Research Study Informed Consent Document

Study Title for Participants: Testing immunotherapy (Atezolizumab) with or without chemotherapy in Locoregional MSI-H/DMMR Gastric and Gastroesophageal Junction (GEJ) Cancer

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: EA2212, "A Randomized Phase II Study of Perioperative Atezolizumab +/- Chemotherapy in Resectable MSI-H/dMMR Gastric and Gastroesophageal Junction (GEJ) Cancer" (Insert NCT)*

Version Date: December 8, 2023

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you have locally advanced gastric or gastroesophageal junction 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 lower the chance of locally advanced gastric or GEJ cancer growing or spreading by using the immunotherapy drug atezolizumab with and following chemotherapy versus atezolizumab alone prior to and after surgery?

Our body has a system to identify and correct errors made in DNA when it is copied. This is called MMR or mismatch repair. If this system isn't working correctly, mutations in DNA occur which can allow the cancer to grow or spread. This is called dMMR (deficient mismatch repair).

We are doing this study because we want to find out if this approach is better or worse than the usual approach for your locally advanced gastric or GEJ cancer. We want to find out if this approach is same, better or worse than the usual approach for locally advanced gastric or GEJ cancer. The usual approach is defined as care most people get for locally advanced gastric or GEJ cancer.

What is the usual approach to my advanced gastric or GEJ cancer?

The usual approach for patients who are not in a study is treatment with surgery, chemotherapy, and/or chemoradiation. There are several chemotherapy drugs approved by the Food and Drug Administration (FDA) that are commonly used. However, given impressive activity observed with immunotherapy in this setting, most oncologists consider that as the usual approach.

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 not to be treated for cancer.
- 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 either get chemotherapy and atezolizumab for 2 months followed by surgery and then chemotherapy and atezolizumab for an additional 2 months followed by atezolizumab for 5 months or your will get atezolizumab for 2 months followed by surgery and then additional atezolizumab for 7 months.

After you finish your study treatment, your doctor will continue to follow your condition closely and watch you for side effects and disease recurrence. They will follow you in the clinic every 3 months in the first two years, every 6 months for two years and then annually for an additional 6 years. This means your condition will be followed for a total of 10 years, or longer if needed.

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 shrinking and/or preventing your cancer from coming back.

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

- Fatigue
- Thyroid problems, where your thyroid hormone could become too low or too high
- Diarrhea
- Shortness of breath

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

Benefits

There is evidence that immunotherapy may shrink or stabilize your type of cancer. Given impressive activity observed with immunotherapy in this setting, most oncologists consider that as the usual approach. It is not possible to know now if the immunotherapy alone or immunotherapy combined with chemotherapy will extend your time without disease 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). 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 atezolizumab alone versus atezolizumab combined with chemotherapy. There is evidence that atezolizumab compared to the usual approach is more likely to shrink cancer. It is not possible to know right now if atezolizumab alone or the combination of atezolizumab and chemotherapy will work in everyone with your cancer or if it will help you live longer. Using atezolizumab alone or in combination with chemotherapy compared to the usual treatment may shrink or stabilize your type of cancer, But, it could also cause side effects, which are described in the risks section above.

This study will help the study doctors find out how these different approaches compare to each other. To decide if it is better, the study doctors will be looking to see if the immunotherapy extends your time without disease compared to the usual approach.

There will be about 240 people taking part in this study.

What are the study groups?

This study has two study groups.

Neither you nor your doctor will be told which group you are in. Once randomly assigned to a group, you will know what group you have been placed in.

Group A:

Group A will get the usual chemotherapy which is one of the three chemotherapy regimens selected by you and your physician, either mFOLFOX / CAPOX or FLOT, in combination with atezolizumab followed by atezolizumab alone.

- If you and your physician elect to receive mFOLFOX, you will have three drugs: oxaliplatin, leucovorin and fluorouracil (5-FU). You will be given leucovorin and oxaliplatin at the same time into a vein. After you receive leucovorin and oxaliplatin, an injection of 5-FU will be given into a vein over a few minutes. You will get atezolizumab by vein over about 1 hour the first time you get it. If you don't have an allergic reaction, each time after that will take about 30 minutes on day 1 of every 14-day cycle. This will then be followed by a larger dose of 5-FU which will be given into a vein over the next 46 hours. The bigger dose of 5-FU is given through a small, portable infusion pump that

you wear at home. Depending on certain factors, the pump can be disconnected by a nurse who comes to your home, or you might come back to your doctor's office to have the pump disconnected. Your doctor may need to put a temporary tube into a vein in your chest or your arm for you to receive FOLFOX treatments.

You may receive FOLFOX treatments as an outpatient, using a small portable pump for the 46-hour infusion or you may be admitted to the hospital. You and your study doctor will decide which setting is best for you.

Each cycle lasts 14 days. You will receive 4 cycles before surgery and 4 cycles after surgery.

- If you and your physician elect to receive CAPOX, you will have an oxaliplatin by vein over 2 hours on day 1 of each 21-day cycle in the clinic. You will get atezolizumab by vein over about 1 hour the first time you get it. If you don't have an allergic reaction, each time after that will take about 30 minutes on day 1 of every 21-day cycle. You will take capecitabine as a pill by mouth within 30 minutes after a meal twice a day on days 1-14 of each 21 day cycle. Capecitabine should not be crushed. You will receive 3 cycles before surgery and 3 cycles after surgery.
- If you and your physician elect to receive FLOT, you will have four drugs oxaliplatin, leucovorin, docetaxel and fluorouracil (5-FU). You will be given docetaxel first, followed by leucovorin and oxaliplatin at the same time into a vein. After you receive docetaxel leucovorin and oxaliplatin. You will get atezolizumab by vein over about 1 hour the first time you get it. If you don't have an allergic reaction, each time after that will take about 30 minutes on day 1 of every 14-day cycle. 5-FU will be given into a vein over the next 24 hours. Your doctor may need to put a temporary tube into a vein in your chest or your arm for you to receive FLOT treatments.

  You may receive FLOT treatments as an outpatient, using a small portable pump for the 5-FU 24 hour infusion or you may be admitted to the hospital. You and your study doctor will decide which setting is best for you. If you are treated in the outpatient setting: 5-FU is given through a small, portable infusion pump that you wear at home. Depending on certain factors, the pump can be disconnected by a nurse who comes to your home, or you might come back to your doctor's office to have the pump disconnected.

  Each cycle lasts 14 days. You will receive 4 cycles before surgery and 4 cycles after surgery. All patients will receive Atezolizumab on day 1 of each cycle of chemotherapy.

  Following the completion of chemotherapy and Atezolizumab you will get Atezolizumab for 6 cycles on day 1 of every 21-day cycle.
- There will be about 120 persons in this group

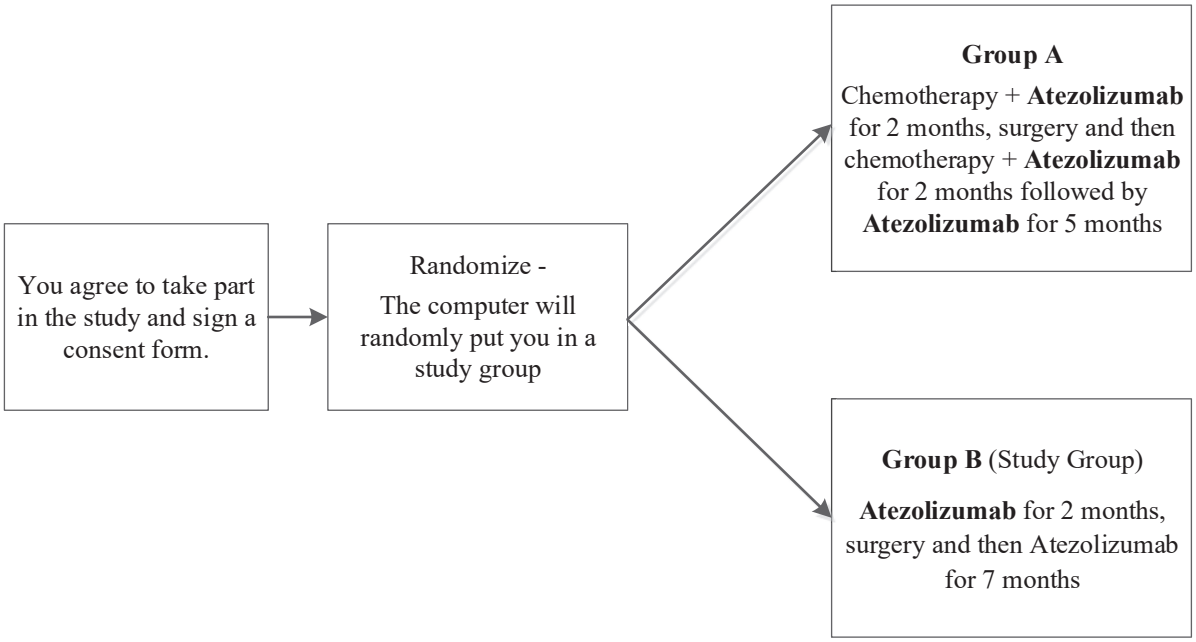
Group B:

- If you are in this group, you will get a study drug called atezolizumab on day 1 of every 21-day cycle. Atezolizumab will be given by vein over about 1 hour the first time you get it. If you don't have an allergic reaction, each time after that will take about 30 minutes on day 1 of every 21-day cycle. You will get atezolizumab for 3 cycles before surgery and for 9 cycles after surgery.
- There will be about 120 persons 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.

Another way to find out about your treatment 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. This helps your doctors 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. Most of these are included in the usual care you would get even if you were not in a study.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects.

These exams, tests, and procedures to monitor your safety and health include:

- Blood counts done weekly during the first cycle of treatment.
- Thyroid testing done every other cycle.

Your tissue was tested and was found to have 'deficient DNA mismatch repair'. This enables you to enroll on the study and start treatment. A sample of your gastric or GEJ cancer tissue that was collected during your diagnosis and at surgery is required to be sent to a central laboratory. There will be no additional procedures you need to complete for this required tissue collection and future analysis.

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 drugs may not be as good as the usual approach for your cancer at shrinking or stabilizing your cancer.

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 atezolizumab and chemotherapy 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 6 months after the last dose of chemotherapy (for male patients with partners of childbearing potential).

Side Effect Risks

The immunotherapy and chemotherapy used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. 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 drugs.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. Some side effects may make it hard for you to have children.
4. 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 the 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.

Study Group A – Possible side effects of mFOLFOX, CAPOX, and FLOT chemotherapy are listed in the tables below. These drugs are part of the usual approach for treating this type

of cancer:

Possible Side Effects of FOLFOX (Leucovorin, 5-Fluorouracil, Oxaliplatin)

(Table Version Date: February 12, 2021)

COMMON, SOME MAY BE SERIOUS In 100 people receiving FOLFOX (Leucovorin, 5-Fluorouracil, Oxaliplatin), more than 20 and up to 100 may have:
• Infection, possibly in the blood, especially when white blood cell count is low • Bruising, bleeding • Anemia which may require a blood transfusion • Diarrhea, nausea, vomiting, constipation, loss of appetite • Sores in mouth which may cause difficulty swallowing • Swelling and redness at the site of the medication injection • Numbness, pain and tingling of the arms, legs, fingers, and/or toes • Tingling or a loss of feeling in your hands, feet, nose, or tightness in throat or jaw, or difficulty swallowing or breathing which may be made worse by exposure to cold (may occur more than 14 days after administration of the drug) • Difficulty walking, using your hands, opening mouth, talking, with balance and hearing, smelling, eating, sleeping, emptying the bladder (may occur more than 14 days after administration of the drug) • Hand-foot syndrome (palmar-plantar erythrodysesthesia) redness, pain or peeling of palms and soles • Rash, increased risk of sunburn, itching, blisters on the skin, dry skin • Tiredness • Pain • Fever, cough

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving FOLFOX (Leucovorin, 5-Fluorouracil, Oxaliplatin), from 4 to 20 may have:
• Chest pain • Abnormal heartbeat which may cause fainting • Stroke, which may cause paralysis, weakness, headache • Blockage of the airway which may cause shortness of breath, cough, wheezing • Swelling of the body which may cause shortness of breath • Altered mental status, confusion, disorientation, intense feelings of joy, difficulty walking and balancing, coma

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving FOLFOX (Leucovorin, 5-Fluorouracil, Oxaliplatin), from 4 to 20 may have:
• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Bleeding from multiple sites including vaginal bleeding, bleeding of the testis, or bleeding of the brain • Internal bleeding which may cause black tarry stool, blood in vomit or urine, or coughing up blood • Blood clot which may cause swelling, pain, shortness of breath • Liver damage which may cause yellowing of eyes and skin • Visual disturbances, abnormal eye movement, discomfort from light, and watering eyes • Hearing loss • Sores in stomach which may cause belly pain • Damage to the muscles which may cause muscle pain, dark red urine • Muscle weakness • Inability to move shoulder or turn head • Weight loss, dehydration • Dizziness, headache • Changes in taste, voice • Change in skin or nails • Hair loss

RARE, AND SERIOUS In 100 people receiving FOLFOX (Leucovorin, 5-Fluorouracil, Oxaliplatin), 3 or fewer may have:
• Heart attack or heart failure, which may cause shortness of breath, swelling of ankles, and tiredness • Brain damage, Posterior Reversible Encephalopathy Syndrome, which may cause headache, seizure, blindness • Scarring of the lungs • Stevens-Johnson syndrome which may cause severe skin rash with blisters and peeling which can involve the mouth and other parts of the body

Possible Side Effects of Docetaxel

(Table Version Date: April 29, 2021)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Docetaxel, more than 20 and up to 100 may have:
• Swelling of the body • Infection, especially when white blood cell count is low • Anemia which may require blood transfusions • Vomiting, diarrhea, nausea • Sores in mouth which may cause difficulty swallowing • Tiredness • Fever • Pain in muscles • Watering, itchy eyes • Hair loss • Change in nails • Rash, itching

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Docetaxel, from 4 to 20 may have:
• Abnormal heart rate • Chest pain • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Bruising, bleeding • Liver damage, which may cause yellowing of eyes and skin, swelling • Constipation, bloating, weight loss • Numbness, pain, and/or tingling of the arms and legs, fingers, and/or toes • Change in taste

RARE, AND SERIOUS In 100 people receiving Docetaxel, 3 or fewer may have:
• Damage of the bone marrow, caused by chemotherapy, which may lead to cancer of bone marrow (leukemia) • Stevens-Johnson syndrome which may cause severe skin rash with blisters and peeling which can involve mouth and other parts of the body

Patients should be aware that Docetaxel may cause them to become intoxicated from the alcohol it contains. Patients should avoid driving, operating machinery, or performing other activities that are dangerous within one to two hours after the infusion of Docetaxel. In

addition, some medications, such as pain relievers and sleep aids, may interact with the alcohol in the Docetaxel infusion and worsen the intoxicating effects.

Possible Side Effects of Oxaliplatin

(Table Version Date: January 25, 2021)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Oxaliplatin, more than 20 and up to 100 may have:
• Infection, possibly in the blood, especially when white blood cell count is low • Bruising, bleeding • Anemia which may require blood transfusions • Diarrhea, nausea, vomiting, constipation, loss of appetite • Numbness, pain and tingling of the arms, legs, fingers, and/or toes • Tingling or a loss of feeling in your hands, feet, nose, or tightness in throat or jaw, or difficulty swallowing or breathing which may be made worse by exposure to cold (may occur more than 14 days after administration of the drug) • Difficulty walking, using your hands, opening mouth, talking, with balance and hearing, smelling, eating, sleeping, emptying the bladder (may occur more than 14 days after administration of the drug) • Tiredness • Pain • Fever, cough

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Oxaliplatin, from 4 to 20 may have:
• Abnormal heartbeat or change in heart rhythm which may cause fainting • Blockage of the airway which may cause shortness of breath, cough, wheezing • Swelling of the body which may cause shortness of breath • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Bleeding from multiple sites including vaginal bleeding, bleeding of the testis, or bleeding of the brain • Internal bleeding which may cause black tarry stool, blood in vomit or urine, or coughing up blood • Liver damage which may cause yellowing of eyes and skin • Hearing loss • Sores in throat or mouth which may cause difficulty swallowing • Changes in taste, voice • Damage to the muscles which may cause muscle pain, dark red urine

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Oxaliplatin, from 4 to 20 may have:
• Muscle weakness • Inability to move shoulder or turn head • Abnormal body movement including the eye and eyelid • Dizziness, headache • Weight loss, dehydration • Hair loss

RARE, AND SERIOUS In 100 people receiving Oxaliplatin, 3 or fewer may have:
• Brain damage, Posterior Reversible Encephalopathy Syndrome, which may cause headache, seizure, blindness • Scarring of the lungs

Possible Side Effects of Capecitabine

(Table Version Date: October 17, 2019)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Capecitabine, more than 20 and up to 100 may have:
• Infection, especially when white blood cell count is low • Bruising, bleeding • Anemia which may require blood transfusions • Diarrhea, loss of appetite, nausea, vomiting • Sores in mouth which may cause difficulty swallowing • Swelling of the body • Pain • Feeling of "pins and needles" in arms and legs • Tiredness • Fever • Blisters on the skin • Redness, pain or peeling of palms and soles

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Capecitabine, from 4 to 20 may have:
• Abnormal heartbeat • Constipation • Blurred vision, dry or itchy eyes • Muscle spasms, body aches • Restlessness, irritability • Swelling of face, fingers and lower legs • Difficulty with balancing

RARE, AND SERIOUS In 100 people receiving Capecitabine, 3 or fewer may have:
• Damage to the heart • Internal bleeding which may cause blood in vomit or black tarry stools • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Difficulty speaking, walking or seeing

Study Group A and B – Patients who are in this study may experience the side effects of atezolizumab as listed below:

Possible Side Effects of Atezolizumab

(Table Version Date: September 14, 2023)

COMMON, SOME MAY BE SERIOUS In 100 people receiving atezolizumab (MPDL3280A), more than 20 and up to 100 may have:
• Tiredness • Infection

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving atezolizumab (MPDL3280A), from 4 to 20 may have:
• Anemia which may require blood transfusion • Diarrhea, nausea, vomiting • Difficulty swallowing • Fever • Flu-like symptoms including body aches

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving atezolizumab (MPDL3280A), from 4 to 20 may have:

- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Reaction during or following a drug infusion which may cause fever, chills, rash
- Loss of appetite
- Pain in back
- Cough, shortness of breath, stuffy nose
- Itching, acne, rash

Atezolizumab (MPDL3280A) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may 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.
- Pain in belly
- Pain or swelling of the joints
- Rash that develops on skin, nails, scalp and inside of mouth or vagina that may be painful

RARE, AND SERIOUS

In 100 people receiving atezolizumab (MPDL3280A), 3 or fewer may have:

- Bruising, bleeding

Atezolizumab (MPDL3280A) may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may include but are not limited to:

- Heart problems including swelling and heart failure. Symptoms and signs of heart problems may include: shortness of breath, swelling of the ankles and body.
- A condition with high blood sugar which leads to tiredness, frequent urination or excessive thirst.
- 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.
- 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.
- Damage to organs in the body when the body produces too many white cells

RARE, AND SERIOUS In 100 people receiving atezolizumab (MPDL3280A), 3 or fewer may have:
• Swelling of the brain (meningitis/encephalitis), which may cause: headache, confusion, sleepiness, seizures, and stiff neck. • Abnormal movement of the facial muscles • Swelling of the spinal cord • Problem of the muscle, including swelling, which can cause muscle pain and severe muscle weakness sometimes with dark urine. • Problem of the nerves that can cause paralysis. Signs and symptoms may include: numbness, tingling of hands and feet; weakness of the arms, legs. • 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. • Lung problems (pneumonitis and pleural effusion). Symptoms may include: new or worsening cough, chest pain, shortness of breath. • Skin: blisters on the skin, including inside the mouth (can be severe), rash with blisters, skin rash developing 1-8 weeks after a drug is given, which may be accompanied by fever, lymph node swelling and organ failure.

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: Do not get pregnant or breastfeed while taking part in this study and for 5 months after the last dose of atezolizumab and for 9 months after the last dose of chemotherapy. **For men:** Do not father a baby while taking part in this study and for 6 months after the last dose of chemotherapy. **For all:** Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 9 months after your last dose of study drug.

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 cost of tests, exams, and procedures that you get during the study to monitor your safety, and prevent and treat side effects.
- The cost of getting the atezolizumab ready and giving it to you.
- The cost of chemotherapy and supportive care medications.
- Your insurance co-pays and deductibles.

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.

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.

There are organizations that may look at or receive copies of some of the information in 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. This would include any organization helping the company with the study.
- The NCI Central 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).

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now 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 study doctor[s]*) at (*insert 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. The 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 the studies for any reason, you can still take part in the main study.

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

Optional Sample Collections for Laboratory Studies and/or Biobanking 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.

Unknown future studies

If you choose to take part in this optional study, tissue from your surgery, blood samples, and tissue from a biopsy should your cancer recur, will be collected and stored. Storing samples for future studies is called "biobanking." 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 blood and/or tissue 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 these optional sample collections?

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

1. About 3-4 tablespoons of blood will be collected from a vein in your arm after completing neoadjuvant therapy, after surgery but prior to adjuvant therapy, at the end of treatment, at 6, 12, and 24 months after the end of treatment, and in the event of disease progression or recurrence. These samples will be collected at the same time the blood samples to monitor your health are collected, and should not require an additional stick. If you agree to allow samples to be collected and submitted for research, you can still say no at any time point we are asking for research samples to be submitted.
2. Your sample 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.
3. 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.
4. 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. Rarely, an infection can occur.
- Collection of a sample of your tumor tissue from the biopsy or from the surgery that you had when your cancer was first discovered does not require additional procedures or tests. The tumor tissue from your biopsy or surgery has already been removed.
- Generally, hospitals will keep some of your blood. This blood may be used to help treat your cancer in the future. There is a small risk that when this blood sample is submitted to the biobank for this optional sample collection, your blood could be used up. 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 or 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:

1. They will remove identifiers, such as your initials, from your sample 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.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.
4. 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 sample that remains 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:

Samples for unknown future studies:

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. I also agree to take part in any additional studies where I circled "yes".

Participant's signature _____

Date of signature _____

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

Date of signature _____