of sperm) partner (vasectomized or due to medical cause); Combined hormonal contraception; Progestogen-only hormone contraception and sexual abstinence. Please ensure you follow these instructions or if you are unable to, discuss with

the clinical staff. Please inform your clinical staff if you change your birth control methods during the study.

If you become pregnant during the study, you must tell clinical staff immediately. They will advise you about continuing the study treatment, medical care, and collecting information about the pregnancy and the baby. By signing this consent, you agree to share relevant medical information about 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 the pregnancy and the health of the baby. This is optional for your pregnant partner, and they can change their mind at any time. When you sign this main consent as the study participant, you agree to this information being collected.

The study may involve risk to your embryo or fetus that are currently unforeseeable.

Will I be paid?

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

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

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

Your caregiver will get upto 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 the clinical staff about the reimbursement allowed by sponsor for you and 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.

The sponsor will not pay for doctor visits, tests and procedures that are not part of this study. These will be covered by you or your insurance company or government health plan. Discuss with the clinical staff if you have any concerns.

The investigator **has no** financial relationships or interests associated with the study.

Can I change my mind about participating?

You can change your mind at any time for any reason, but we encourage you to talk to the clinical staff before making this decision. You may be asked to confirm your decision in writing, but this is not mandatory. Please refer to the “Withdrawal of Consent” section.

Can I be removed from the study?

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

Reasons can include:

- It is in your best medical interest to stop.
- You do not follow clinical staff instructions.
- The study is cancelled or stops accepting new participants, before you enroll.
- You no longer meet the eligibility requirements.
- Start of subsequent therapy

Can I take the study drug after the study is over?

If you complete the study and the clinical staff determines that continuing amivantamab will benefit you, you will be offered this option then upon receiving approval of the 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) In the event of an injury occurring to you during the study, you shall be provided free medical management as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

(b) In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, shall provide financial compensation for the injury or death in accordance with Rule 39 of New Drugs and Clinical Trial Rules, 2019.

The above statement does not limit your legal rights.

HOW IS MY PRIVACY PROTECTED?

The Study Staff and the Sponsor will manage your personal data (information about you) in compliance with applicable Indian data protection and privacy laws and in the manner described in this consent form

The “Privacy Appendix” in this document describes your rights about the 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 the site appointed laboratory or an authorized representative, as described in this consent form. Clinical staff will tell you if there are any changes to testing on your samples during the study.

How are my samples kept private?

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 the 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 done on my samples?

No genetic research will be done on your samples.

What are the risks of Genetic Analysis?

No genetic research will be done on your samples.

Will I receive the results of the Genetic Analysis?

No genetic research will be done on your samples.

USE OF STUDY RECORD AND SAMPLES

This section describes how your Study Record and samples may be used, shared and the measures in place to protect participant privacy.

Coded Data and Samples

The 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 associated health problems.
- To support the development and approval of amivantamab
- To apply learnings from past studies to new ones or improve scientific analysis methods
- To ensure the sponsor complies with decisions and/or approvals from the Regulatory authorities for study drug availability and reimbursement (where applicable)
- To meet 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 the purposes of scientific research. Research using anonymous data may have a scientific purpose beyond the compatible research described above. To generate anonymous data, your coded participant number and other information that could indirectly identify you, such as your exact dates of treatment, will be removed from your data. The sponsor may share anonymous data with others for scientific research purposes, as allowed by applicable laws.

For any scientific research that might be conducted that is not part of the study, you will not receive details nor results of the research and that research is not expected to provide any financial or direct benefit to you.

WITHDRAWAL OF CONSENT

You may withdraw your consent or change your mind about participating in the study at any time. This means you can either stop taking study treatment or you can stop taking study treatment and stop coming to any further study visits. 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 stop coming to study visits, no further study-related tests will be done. The clinical staff will discuss with you how your health will be managed if you do not want to come to further study visits. The clinical staff may also discuss how they will follow up on your health status, 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:

The clinical staff may contact you directly by the methods described below.	If you prefer not to be contacted directly, the clinical staff may use the sources described below:	If you don’t agree to direct or indirect contact as described previously, if allowed in your country, the clinical staff can use the following:
Telephone/video calls, Text/email messages, 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 the 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 the information collected about you for the purposes of the study and for scientific research, such as study of your disease and genetic research [if applicable]. Johnson & Johnson Private Limited may also use this 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 privacy, the information will be labeled in a way that will not identify you. If the results of the study are published your identity is kept confidential. By signing this form, you are permitting this use of your information.

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

Regulatory authorities, members of the ethics committee/institutional review board, employees at the study site and representatives of Johnson & Johnson Private Limited will have access to this list and be able to compare and check the study information collected about you with information in your medical records. As far as the law allows, your medical records will not be made public. By signing this form, you are allowing direct access to your medical records by those who have legitimate reason to look at 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 can arrange with your study doctor to see the information collected about you, and you can ask for any mistakes to be corrected. 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, recorded by the clinical staff; stays on-site

Study Record– Medical Record data (without personal details) documented by the clinical staff and shared with the sponsor

1. What personal data will the clinical staff collect?

If you join the study, the clinical staff collects and shares your personal data for research purposes.

Personal data may include:

- information about your health found in current or past medical records or collected during this study. This may include medical images, written descriptions (including records about phone calls, visits and examinations) and other formats like health questionnaires.

- information collected from analyzing your biological samples
- information connected with an 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, sex assigned at birth, gender identity, lifestyle, religious or philosophical beliefs, sexual behaviors or sexual orientation which are only collected when necessary to evaluate the study results

2. Who will have access to my Medical Record?

Your personal data will be recorded in your **Medical Record**, which may be stored in paper files and electronic databases, including those that may be accessed remotely (if approved in your country). The clinical staff will have access to your **Medical Record**. In addition, the people below may have direct access to your medical record to ensure 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 your country. Laws in other countries have a different protection level for your information.

3. How will my personal data be protected?

The clinical staff will also record information from your medical record into your **Study Record**. These data are provided to the sponsor for study purposes. This will only be identified by the 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**. The clinical staff can match the Study Record to your name, but this information will be kept confidential and not be shared with the sponsor or anyone else, except where required by law.

4. How will my Study Record be used and shared?

The sponsor and other authorized parties described in this consent form will use and share your coded **Study Record** for scientific research purposes and compatible research as described and authorized in this 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 the disease. The sponsor, other authorized parties and Regulatory Authorities may be located outside your country, where laws may provide a different protection level.

5. Transfer of data

As required by applicable laws, there are safeguards in place to protect your personal data when it is transferred outside your country. This also applies to people who have access to your data remotely as well as when this is shared as described above.

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

Clinical staff may share some personal identifiers such as your name, home, email address or phone number with a service provider for applicable service, e.g., taxi, patient transport, locator agency or DCT capability. Clinical staff will discuss the details with you. These identifiers will not be 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 retain your **Medical Record** at the site according to local laws and requirements. The Sponsor may retain your **Study Record** for as long as required in accordance with applicable laws.

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

If you would like to review, correct, delete personal data, or make other requests in accordance with the laws in your country, 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

A description of this clinical trial will be available on www.clinicaltrials.gov as required by U.S. law. In addition, it will also be available on www.clinicaltrialsregister.eu and <http://ctri.nic.in/Clinicaltrials/login.php>. These website[s] will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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

Participant Initials: _____

Name of Participant: _____

Date of Birth / Age of Participant: _____

Address of the Participant: _____

Qualification of the Participant: _____

Occupation of the Participant (*Please tick as appropriate*)

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

Annual Income of the Participant: Rs. _____

Name and address of the nominee(s) and relation to the participant (for the purpose of compensation in case of trial related death): _____

YOUR CONSENT TO PARTICIPATE

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

HIV (Human immunodeficiency Viruses) 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 pertaining 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.

Based 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 provide consent for providing history or HIV test or if I test positive then 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 I test positive for HIV, 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

The clinical staff and I 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 this study and of any side effects.
- 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 be required to keep confidential (a) "Confidential Information" as defined in the above Information Sheet and (b) the information I gain during the study and to return all the 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:

Sr. No.	Declaration	Subject Initials
(i)	I confirm that I have read and understood the Information Sheet dated Version 2.1.0 dated 17-June-2026 for the above study and have had the opportunity to ask questions and 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 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 on the terms set out in the above Information Sheet.	[]
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Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:

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

Signatory's Name: _____

Signature of the Investigator: _____

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

Study Investigator's Name: _____

Impartial Witness Statement: 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.