# Informed Consent/Authorization for Participation in Research

**Title of Research Study:** Magrolimab and cetuximab with pembrolizumab or docetaxel for recurrent/metastatic head neck squamous cell carcinoma

**Study Number:** 2022-0903

**Principal Investigator:** Renata Ferrarotto

_____ _____
Participant's Name Medical Record Number

## ***Key Information***

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

### *Why am I being invited to take part in a research study?*

You are invited to take part in a research study because you have a type of cancer called Head Neck Squamous Cell Carcinoma (HNSCC).

### *What should I know about a research study?*

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

### *Why is this research being done?*

The goal of this clinical research study is to learn if magrolimab, along with a combination of commercially-available drugs (cetuximab, pembrolizumab, and docetaxel) can help to control HNSCC in combination with other drugs. The safety of magrolimab will also be studied.

**This is an investigational study.** Magrolimab is not FDA approved or commercially available. It is currently being used for research purposes only. The study doctor can explain how magrolimab is designed to work.

## *How long will the research last and what will I need to do?*

You are expected to be in this research study for up to 2 years, or until the study doctor decides it is no longer safe for you to continue.

You will be given a combination of cetuximab and the investigational drug magrolimab, along with either pembrolizumab or docetaxel, depending on your cancer. You will be asked to attend all study visits; this includes screening visit(s), 3-4 study visits every 21 days, and follow-up visits.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

## *Is there any way being in this study could be bad for me?*

Magrolimab may cause low blood cell counts (red blood cells). A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion. Other risks include nausea, vomiting, diarrhea, chills, fatigue, fever, infusion-related reaction, loss of appetite, and headache. Additionally, other risks may include unforeseeable side effects.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

## *Will being in this study help me in any way?*

The study drugs may help to control the disease. Future patients may benefit from what is learned. However, it cannot be promised that there will be any benefits to you or others from taking part in this research.

## *What happens if I do not want to be in this research?*

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Instead of being in this research study, you may receive standard-of-care treatments, including pembrolizumab, or supportive care. These alternative treatments have risks and benefits that may be the same or different than those in this research study. The

study doctor can discuss these alternative treatments, including their risks and benefits with you.

Your alternative to participating in this research study is to not participate.

# ***Detailed Information***

The following is more detailed information about this study in addition to the information listed above.

## *Who can I talk to if I have questions or concerns?*

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 713-745-6774.

This research has been reviewed and approved by an Institutional Review Board (IRB – an ethics committee that reviews research studies). You may talk to them at (713) 792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

## *How many people will be in this study?*

It is expected about 61 people at MD Anderson will be enrolled in this research study.

## *What happens if I agree to be in this research?*

**Screening Tests**
Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will help the doctor decide if you are eligible:

- You will have a physical exam
- Routine blood tests. If you can become pregnant, blood (about 1/2 a teaspoon) will be drawn for a pregnancy test. To take part in this study, you must not be pregnant.
- You will have an EKG to check your heart function.
- You will have imaging scans (such as CT scans, MRIs, or PET-CT scans) to check the status of the disease. If you have had these scans done within the last 28 days, the results of those scans can be used instead.
- If the study doctor thinks it is safe to do so, you will have a biopsy taken for biomarker testing. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drugs. The study doctor will tell you what kind of

biopsy you will have, and any risks. If you have leftover tissue available from a recent procedure, that tissue may be collected instead, and you will not have a biopsy. This will be discussed with you.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other treatment options will be discussed with you.

## Study Groups

If you are found to be eligible to take part in this study, you will be assigned to a study part based on your disease. Your doctor will tell you which group you will be in.

If you are enrolled in Cohort A, you will receive magrolimab and cetuximab along with pembrolizumab.

If you are enrolled in Cohort B, you will receive magrolimab and cetuximab along with docetaxel.

Treatment on this study is given in 3 phases: Staggered Phase, Induction Phase, and Maintenance Phase. Depending on which Cohort you are enrolled in, your treatment schedule will be slightly different.

- During **Staggered Phase**, Cohort A will receive magrolimab 1 time each week for 3 weeks (1 study cycle) and pembrolizumab 1 time during the 3-week study cycle. Cohort B will receive magrolimab and cetuximab 1 time each week during the 3-week study cycle.
- During **Induction Phase**, Cohort A will receive 1 cycle of magrolimab and cetuximab given 1 time each week and pembrolizumab given 1 time during the 3-week cycle. Cohort B will receive magrolimab, docetaxel, and cetuximab 1 time each week for 2-4 study cycles.
- During **Maintenance Phase**, Cohort A will receive magrolimab and cetuximab every 2 weeks and pembrolizumab every 6 weeks, during each 6-week maintenance cycle. Cohort B will receive magrolimab and cetuximab every 2 weeks during the maintenance cycle.

## Study Drug Administration

Each study cycle is **21 days**.

You will receive the study drugs by vein:

- You will receive magrolimab every week over about 3 hours on **Day 1** of **Cycle 1**, and over about 2 hours on all other days.
- You will receive cetuximab every week over about 2 hours on **Day 1** of **Cycle 1**, and over about 1 hour on all other days.
- If you are in Cohort A, you will receive pembrolizumab over about 30 minutes every 3 weeks.

- If you are in Cohort B, you will receive docetaxel over about 1 hour every week.

**Study Visits**

Each day that you receive study treatment, you will be observed and your vital signs will be checked.

At **most study visits**, you will have procedures that are part of routine doctor visits. This may include questions about your medical history, medication use, and/or side effects. Your ability to perform everyday tasks may also be recorded.

***Staggered and Induction Phase Study Visits***
The number of Induction Phase cycles you complete will depend on which cohort you are assigned.

Blood (about 4-5 tablespoons) will be drawn for research testing for biomarkers before receiving treatment on Day 1 of Cycle 1, 2, and 3. Biomarkers are found in the blood/tissue and may be related to your body's response to the study drug. At any point that the disease gets worse, this blood draw will be repeated.

On **Day 1 of each cycle**:
- You will have a physical exam.
- Blood will be drawn for routine laboratory tests

On **Day 1** of **Cycle 1**, you will receive magrolimab.

On **Day 2** of **Cycle 1**:
- If you are in Cohort 1, you will receive pembrolizumab.
- If you are in Cohort 2, you will receive cetuximab.

On **Day 8** of **Cycle 1**, you will have blood drawn for a blood level test. This test will check for low red blood cell counts (anemia).

On **Day 8 and Day 15** of **Cycle 1**:
- You will receive a physical exam.
- You will receive magrolimab.
- You will receive cetuximab if you are in Cohort 2.

On **Day 1** of **Cycle 2** and **Cycle 3**:
- You will receive magrolimab.
- You will receive cetuximab.
- If you are in Cohort 1, you will receive pembrolizumab.
- If you are in Cohort 2, you will receive docetaxel.

On **Day 8** and **Day 15** of **Cycles 2-4**:
- You will receive a physical exam.

- You will receive magrolimab.
- You will receive cetuximab.
- If you are in Cohort 2, you will receive docetaxel.

On **Day 1** of **Cycle 3-4 (Cohort 2 only)**:
- You will receive magrolimab.
- You will receive cetuximab.
- You will receive docetaxel.

**Every 6 weeks**, you will have the same imaging scans you had at screening.

***Maintenance Phase Study Visits***

During the Maintenance Phase, every treatment cycle is 6 weeks long.

On **Day 1 of each maintenance cycle**:
- You will have a physical exam.
- Blood will be drawn for routine safety tests and thyroid function tests. If you can become pregnant, part of this blood sample will be used for a pregnancy test.
- You will have the same imaging scans you had at screening to check the status of the disease.

On **Days 15 and 29 of each maintenance cycle**, blood will be drawn for routine safety tests and thyroid function tests.

**End-of-Treatment**
After you stop receiving the study drugs:
- You will have a physical exam.
- Blood (about 2-3 tablespoons) will be drawn for routine tests.

**Follow-Up**

You (or your family members or designees) may be contacted by telephone or in writing or by electronic mail or during clinic visits after the end of study treatment for collection of long-term follow-up data. The study staff may ask if they can continue collecting the results of routine care from your medical record.

## *What are my responsibilities if I take part in this research?*

If you take part in this research, you will be responsible for attending all clinic visits and following all study rules.

## *What happens if I say yes, but I change my mind later?*

You can leave the research at any time; it will not be held against you.

If you decide to withdraw, tell the study doctor so they can help you safely stop study treatment. It may be dangerous to suddenly stop.

The study staff may ask if they can continue collecting the results of routine care from your medical record.

If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

All laboratory and clinical data gathered in this protocol will be stored in a password protected database. All patient information will be handled using anonymous identifiers. Linkage to patient identity is only possible after accessing a password-protected database. Access to the database is only available to individuals directly involved in the study.

## *Is there any way being in this study could be bad for me? (Detailed Risks)*

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Side effects will vary from person to person, and some may occur after you have stopped receiving treatment. Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs/procedures.

Magrolimab, cetuximab, pembrolizumab, and docetaxel may cause low blood cell counts (red blood cells, platelets, and/or white blood cells):

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.
- A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

**Magrolimab Side Effects**

**This is an early study of magrolimab so the side effects are not well known**. Based on human studies, magrolimab may cause:

| | | |
|---|---|---|
| • fatigue<br>• fever<br>• chills<br>• headache<br>• destruction of red blood cells<br>• abnormal blood test (possible increased risk of bleeding and/or problems with blood clotting)<br>• low blood levels of potassium (possible weakness and/or muscle cramps) | • nausea/vomiting<br>• diarrhea<br>• constipation<br>• abdominal pain<br>• loss of appetite<br>• darkening or change in the color of urine<br>• low blood cell counts (red, white, platelets)<br>• abnormal liver tests (possible yellowing of the skin and/or eyes)<br>• back pain<br>• infusion reaction (possible fever, headache, chills, skin rash, swelling, and/or nausea/vomiting) | • immune reaction (possible loss of drug function and/or kidney damage)<br>• breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)<br>• difficulty breathing<br>• cough |

Magrolimab attaches itself to your red blood cells, which may cause older cells to die (causing anemia), especially at the beginning of the treatment. In a few patients treated with magrolimab, anemia or the effects of anemia have been life-threatening or fatal. Sudden deaths have occurred during or shortly after initial treatment doses. The study doctor will test your blood for anemia before each magrolimab infusion and a few hours after you start the first and second infusion of magrolimab. Your blood may be tested more often if the study doctor thinks it is needed. If you experience severe anemia, the study doctor may recommend a blood transfusion to increase the number of your red blood cells before and/or after receiving magrolimab. The study doctor may also stop treatment altogether with magrolimab.

It is important that you tell the study doctor about any past known or suspected cardiovascular (heart) disease and any related symptoms, including but not limited to, chest pain, difficulty breathing, and swelling of the lower limbs before participating in the study. These conditions may increase your risk of side effects from anemia.

The study drug can also make the red blood cells "sticky." In severe cases, the blood becoming sticky could cause kidney and/or lung failure, headaches, changes in vision, changes in mental status, or multi-organ failure.

Magrolimab may affect some of the tests used to determine your blood type. This may require that special additional testing be performed on your blood if you were to need a blood transfusion for any reason. For any non-emergency blood transfusion, you will be

required to come to MD Anderson where the appropriate testing can be performed. In the event of an emergency and you are taken to another hospital, the emergency doctors should contact the magrolimab study doctor right away. It is possible that the study drug may change the blood type test, which means you could receive the wrong type of blood during a transfusion. This could result in a serious, life-threatening reaction.

## Cetuximab Side Effects

### Common (occurring in more than 20% of patients)

| | | |
|---|---|---|
| • fatigue/lack of energy<br>• headache<br>• difficulty sleeping<br>• fever<br>• skin rash (possibly acne-like), peeling, and/or itching<br>• dry skin<br>• nail changes<br>• low blood levels of magnesium (possible weakness and/or seizures)<br>• weight loss | • dehydration<br>• constipation<br>• diarrhea<br>• mouth blisters/sores (possible difficulty swallowing)<br>• vomiting<br>• nausea<br>• abnormal liver tests (possible liver damage)<br>• weakness | • pain<br>• nerve damage (loss of sensory function)<br>• difficulty breathing<br>• cough<br>• sore throat<br>• infection<br>• severe rash at the site of previous radiation<br>• |

### Occasional (occurring in 3-20% of patients)

| | | |
|---|---|---|
| • confusion<br>• depression<br>• anxiety<br>• chills/shivering<br>• | • abnormal taste<br>• upset stomach<br>• joint/bone pain<br>• | • immune reaction<br>• infusion reaction (possible chills and/or hives)<br>• |

### Rare but serious (occurring in fewer than 3% of patients)

| | |
|---|---|
| • inflammation of the membranes around the spinal cord and brain (possible headache and/or coma) | • severe skin reactions, such as a very severe blistering skin disease (loss of large portion of skin and/or ulcers of the skin and digestive tract) |

It is possible that if you experience side effects from magrolimab and cetuximab, you may not be able to receive pembrolizumab. Your study doctor will tell you if it is in your best interest to receive pembrolizumab if you have received magrolimab and cetuximab.

## Docetaxel Side Effects

### Common (occurring in more than 20% of patients)

| | | |
|---|---|---|
| • swelling<br>• nerve damage (loss of motor or sensory function)<br>• fever<br>• hair loss (partial or total)<br>• skin rash/itching<br>• nail changes | • mouth blisters/sores (possible difficulty swallowing)<br>• diarrhea<br>• nausea<br>• vomiting<br>• low blood cell counts (red, white, platelets) | • weakness<br>• muscle pain<br>• lung problems (possible shortness of breath)<br>• infection<br>• allergic reaction |

### Occasional (occurring in 3-20% of patients)

| | | |
|---|---|---|
| • low blood pressure (possible dizziness/fainting)<br>• nerve damage (affecting movement)<br>• painful or abnormal skin sensations<br>• abnormal sensation (such as pins and needles)<br>• abnormal taste<br>• low platelet counts | • abnormal liver tests (possible liver damage and/or yellowing of the skin and/or eyes)<br>• severe weakness<br>• joint pain<br>• reaction affecting muscle and nerve function | • infusion-site reactions (such as darkening of the skin, inflammation, redness, dryness, drug leakage from the injection site, and/or vein inflammation/ swelling)<br>• life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure) |

### Rare but serious (occurring in fewer than 3% of patients)

| | | |
|---|---|---|
| • lymphedema (swelling of arms/legs)<br>• fast/irregular heartbeat<br>• chest pain/tightness (possibly due to heart trouble)<br>• heart attack/failure<br>• high blood pressure<br>• blood clots in a vein (possible pain, swelling, and/or redness)<br>• loss of consciousness<br>• fainting<br>• seizure<br>• very severe blistering skin disease (with ulcers of the skin and digestive tract)<br>• very severe blistering skin disease (loss of large portion of skin)<br>• hand-foot syndrome (palms of hands/soles of feet having pain, swelling, and blistering)<br>• severe hardened skin (possible difficult movement)<br>• allergic skin reaction<br>• skin reaction at previous injection site | • severe sunburn-like rash at site of previous radiation (called radiation recall)<br>• abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure)<br>• digestive system bleeding<br>• intestinal blockage<br>• hole in the intestines (possibly leaking contents into the abdomen)<br>• decreased blood flow to part of the bowel (possibly causing death of tissue)<br>• small intestine ulcer<br>• abnormal blood clotting<br>• DIC (breakdown of the blood clotting system) (possible severe bleeding, organ dysfunction, and/or organ failure)<br>• liver damage/failure<br>• blockage of the tear ducts (possible teary eyes)<br>• swelling under the central part of the retina (possible vision loss) | • eye disorder (possible vision loss)<br>• hearing loss<br>• kidney failure<br>• decreased kidney function<br>• difficulty breathing (possibly due to narrowing of the airways)<br>• fluid in or around the lung (possible difficulty breathing)<br>• blockage in the lung (possible pain and/or shortness of breath)<br>• lung damage/inflammation (possible difficulty breathing)<br>• breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)<br>severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)<br>• lupus (an immune system disease)<br>• multiorgan failure |

Docetaxel may rarely cause you to develop another type of cancer (such as acute myeloid leukemia, myelodysplastic syndrome [a type of blood cancer], non-Hodgkin's Lymphoma, and kidney cancer).

**It is not known how often the following side effects may occur:**

| | | |
|---|---|---|
| • severe heart problems<br>• vein inflammation | • fatigue | • lightening or darkening of nails |

Docetaxel contains alcohol and may cause you to feel drunk. You should avoid driving, operating heavy machinery, or performing other activities that are dangerous for 1-2 hours after your dose of docetaxel. Certain drugs, such as pain relievers and sleep aids, may make this side effect worse.

There may be a higher chance of death from docetaxel in people with certain medical histories. Your doctor can discuss this with you.

**Pembrolizumab Side Effects**

**Common (occurring in more than 20% of patients)**

| | | |
|---|---|---|
| • fatigue<br>• fever<br>• skin rash and/or itching<br>• abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure) | • high blood sugar (possible diabetes)<br>• high blood levels of fat (possible heart disease and/or stroke)<br>• loss of appetite<br>• nausea<br>• constipation<br>• diarrhea<br>• abdominal pain | • abnormal liver test (possible liver damage)<br>• pain<br>• abnormal kidney test (possible kidney damage)<br>• cough<br>• difficulty breathing |

Pembrolizumab may commonly cause low blood cell counts (red, white, and/or platelets):

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
- A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.
- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.

**Occasional (occurring in 3-20% of patients)**

| | | |
|---|---|---|
| • swelling (face/arm/leg)<br>• irregular heartbeat<br>• headache<br>• confusion<br>• patches of skin color loss | • overactive thyroid gland (possible weight loss, diarrhea, mood swings, difficulty sleeping, heart rate changes, and/or sweating) | • weakness<br>• nerve damage (possible numbness, pain, and/or loss of motor function)<br>• difficulty breathing |

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|---|---|---|
| • underactive thyroid gland (possible weight gain, heart failure, and/or constipation) | • low blood sugar<br>• weight loss<br>• fluid in the abdomen<br>• blood in the urine<br>• vomiting<br>• abnormal liver test (possible yellowing of the skin and/or eyes) | (possibly due to lung inflammation)<br>• flu-like symptoms<br>• infusion reaction (possible dizziness, low blood pressure, nausea, pain, and/or difficulty breathing) |

**Frequency Unknown**

| | | |
|---|---|---|
| • heart failure<br>• heart attack<br>• build-up of fluid around the heart (possible heart failure) | • abnormal connections or passageways between organs or vessels<br>• bleeding in the rectum and/or uterus | • blockage in the lung (possible pain and/or shortness of breath)<br>• nosebleed<br>• coughing up blood |

**Rare but serious (occurring in fewer than 3% of patients)**

| | | |
|---|---|---|
| • low blood pressure (possible dizziness/fainting)<br>• heart inflammation<br>• build-up of fluid in the tissue around the heart<br>• blood vessel inflammation (possible bleeding, skin rash, numbness/weakness, fever, weight loss, fatigue, and/or bruising, depending on where the inflammation occurs)<br>• seizure<br>• immune system damage to the nervous system (causing muscle weakness, numbness and/or paralysis)<br>• spinal cord inflammation (possible pain, weakness, loss | • low hormone blood levels (possible weakness, bone changes, and/or cramping)<br>• hormonal deficiency that affects the body's ability to control blood pressure and react to stress<br>• pituitary gland inflammation (possible headaches)<br>• inflammation of the thyroid gland (possible tenderness in the neck)<br>• diabetes requiring insulin<br>• severe high blood sugar due to uncontrolled diabetes<br>• decreased production of adrenal hormones (possible weakness | • inflammation inside the eye (possible vision problems)<br>• kidney inflammation (possible kidney damage/failure)<br>• kidney failure<br>• build-up of fluid around the lungs<br>• immune response that causes the body to attack itself (possible organ damage)<br>• multi-organ disease causing lesions, most often in the lungs (sarcoidosis)<br>• immune response (causing muscle weakness)<br>• immune system reaction (possible fever, jaundice, liver/spleen enlargement, |

| | | |
|---|---|---|
| of feeling or movement, and/or paralysis)<br>• brain inflammation (possible paralysis and/or coma)<br>• shedding, scaling and/or inflammation of the skin (possible fatal loss of bodily fluids)<br>• large skin blisters<br>• very severe blistering skin disease (loss of large portion of skin and/or with ulcers of the skin and digestive tract) | and/or low blood pressure)<br>• inflammation of the pancreas (possible abdominal pain)<br>• inflammation of the intestines (possibly with a hole in the intestines, which may lead to contents leaking into the abdomen)<br>• anemia due to destruction of red blood cells<br>• liver damage (hepatitis) | irritability, and/or seizures)<br>• severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)<br>• Vogt Koyanagi Harada syndrome -- pigmented tissue (possible eye pain/swelling and changes in vision, hearing loss, and/or white patches on the skin)<br>• inflammation/scarring of the bile ducts (tubes that carry digestive fluid that is made in the liver), which may cause liver damage, stomach pain, yellowing of the skin/eyes, fatigue, and/or itching |

If you have a solid tumor type and you have an organ transplant, pembrolizumab may increase your risk for the transplant to be rejected by your body.

If you receive pembrolizumab as an injection, you may experience pain, itching, swelling, redness, rash and other reactions at the injection site.

Pembrolizumab works by boosting the immune system. This may cause unknown side effects resulting from your immune system attacking your organs. This may cause inflammation and inflammation-related side effects in any organ or tissue. These side effects can affect more than one of your normal organs and tissues at the same time.

**Using the study drugs together** may cause side effects that are not seen when each is given alone. The study drug combination may also increase the frequency and/or severity of the side effects listed above.

## Other Risks

**Blood draws** may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn.

Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

**EKGs** may cause discomfort while lying on the exam table, and the tape on the EKG pads may cause skin irritation.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.
The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

**CT scans** send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

A **PET scan** may cause you to feel “closed in” while lying in the scanner. However, the scanner is open at both ends and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or technicians will give comfort or the scanning will be stopped.

The PET scan exposes your body to radiation. The radioactive solution does not remain in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

The radioactive solution used in PET-CT scans may rarely cause side effects like uncomfortable feeling of warmth, nausea/vomiting, and/or allergic reactions, especially for those who may have an iodine allergy. Please discuss this with the study team.

**Confidentiality Risk:** Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

**Pregnancy Related Risks**

Taking part in this study can result in risks to an unborn or breastfeeding baby, which are currently unforeseeable, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications: You should use either 2 barrier methods or a barrier method in combination with a hormonal method of birth control. The study doctor can discuss acceptable methods with you.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant will result in your removal from this study.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

## *Will it cost anything to be in this study? Will I be paid to be in this study?*

Magrolimab, cetuximab, and either pembrolizumab or docetaxel (whichever you receive) will be provided to you at no cost.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your

insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

You will not receive any compensation for taking part in this study.

## *What happens to the information collected for the research?*

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. The results of this research may be published. However, your name and other identifying information will be kept confidential.

Federal law provides additional protections of your medical records and related health information. These are described below.

## *Will my data or samples be used for future research?*

As part of the study, a tissue and blood sample repository will be created. The objective of this biospecimen sample repository will be to provide material for future evaluations of other relevant biomarkers that may be associated with clinical outcomes. Some of the de-identified tissue, blood, and oral rinse samples might be transferred to outside vendors for biomarker analysis. Samples will be banked at MD Anderson. If a subject withdraws consent to the use of donated samples, the samples will be disposed of/destroyed, and the action documented.

Your personal information and/or samples are being collected as part of this study. These data and/or samples may be used by researchers at MD Anderson, Gilead Sciences, or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD

Anderson, the researchers must get approval from the MD Anderson IRB before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

You will not receive any financial benefit or other type of benefit (such as goods or services) associated with the development of any new therapies developed from the use of your samples, which may be of commercial value.

## *Can I be removed from the research study without my permission?*

The person in charge of the research study or the sponsor can remove you from the research study without your approval. The sponsor reserves the right to terminate the study at any time for any reason (including safety).

## *What happens if I get hurt from being in this study?*

If you get sick or hurt and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic when you are sick or hurt). If you get hurt or sick and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)
- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form or show them your participant card)
- call the study doctor (Dr. Renata Ferrarotto, at 713-745-6774) or MD Anderson at 713-792-2121 (24-hours)

You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. Costs of treatment received because you were hurt or sick will be billed to you or your insurance company. No other form of payment is available.

You may also contact the MD Anderson IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

## *What else do I need to know?*

This research is being funded by Gilead Sciences.

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will not contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

## Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Gilead Sciences, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study, and/or licensees of the study technology
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

## CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

## WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

## PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

**TRANSLATOR**

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

| _____ | _____ | _____ |
|---|---|---|
| NAME OF TRANSLATOR | SIGNATURE OF TRANSLATOR | DATE |

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line.)