Research Study Informed Consent Document

Study Title for Participants: Testing the Addition of an Antibody to Standard Chemoradiation Followed by the Antibody for One Year to Standard Chemoradiation Followed by One Year of the Antibody in Patients With Unresectable Stage III Non-Small Cell Lung Cancer

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: EA5181: Randomized Phase III Trial of MEDI4736 (durvalumab) as Concurrent and Consolidative Therapy or Consolidative Therapy Alone for Unresectable Stage 3 NSCLC (NCT04092283)

Version Date: November 15, 2024

Overview and Key Information

What am I being asked to do?

You are being asked to take part in this research study because you have locally advanced non-small cell lung cancer that cannot be removed. People who are not in a research study are usually treated with standard chemotherapy and radiation given together followed by one year of an antibody that will stimulate your own immune system. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is This Study Being Done?

This study is being done to answer the following question:

Can we extend your life and/or prevent your tumor from coming back by adding a study drug (MEDI4736 [durvalumab]) during chemotherapy and radiation therapy?

We are doing this study because we want to find out if this approach is better or worse than the usual approach for your advanced non-small cell lung cancer. The usual approach is defined as chemotherapy and radiation given together followed by the MEDI4736 (durvalumab) for one year.

What is the usual approach to my Lung Cancer?

The usual treatment approach for patients with your type of lung cancer who are not in a study is treatment with chemotherapy and radiation therapy given together followed by MEDI4736 (durvalumab) for one year. A recent study showed that patients treated with this approach had a better than even chance (57%) of living longer than 3 years from diagnosis, and lived significantly longer on average than patients treated with chemotherapy and radiation therapy alone.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will be randomly assigned to one of two study groups. Depending on the study group that you are assigned to, you will either get the study drug, MEDI4736 (durvalumab) during chemo/radiation or chemo/radiation alone for about 6 weeks followed by one additional year of MEDI4736 (durvalumab) alone. There is no standard chemotherapy regimen, and your treating physicians will select either cisplatin/etoposide, cisplatin/pemetrexed, or carboplatin/paclitaxel based upon their impression of which drugs are best for you.

For this study, all patients, including those who discontinue protocol therapy early, will be followed for response until progression, even if non-protocol therapy is initiated and after consolidation has ended, and for survival for 10 years from the date of registration.

After you finish your study treatment or observation (1 year), your doctor will continue to follow your condition for 9 years and watch you for side effects and signs that your cancer has come back. During this follow-up period, you will have clinic visits every 3 months until the end of your 2nd year on the study, and then every 6 months until the end of your 10th year on study. This means you will keep seeing your doctor for a total of 10 years.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

If you choose to take part in this study, there is a risk that the study approach may not be as good as the usual approach for your cancer at preventing your cancer from coming back.

There is also a risk that you could have side effects from the study approach. These side effects may be worse and may be different than you would get with the usual approach for your cancer.

Some of the most common side effects that the study doctors know about are:

- The study drug, MEDI4736 (durvalumab), may cause your immune system to attack normal organs and cause side effects in many parts of the body. These effects may be intensified when this drug is given with chemotherapy and radiation. Some of the most common side effects include problems with your intestines, hormone glands, liver, lungs, and/or skin.
- The study approach of starting the study drug during chemo/radiation means that you may experience side effects during chemo/radiation or receiving the drug after the course of chemo/radiation.

There may be some risks that the study doctors do not know about yet.

Benefits

There is evidence that this study drug is effective in preventing your type of cancer from returning. It is not possible to know now if giving the study drug during chemo/radiation will extend your survival compared to the usual approach. This study will help the study doctors learn things that will help people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. This may mean slowly stopping the study drugs so that there is not a sudden unsafe change or risk to your health. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- For women: You become pregnant while on the study.
- The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (National Cancer Institute (NCI)). The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

The purpose of this study is to compare the usual approach of chemo/radiation followed by one year of MEDI4736 (durvalumab) to chemo/radiation with MEDI4736 (durvalumab) followed by one year of MEDI4736 (durvalumab). The addition of MEDI4736 (durvalumab) during chemo/radiation could prevent your cancer from returning and extend your life. But, it could also cause side effects, which are described in the risks section below.

This study will help the study doctors find out if this different approach is better, the same, or worse than the usual approach. To decide if it is better, the study doctors will be looking to see if the study drug extends the life of patients and/or prevents the tumor from coming back as compared to the usual approach.

This drug, MEDI4736 (durvalumab), is already approved by the FDA for use in other cancers, and for use in your type of cancer after the completion of chemotherapy and radiation. At this time MEDI4736 (durvalumab) is not yet approved (experimental) when given with chemotherapy and radiation. There will be about 660 people taking part in this study.

What are the study groups?

This study has 2 study groups.

- **Group 1 (Arm A, Arm C)**

  If you are in this group, you will get the study drug, MEDI4736 (durvalumab), once every other week during the first, third, and fifth weeks of chemo/radiation (Arm A). If your disease gets worse or there are major side effects, you will not receive further study therapy. Otherwise, you will then receive MEDI4736 (durvalumab) through a vein in your arm every 4 weeks for 1 year (Arm C). This group will receive up to 15 cycles (15 doses) of MEDI4736 (durvalumab) in total.

  There will be about 330 people in this group.

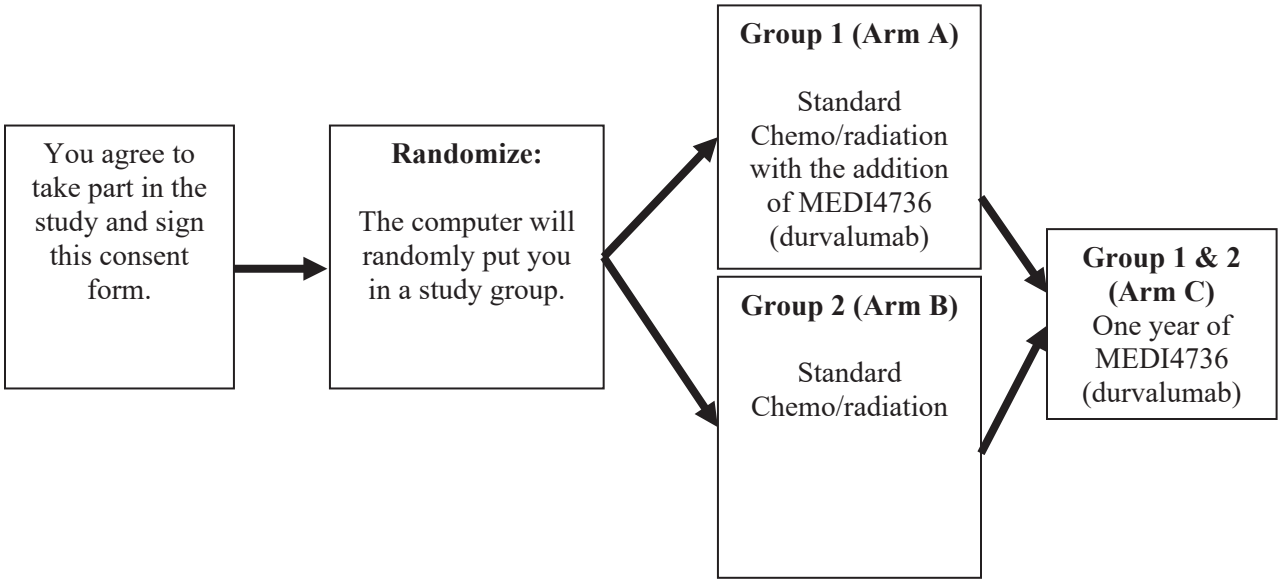
- **Group 2 (Arm B, Arm C)**

  If you are in this group, you will receive only standard chemo/radiation (Arm B). If your disease gets worse or there are major side effects, you will not receive further study therapy. Otherwise, you will then receive MEDI4736 (durvalumab) through a vein in your arm once every 4 weeks for 1 year (Arm C). This group will receive up to 12 cycles (12 doses) of MEDI4736 (durvalumab) in total.

  There will be about 330 people in this group.

We will use a computer to assign you to one of the study groups. This process is called "randomization." It means that your doctor will not choose, and you cannot choose which study group you are in. You will be put into a group by chance. You will have an equal chance of being in Group 1 or Group 2. This trial is "open-label" so you and your doctors will know whether you will be receiving the study drug, MEDI4736 (durvalumab), during the course of chemo/radiation, and all patients will be receiving this drug after chemo/radiation.

Another way to find out what will happen to you during this study is to read the chart below. Start reading: at the left side and read across to the right, following the lines and arrows.



What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures such as blood tests, baseline ECG, CT and PET scans, biopsy results, and MRI scans. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. All of these are included in the usual care you would get even if you were not in a study.

What risks can I expect from taking part in this study?

General Risks

If you choose to take part in this study, there is a risk that the study approach in Group 1 may not be as good as the usual approach for your cancer or condition at preventing your cancer from coming back.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The study drug used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for three months after you have completed the study.

Side Effect Risks

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The study drug, MEDI4736 (durvalumab), used in this study may affect how different parts of your body work such as your liver, lungs, heart, blood, bowels, and skin. The study doctor will test your blood and let you know if changes occur that may affect your health.

There is also a risk that you could have other side effects from the study drug.

Here are important things to know about side effects:

- The study doctors do not know who will or will not have side effects.

  Some side effects may go away soon, some may last a long time, and some may never go away.

  Some side effects may make it hard for you to have children.

  Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

Drug Risks

The tables below show the most common and most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible Side Effects of MEDI4736 (durvalumab) (Table Version Date: February 29, 2024)

Study Group 1 – In addition to side effects outlined above, people who are in Group 1 may also experience the possible side effects of MEDI4736 (durvalumab) when it is given with radiation listed below

Special precautions

Side effects of MEDI4736 (durvalumab) may happen anytime during treatment or even after your treatment has ended. **Call or see your healthcare provider right away if you develop any problems listed below or the symptoms get worse.**

COMMON, SOME MAY BE SERIOUS

In 100 people receiving durvalumab (MEDI4736), more than 20 and up to 100 may have:

- Cough

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving durvalumab (MEDI4736), from 4 to 20 may have:

- Anemia which may require blood transfusion
- Pain in the muscles, joints
- Diarrhea, nausea, vomiting
- Swelling of the body
- Tiredness, fever
- Infections. Infections can be severe and involve jaws and fatty tissues
- Loss of appetite
- Painful urination
- Shortness of breath
- Changes in voice
- Increased sweating

Durvalumab (MEDI4736) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems include but are not limited to:

- Hormone gland problems (especially the thyroid, pituitary and adrenal glands, and pancreas). Signs and symptoms may include: headaches that will not go away or unusual headaches, extreme tiredness or changes in mood or behavior; decreased sex drive; weight loss or weight gain; excessive thirst or urine; dizziness or fainting.
- Liver problems (hepatitis) which can cause liver failure. Signs and symptoms of hepatitis may include: yellowing of your skin or the whites of your eyes, severe nausea or vomiting; drowsiness; pain in the right upper belly.
- Lung problems (pneumonitis and pleural effusion). Symptoms may include: new or worsening cough, chest pain, shortness of breath.
- Skin: itching; rash, patches of light skin color

RARE, AND SERIOUS
In 100 people receiving durvalumab (MEDI4736), 3 or fewer may have:

- Pain and swelling of thyroid
- Reaction during or following a drug infusion which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat

Durvalumab (MEDI4736) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems include but are not limited to:

- Damage to blood cells that may cause bruises and bleeding
- Blood clots in small blood vessels, which may cause kidney failure, fever, and confusion
- Heart problems including swelling and heart failure. Symptoms and signs of heart problem may include: Shortness of breath, swelling of the ankle and body or abnormal heartbeat
- A condition with high blood sugar (diabetes) which leads to tiredness, frequent urination or excessive thirst which may require treatment with insulin
- Swelling and redness of the eye
- Intestinal problems (colitis) that can rarely lead to tears or holes in your intestine. Signs and symptoms of colitis may include: diarrhea or increase in bowel movements, blood in
- your stools or dark, tarry, sticky stools, severe belly pain or tenderness
- Damage to the pancreas which may cause belly pain and hospitalization
- Problem of the muscle (myositis), which can cause muscle pain and severe muscle weakness sometimes with dark urine
- Problem of the nervous system that can cause weakness and paralysis, which may include: numbness, tingling of hands and feet, and may also cause problems with breathing
- Swelling of the brain which may cause headache, blurred vision, stiff neck, and/or confusion
- Kidney problems, including nephritis and kidney failure requiring dialysis. Signs of kidney problems may include: decrease in the amount of urine, blood in your urine, ankle swelling
- Severe skin reactions with blisters and peeling which can involve mouth and other parts of the body

Study Group 1 & 2: **Possible side effects of cisplatin, etoposide, pemetrexed, carboplatin, and paclitaxel are listed in the tables below.**

Study Groups 1 & 2 **– Possible side effects of MEDI4736 (durvalumab) are listed in the tables below.**

Please note the following in reviewing these risks:

MEDI4736 (durvalumab) can cause your immune system to attack normal organs and tissues in many areas of your body and can affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death. Getting medical

treatment right away may help keep these problems from becoming more serious. Your doctor will check you for these problems during treatment with MEDI4736 (durvalumab). Your doctor may treat you with corticosteroids or other therapy or may need to delay or completely stop treatment if you have severe side effects.

Possible Side Effects of Cisplatin (Table Version Date: April 20, 2015)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, more than 20 and up to 100 may have:
• Nausea, vomiting, • Infection, especially when white blood cell count is low • Anemia which may cause tiredness, or may require blood transfusions • Bruising, bleeding • Kidney damage which may cause swelling, may require dialysis • Hearing loss including ringing in ears

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cisplatin, from 4 to 20 may have:
• Hair loss • Change in taste • Diarrhea • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Confusion • Difficulty with balance • Numbness and tingling of the arms and legs • Blurred vision or changes in ability to see colors (especially blue or yellow)

RARE, AND SERIOUS In 100 people receiving Cisplatin, 3 or fewer may have:
• Cancer of bone marrow caused by chemotherapy later in life • Seizure

Possible Side Effects of Etoposide (Table Version Date: September 25, 2017)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Etoposide, more than 20 and up to 100 may have:
• Infection, especially when white blood cell count is low • Anemia which may require transfusion

COMMON, SOME MAY BE SERIOUS In 100 people receiving Etoposide, more than 20 and up to 100 may have:
• Bruising, bleeding • Sores in mouth which may cause difficulty swallowing • Diarrhea, loss of appetite, nausea, vomiting • Tiredness • Fever • Chills • Hair loss

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OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Etoposide, from 4 to 20 may have:
• Heart failure or heart attack which may cause chest pain, shortness of breath, swelling of ankles, and tiredness • Liver damage which may cause yellowing of eyes and skin, swelling • Severe skin rash with blisters and peeling which can involve inside of mouth and other parts of the body • Hypotension • Abdominal pain • Peripheral neuropathy

RARE, AND SERIOUS In 100 people receiving Etoposide, 3 or fewer may have:
• Cancer of bone marrow caused by chemotherapy • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat

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Possible Side Effects of Pemetrexed (Table Version Date: December 14, 2018)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Pemetrexed, more than 20 and up to 100 may have:
• Infection, especially when white blood cell count is low • Bruising, bleeding • Anemia which may cause tiredness, or may require blood transfusions • Constipation, nausea, vomiting, loss of appetite • Sores in mouth which may cause difficulty swallowing • Tiredness • Peeling of skin

COMMON, SOME MAY BE SERIOUS In 100 people receiving Pemetrexed, more than 20 and up to 100 may have:
• Dyspepsia/heartburn • Stomatitis/pharyngitis

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Pemetrexed, from 4 to 20 may have:
• Damage to the lungs which may cause shortness of breath • Scarring of the lungs • Liver damage which may cause yellowing of eyes and skin • Kidney damage which may cause swelling, may require dialysis • Diarrhea • Severe skin rash with blisters and peeling which can involve mouth and other parts of the body • Swelling and redness of the area of radiation • Itching

RARE, AND SERIOUS In 100 people receiving Pemetrexed, 3 or fewer may have:
• Blood clot which may cause swelling, pain • Blockage of the bowels • Numbness and tingling of the arms and legs • Hair loss

Possible Side Effects of Carboplatin (Table Version Date: October 23, 2018)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Carboplatin, more than 20 and up to 100 may have:
• Infection, especially when white blood cell count is low • Bruising, bleeding • Anemia which may cause tiredness, or may require blood transfusions • Vomiting, nausea • Pain • Hair loss

Rev. Add2

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Carboplatin, from 4 to 20 may have:

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Carboplatin, from 4 to 20 may have:
• Visual loss • Diarrhea, Constipation, belly pain • Changes in taste • Numbness and tingling in fingers and toes • Nail changes • Liver abnormalities

RARE, AND SERIOUS In 100 people receiving Carboplatin, 3 or fewer may have:
• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat

Possible Side Effects of Paclitaxel (Table Version Date: September 26, 2017)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Paclitaxel, more than 20 and up to 100 may have:
• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Infection, especially when white blood cell count is low • Bruising, bleeding • Anemia which may cause tiredness, or may require blood transfusions • Pain • Sores in mouth which may cause difficulty swallowing • Diarrhea, nausea, vomiting • Muscle weakness • Numbness, tingling or pain of the arms and legs • Hair loss

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Paclitaxel, from 4 to 20 may have:
• Abnormal heartbeat • Blood clot which may cause swelling, pain, shortness of breath • Damage to the lungs which may cause shortness of breath

RARE, AND SERIOUS In 100 people receiving Paclitaxel, 3 or fewer may have:

RARE, AND SERIOUS In 100 people receiving Paclitaxel, 3 or fewer may have:
• Heart attack or heart failure which may cause shortness of breath, swelling of ankles, and tiredness • A tear or a hole in the bowels which may cause pain or that may require surgery • Severe skin rash with blisters and peeling which can involve mouth and other parts of the body

The study drugs could interact with other drugs, so it is recommended that you discuss any potential drug interactions with your study doctor.

Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

Rev. Add2 **Possible Side Effects of Lung Radiation**

COMMON, SOME MAY BE SERIOUS In 100 people receiving lung radiation, more than 20 and up to 100 may have:
• Fatigue • Swelling and redness, tanning, thickening, numbness, or peeling of the skin in the area of radiation • Difficulty and/or pain with swallowing • Hair loss in the treatment area, may be permanent • Shortness of breath • Cough with or without increased phlegm production • Tiredness • Diarrhea, nausea • Anemia, which may require blood transfusion • Infection, especially when white blood cell count is low • Bleeding, bruising • Rib pain, increased risk of rib fracture

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving lung radiation, from 4 to 20 may have:
• Bleeding, bruising • Inflammation of the lung that may cause difficulty breathing and can be life-threatening • Narrowing of the throat which may cause vomiting, difficulty swallowing • Scarring in the lung • Lung collapse • Fluid around lungs

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving lung radiation, from 4 to 20 may have:
• Bleeding from the lungs which may cause coughing up blood • Fever • Narrowing of the esophagus • Pain in chest wall

RARE, AND SERIOUS In 100 people receiving lung radiation, 3 or fewer may have:
• Narrowing of the esophagus • Lung damage, may be life threatening • Abnormal opening in internal organs which may cause pain and bleeding • Irritation of the heart causing heart failure, heart attack, chest pain, abnormal heartbeat, shortness of breath, swelling of ankles, cough or tiredness • Transverse myelitis – irritation of the spinal cord causing weakness, tingling or numbness of the lower body and legs, or paralysis of the lower half of the body • Brachial plexopathy – irritation of the nerves controlling the arm, causing weakness or paralysis • Bleeding from the airway (windpipe) • Narrowing of the airway causing shortness of breath • Death Rev. Add3 • Damage to the large blood vessels surrounding the heart, which could cause coughing up of blood and possibly death • Sores and skin damage causing bleeding and severe pain and may lead to an open wound

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Tell your doctor about:
  - all medications and supplements you are taking
  - any side effects
  - any doctors' visits or hospital stays outside of this study
  - if you have been or are currently in another research study.

For women of childbearing potential: Do not get pregnant while taking part in this study and for 90 days after you have completed the study. Do not breastfeed while taking part in this study.

For men: Do not father a baby while taking part in this study or donate sperm while taking

part in this study and for 90 days after you have completed the study.

For all: Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 90 days after your last dose of study drug. The outcome of all pregnancies occurring while you are on study and for up to 3 months after you have completed the study may be followed up on.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your cancer. This includes:

- the costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.

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- the costs of getting the durvalumab ready and giving it to you.
- your insurance co-pays and deductibles.
- Pre-screening ECG will be funded by the study

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You or your insurance provider will not have to pay for the supply of MEDI4736 (durvalumab) while you take part in this study. However, there may be additional costs for getting the MEDI4736 ready and giving it to you.

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What happens if I am injured because I took part in this study?

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a

study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

The ECOG-ACRIN Cancer Research Group is conducting this study. ECOG-ACRIN is a cancer research group that conducts studies for the National Cancer Institute. Your doctor is a member of ECOG-ACRIN or another group that is participating in this study. To help protect your privacy, ECOG-ACRIN has obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, ECOG-ACRIN cannot be forced (for example, by court subpoena) to disclose information that may identify you in any federal, state or local civil, criminal, administrative, legislative or other proceeding. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

There are organizations that may look at your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsor and any company supporting the study now or in the future.
- The IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The FDA and the groups it works with to review research.
- The NCI and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research including the Imaging and Radiation Oncology Core (IROC).

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.

- You will not get reports or other information about any research that is done using your information.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor *(*insert name of local study doctor[s]*)* at *(*insert local telephone number, and email address if appropriate*).*

For questions about your rights while in this study, call the *(*insert name of organization or center*)* Institutional Review Board at *(*insert telephone number*)*.

Optional studies that you can choose to take part in.

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading these optional studies hope the results will help other people with cancer in the future. The results will not be added to your medical records and you or your study doctor will not know the results.

Taking part in these optional studies is your choice. You can still take part in the main study even if you say "no" to any or all of these studies. There is no penalty for saying "no." You and your insurance company will not be billed for these optional studies. If you sign up for, but cannot complete any of these studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for the following study.

Optional sample collections for storage for possible future studies

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Known future studies

If you choose to take part in this optional study, researchers will collect tissue for research to understand who will and will not benefit from the study drug MEDI4736 (durvalumab).

Unknown future studies

If you choose to take part in this optional study, a sample of tissue from your previous diagnostic biopsy and the biopsy performed as part of your routine care if your cancer worsens and blood will be collected and stored. Storing samples for future studies is called "bio-banking." The biobank is being run by ECOG-ACRIN and is supported by the NCI. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people's health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use.

Right now, we don't know what research may be done in the future using your tissue and blood samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumor tissue. These are called somatic changes. Changes may also be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes.

If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue. This is why sometimes both normal tissue and tumor tissue are sequenced. This helps researchers understand if a genetic change happened only in your cancer tissue, or in your normal tissue as well.

What is involved in this optional sample collection?

If you agree to take part, here is what will happen next:

- Archived tumor tissue that was collected at the time of your diagnostic biopsy and tumor tissue collected as part of your routine care if your cancer worsens will be sent to the biobank for undefined future research. Only tumor tissue from procedures performed as part of your standard of care will be sent.
- About four [4] teaspoons of blood will be collected from a vein in your arm before you start therapy, weeks three and five of chemoradiotherapy, cycle one, day one of consolidation therapy, after three and twelve months of consolidation therapy, and if your cancer worsens. The blood will usually be collected at the same time as the blood collected for your clinical tests to monitor your health. In most cases an additional needle stick will not be required to collect the blood.
- Your tissue and blood will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
- Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
- Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.

Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database

back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.

In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

How will information about me be kept private?

Your privacy is very important to the study researchers and biobank. They will make every effort to protect it. Here are just a few of the steps they will take:

- They will remove identifiers, such as your initials, from your samples and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
- Researchers who study your samples and information will not know who you are. They also must agree that they will not try to find out who you are.
- Your personal information will not be given to anyone unless it is required by law.
- If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?

You will not benefit from taking part.

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments to this optional sample collection?

There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about this optional sample collection?

If you decide you no longer want your samples to be used, you can call the study doctor, *(*insert name of study doctor for main trial*)*, at *(*insert telephone number of study doctor for main trial*)*, who will let the biobank know. Then, any samples that remain in the biobank will be destroyed or returned to your study doctor. This will not apply to samples or related health information that have already been given to or used by researchers.

What if I have questions about this optional sample collection?

If you have questions about the use of your samples for research, contact the study doctor, *(*insert name of study doctor for main trial*)*, at *(*insert telephone number of study doctor for main trial*)*.

Please circle your answer below to show if you would or would not like to take part in each

optional study:

May we have samples of your tissue and blood for future research?

I agree that my samples and related health information may be kept in a Biobank for use in future health research.

YES NO

This is the end of the section about optional studies.

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study.

Participant's signature _____

Date of signature _____

Signature of person(s) conducting the informed consent discussion _____

Date of signature _____