THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Daratumumab-Based Maintenance in Patients with Relapsed Multiple Myeloma after Salvage Autologous Stem Cell Transplantation 2016-0681

Subtitle: 54767414MMY2016

Study Chair: Muzaffar H. Qazilbash

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this clinical research study is to learn if daratumumab and hyaluronidase-fihj in combination with pomalidomide can help to prevent multiple myeloma (MM) from coming back after patients have had an autologous stem cell transplant (ASCT). The safety of this drug combination after transplant will also be studied.

This is an investigational study. Daratumumab and hyaluronidase-fihj are FDA approved and commercially available for the treatment of MM. Pomalidomide is FDA approved and commercially available for the treatment of MM. It is considered investigational to give daratumumab and hyaluronidase-fihj as an injection under the skin in combination with pomalidomide after an ASCT.

The study drugs may help prevent MM from coming back. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment.

You can read a list of potential side effects below in the Possible Risks section of this consent.

You may continue taking the study drugs for as long as the doctor thinks it is in your best interest, up to a maximum of 3 years.

Daratumumab and hyaluronidase-fihj will be provided at no cost to you while you are on study. You and/or your insurance provider will be responsible for the cost of pomalidomide, the costs related to receiving the study drugs by an injection under the skin, and all other tests and procedures in this study.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive other maintenance therapy or no maintenance therapy. The study doctor will discuss the possible risks and benefits of these treatments. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

1. STUDY DETAILS

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. If you have had some of these tests recently, they may not need to be repeated:

- You will have a physical exam.
- Blood (about 3 tablespoons) and urine will be collected for routine tests and to check the status of the disease. Part of this blood draw will be used to test for Hepatitis B and C and HIV (the AIDS virus).
- You will have an EKG to check your heart function. An echocardiogram (ECHO) performed before your stem cell transplant will also be reviewed to check your heart health. However, if the study doctor thinks it is needed, you will have another ECHO.
- You will have a bone marrow aspirate and/or biopsy to check the status of the disease. To collect a bone marrow aspirate/biopsy, an area of the hip or other site is numbed with anesthetic, and a small amount of bone marrow and bone is withdrawn through a large needle.
- You will have pulmonary function testing (PFT) completed to check the function of your lungs if you have COPD or asthma.
- If the doctor thinks it is needed, you will have radiological studies, which may include a bone survey, an MRI, or a PET-CT scan to check the status of the disease. A bone survey is a series of x-rays of all or most of the bones in your body.
- If you can become pregnant, 10-14 days before starting the study drugs, blood (about 1-2 teaspoons) will be drawn for a pregnancy test. To take part in this

study, you must not be pregnant. This test will be repeated if it is believed that you may be pregnant.

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 this study, you will not be enrolled. Other treatment options will be discussed with you.

If you test positive for Hepatitis B at screening, blood (about 1 teaspoon) will be drawn to test for Hepatitis B every 12 weeks during treatment, at the end of treatment, and every 12 weeks for up to 6 months after the last dose of daratumumab and hyaluronidase-fihj.

Study Drug Administration

Each study cycle is 28 days.

If you are found to be eligible to take part in this study, 60 to 180 (+/-14) days after your transplant, you will receive 1 injection ("shot") of daratumumab and hyaluronidase-fihj in the right or left abdomen on Days 1 (+/-3 days), 8 (+/-3 days), 15 (+/-3 days), and 22 (+/-3 days) of Cycles 1 and 2, then on Days 1 (+/-3 days) and 15 (+/-3 days) for the next 4 cycles (Cycles 3, 4, 5, and 6) and then on Day 1 (+/- 7 days) of each cycle after that.

Before and after your dose of daratumumab and hyaluronidase-fihj, you will be given standard drugs to help decrease the risk of side effects. You may ask the study staff for information about how the drugs are given and their risks. The standard drugs may be discontinued (stopped) after the first 3 injections, if the study doctor thinks they are no longer needed.

You will take one capsule of pomalidomide by mouth 1 time a day on Days 1-21 of each 28-day cycle. You should take pomalidomide at about the same time each day. You must swallow the capsules whole with water, with or without food.

Do not open, break, or chew the capsules. If you touch a broken capsule of pomalidomide or the medicine in the capsule, wash the area of your body right away with soap and water.

If you vomit or miss a dose of pomalidomide within the 12 hours of the usual dosing time, take your next dose of pomalidomide as soon as possible and resume the normal daily dosing schedule. Do not "make up" the missed or vomited dose that day. If you are on hemodialysis, you should take pomalidomide after hemodialysis, on hemodialysis days.

If the study doctor thinks it is need, the doses of daratumumab and hyaluronidase-fihj and/or pomalidomide you receive may be changed.

During the study, the study team may take other actions to lower the risk of a daratumumab injection related reaction. These may include:

- Giving you supportive medications (for example, steroids, acetaminophen [Tylenol], and/or antihistamines [like Benadryl]) before the dose to lower the risk of side effects -- If you receive supportive drugs, the study team can provide information about the specific drugs you will receive and their risks.
- Pausing the dose if you have a reaction, in order to treat the symptoms, and then either restarting at a slower rate or stopping entirely, depending on the type of reaction – If this happens, your doctor will discuss alternative treatments with you.
- Giving your medications (such as inhaled steroids) after the dose if you are considered higher risk for breathing problems like COPD and asthma
- Admitting you to stay overnight in hospital after your dose, for safety monitoring

You will no longer be able to take the study drug if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

Up to 56 participants will be enrolled in this study. All will take part at MD Anderson.

Study Visits

On **Day 1 of each cycle**:

- You will have a physical exam.
- Blood (about 3 teaspoons) will be drawn for routine tests
- If you can become pregnant, blood (about 1-2 teaspoons) will be drawn for a pregnancy test. During Cycle 1, this will be done every week. After that, this may be done every 2 weeks if you have irregular menstrual cycles.

If needed, some of the above study visits may be done remotely. Video conferences or telephone calls may replace the physical exam, if your doctor thinks it is appropriate. If some of the visits are done remotely, you will need to have your blood tests done either at a laboratory near you or at the clinic. This will be discussed with you.

Every 2-3 cycles during treatment:

- Blood (about 2 teaspoons) will be drawn to check the status of the disease.
- Urine will be collected over 24 hours to check the status of the disease. The study staff will give you a container and instructions on how to collect the urine.

Every 12 weeks or when the study doctor thinks it is needed, you will have radiological studies to check the status of the disease.

About 6 months after Day 1 of Cycle 1, you will have a bone marrow biopsy to check the status of the disease. This biopsy will be repeated 1 time a year (or more often) if your doctor thinks it is needed to check the status of the disease.

End-of-Treatment Visit

About 7 days after the last dose of study drugs:

- You will have a physical exam.

- Blood (about 3 teaspoons) will be drawn for routine tests and to check the status of the disease.
- Urine will be collected over 24 hours to check the status of the disease.
- If the doctor thinks it is needed, you will have a bone marrow aspirate/biopsy to check the status of the disease.
- If the doctor thinks it is needed, you will have a bone survey to check the status of the disease.

Follow-Up Visit

About 90 days after the last dose of study drugs:

- Blood (about 3 teaspoons) will be drawn for routine tests and to check the status of the disease.
- Urine will be collected over 24 hours to check the status of the disease.
- If the doctor thinks it is needed, you will have a bone marrow aspirate/biopsy to check the status of the disease.
- If the doctor thinks it is needed, you will have a bone survey to check the status of the disease.

If you stop receiving the study drug before the disease gets worse, your doctor will continue to perform the above tests if they think it is needed unless the disease gets worse, you start a new therapy, you withdraw consent from the study or the study ends, whichever occurs first:

- Every 4 weeks, you will have a physical exam.
- Every 8-12 weeks, blood will be drawn for routine tests and to check the status of the disease. Urine will also be collected over 24 hours to check the status of the disease.
- Every 12 weeks, you will have radiological studies to check the status of the disease.
- If the doctor thinks it is needed, you will have a bone survey to check the status of the disease.

Long-Term Follow-Up

After you have completed the end-of-treatment visit, every 12 weeks unless the disease has returned, you will meet with the study doctor during regularly schedule, routine visits or be called by a member of the study staff to discuss any new anticancer treatment you may have received. If you are contacted by phone, each call should last about 5 minutes.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects that the drug is known to cause. You should discuss these with the study doctor. 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.

Tell the study staff about any side effects you may have, even if you do not think they are related to the study drug/procedures.

Daratumumab, daratumumab and hyaluronidase-fihj, and pomalidomide may cause low blood cell counts (red blood cells, white blood cells, 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 the flu, pneumonia, upper/lower respiratory tract infection, bronchitis, shingles, and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing. If you have an infection now, have a history of frequent infections, or if you feel sick, you should tell your study doctor right away. Signs of an infection may include fatigue, headache, fever, chills, aches and pains, coughing, congestion, chest tightness, or shortness of breath.
- 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.

Daratumumab Side Effects

Daratumumab is commercially approved for the treatment of multiple myeloma and AL amyloidosis.

Not all the possible side effects and risks related to daratumumab are known. New side effects may happen. You will be watched closely, and you will receive appropriate care if side effects happen. Please tell your study doctor if you have any of the side effects described below or any other ones not listed. You will be told of any new findings that may affect your decision to continue in this study.

The following side effects are observed when daratumumab was given to patients, either alone or in combination with other drugs.

Very common side effects with daratumumab (affects 1 in 10 patients or more).

- Infection of the upper respiratory tract such as nose, sinuses throat or upper airway, including influenza and flu-like symptoms
- Infection of the lung (pneumonia)
- Infection of the lower airway (bronchitis)
- Low white blood cells (including neutrophils and lymphocytes); may increase the risk of getting an infection (see also separate section below)
- Low platelets; may increase the risk of bleeding and bruising (see separate section “Blood Cell Effects” below)
- Low red blood cells (anemia)

- Decreased potassium in the blood
- Decreased appetite
- Sleeplessness (insomnia)
- Abnormal sensation including numbness/tingling of hands, feet or limbs (sensory neuropathy, paresthesia)
- Headache
- High blood pressure
- Cough
- Shortness of breath (dyspnea), including wheezing
- Diarrhea
- Constipation
- Nausea
- Pain in the belly (abdomen)
- Vomiting
- Rash, a noticeable change in the texture or color of your skin
- Pain in the bones and muscles such as back pain or chest pain
- Joint pain
- Muscle spasms
- Swelling of hands, feet, or limbs
- Fatigue, or lack of energy
- Weakness, lack of strength
- Fever

Common side effects with daratumumab (affects 1 in 100 patients or more and fewer than 1 in 10 patients).

- Injection-related reaction (see separate section “Injection-Related Reactions” below)
- Urinary tract infection
- COVID-19
- Sepsis (a life-threatening condition that arises when the body's response to an infection injures its own tissues and organs)
- Hypogammaglobulinemia, a condition with your immune system in which not enough gamma globulin proteins (also known as antibodies) are produced. Decreases in gamma globulin proteins can increase the risk of infections
- High blood glucose levels
- Low blood calcium levels
- Loss of body fluids, also known as dehydration
- Dizziness
- Fainting
- Irregular heartbeat (atrial fibrillation)
- Fluid in lungs (pulmonary edema)
- Inflammation of the pancreas (pancreatitis)
- Itchy skin
- Chills

- Injection site reaction: local reaction reported as mild pain or a burning sensation at the site of injection in the abdominal wall. Redness and hardening of the skin at the injection site was also observed and usually disappeared within a few hours after the administration

Uncommon side effects with daratumumab (affects 1 in 1,000 patients or more and fewer than 1 in 100 patients).

- Cytomegalovirus infection (see separate section on infections below)
- Liver infection (hepatitis) in those patients who are carriers of the hepatitis B virus

Injection-Related Reactions

An antibody is a large protein that is generated as part of the normal immune system to neutralize foreign objects such as bacteria and viruses. Daratumumab is an antibody designed to specifically target and eliminate a specific harmful object in your body, in this case cancerous plasma cells. A non-local hypersensitivity reaction to daratumumab that occurs during or shortly after an administration (IV or SC) is called an injection-related reaction. It usually occurs during or within the first few hours after the start of the first administration. However, delayed reactions can happen up to 3-4 days after the administration. These reactions can be life-threatening and fatal outcomes have been reported.

Signs and symptoms of injection-related reactions may include respiratory symptoms, such as stuffy nose, cough, throat irritation, as well as chills, vomiting and nausea. Most of the observed injection-related reactions were mild or moderate, and ended by temporarily stopping the administration and/or giving medicines to treat the symptoms. Tell your doctor right away if you have above mentioned symptoms.

If you have a breathing problem now or had breathing problems in the past (like chronic obstructive pulmonary disease (COPD) or asthma), you should tell your study doctor. Also, if you start to have breathing problems while you are on the study you should tell your study doctor right away.

Severe reactions have occurred, including sinus tachycardia (fast heartbeat), narrowing and obstruction of the respiratory airway (bronchospasm), low level of oxygen (hypoxia), shortness of breath, high blood pressure, swelling in the throat and fluid in the lungs (pulmonary edema), and complaints of the eyes, such as fluid in the eye (choroidal effusion), blurry vision (acute myopia), and increased pressure in the eye or eye pain (acute angle closure glaucoma). Your study doctor and their staff will be ready to treat such a reaction in case it happens. In the future, you should tell any doctor you visit that you received daratumumab (an antibody) in this research study and if you had an allergic reaction including an anaphylactic reaction, the worst case of allergic reaction.

Anaphylactic reaction

Anaphylactic reaction is a serious allergic reaction that can develop quickly (in minutes to a few hours) and may cause death. Usually, a combination of the following side effects occurs: an itchy rash, throat or tongue swelling, shortness of breath, vomiting,

lightheadedness, and low blood pressure. This type of reaction is for example seen when one is allergic to a bee sting or certain foods like peanuts.

Please inform your doctor immediately if you experience any of these signs and symptoms.

Anaphylactic reactions were rarely reported when commercially available daratumumab was used outside of clinical trials (also called post marketing experience). The reported cases of anaphylactic reaction were believed to be a more severe form of infusion related reactions. More than 227,000 patients globally have been treated with daratumumab. Anaphylactic reaction has not been reported in clinical studies; therefore, the frequency is not known.

The sponsor will continue to monitor injection-related reactions and make changes to the way daratumumab is administered and/or recommend additional medications as necessary.

Blood Cell Effects
Daratumumab can decrease white blood cell counts which help fight infections, and blood cells called platelets which help to clot blood. Tell your healthcare provider if you develop any symptoms of infection such as fever or any symptoms of decreased platelet counts such as bruising or bleeding.

Infection
Different kinds of infection have been seen in patients receiving daratumumab. Most of them are respiratory tract infections. If you have an infection now, have a history of frequent infections, or if you feel sick, you should tell your study doctor right away. The majority of the observed infections so far were mild or moderate. Severe infection such as pneumonia from bacteria, influenza virus, respiratory syncytial virus, and COVID-19, and sepsis have also been reported. Your doctor may also recommend other medications to potentially prevent or reduce the risk of COVID-19 infection or severe infection. It is important to tell your study doctor right away if you are diagnosed with COVID-19 (even if you have no or only minor symptoms) or have been exposed to someone with COVID-19 infection. It is also important to continue general infection prevention practices such as washing hands, wearing masks, social distancing, and avoiding public transportation or travel as much as possible.

Certain infections with viruses, such as shingles (Herpes Zoster virus) and cytomegalovirus, and liver infection (hepatitis B virus) have been observed with daratumumab. Patients who have had prior exposure to hepatitis B virus are at increased risk of recurrence of the virus. Your doctor will test you for the hepatitis B virus before beginning treatment on this study, or if you are already on the study and have been receiving treatment for less than 6 months. If you test positive for the virus, you will be closely monitored for signs of infection during daratumumab treatment and until 6 months after the last dose of daratumumab, and you will be treated, if appropriate, by your doctor.

Blood transfusions:
If you need a blood transfusion, you will have a blood test first to match your blood type. Daratumumab can affect the results of this blood test. These changes can last up to 6 months after your last dose. Your doctor will therefore test your blood type before you start treatment with Daratumumab. The test result will be placed on the patient identification wallet card you will carry for this study. Please tell all your health care providers that you are using daratumumab before receiving a blood transfusion.

When daratumumab is given at the same time with other drugs, some side effects of these drugs may happen more often or may be more severe. There may be other unexpected side effects. The following addresses the side effects seen for these drugs as per reference information for these compounds.

Pomalidomide Side Effects

Common (occurring in more than 20% of patients)

• swelling (arm/leg) fatigue • nerve damage (possible numbness, pain, and/or loss of motor function) • dizziness • fever • skin rash	• 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) • constipation	• nausea • diarrhea • loss of appetite • low blood cell counts (red, white, platelet) • weakness • pain • muscle spasms • difficulty breathing

Occasional (occurring in 3-20% of patients)

• headache • anxiety • confusion • chills • difficulty sleeping • itching/dry skin • increased sweating	• high blood sugar (possible diabetes) • dehydration • weight loss/gain • vomiting • tremors • kidney failure • nosebleed	• cough • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)

Frequency Unknown, but between 1-10%

• heart attack/failure • low blood pressure (possible dizziness/fainting) • mental status change	• inflammation of the intestines • mouth blisters/sores (possible difficulty swallowing)	• broken bone(s) • collapse of bones in the spine • bacteria in the blood

• depression • walking/balance problems (possible falling)	• blood in the urine • abnormal liver tests (possible liver damage, yellowing of the skin and/or eyes)	• multiorgan failure

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

• inability to urinate • liver failure	• breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)	• allergic reaction

Pomalidomide may cause you to develop another type of cancer (such as acute myeloid leukemia, a type of blood cancer).

Pomalidomide may also cause blood-clotting events (such as deep vein thrombosis, blood clots in the lungs, heart attack, and stroke).

Progressive multifocal leukoencephalopathy (PML): At any time during or after your treatment, tell your doctor or nurse immediately if you experience: blurred vision, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion. These may all be symptoms of a serious and potentially fatal brain condition known as progressive multifocal leukoencephalopathy.

Study Drug Combination Side Effects

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 **aspirations/biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the aspiration/biopsy. An

allergic reaction to the anesthetic may occur. A scar may form at the aspiration/biopsy site.

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

X-rays send a small amount of radiation though the body. All radiation adds up over a lifetime and may increase the risk of a new cancer forming.

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.

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.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks
Taking part in this study can result in risks to an unborn or breastfeeding baby, 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: Approved birth control methods include birth control pills, injections, or implants (such as an intrauterine device [IUD] or intrauterine system [IUS]); condom or diaphragm with spermicidal foam/gel/film/cream/ suppository; or sterilization of yourself or partner.

Males: Do not donate sperm during the study and for 3 months after your last dose of study drug. It is not known if this may affect your fertility. Tell the doctor right away if your partner becomes pregnant or suspects pregnancy. If your partner/spouse becomes pregnant while you are on this study, the sponsor would like to collect information about the pregnancy. The study sponsor's contact information will be made available so that, if you and your partner wish to, you can share information about the outcome of the pregnancy with the sponsor. If you and/or your partner choose not to share this information, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

Females: If you are a woman, you must not donate eggs during the study and for 3 months after your last dose of study drug. If you become pregnant or suspect that you are pregnant, you must tell the study doctor immediately. The sponsor will ask for information about the pregnancy.

Getting pregnant will result in your removal from this study.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or Janssen Scientific Affairs, LLC. for this injury. You may also contact the Chair of MD Anderson's IRB at 713-7926477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

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.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Muzaffar H. Qazilbash, at 713-792-8750) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor who can help you safely stop study treatment. The study doctor will also decide if you need to have any visits or tests to check on your health. 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.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, Janssen Scientific Affairs, LLC., the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson. Possible reasons your participation in this study may be stopped include if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

   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 contact you to let you know what they have found.

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

9. This study is supported by: Janssen Scientific Affairs, LLC.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

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 or shared with other researchers and/or institutions for use in future research.

Before being shared for future research, every effort will be made to remove your identifying information from any data and/or samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or samples are used for future research. If this research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research
Samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

Conflict of Interest

Dr. Krina Patel (Study Co-Chair) has received compensation from Janssen as a Consultant/Scientific Advisor. The financial interests are within the limits of the conflict of interest policy.

Dr. Katayoun Rezvani (Collaborator) has received compensation from Janssen as a Scientific Advisor. The financial interests are within the limits of the conflict of interest policy.

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

- Janssen Scientific Affairs, LLC., who is a supporter of this study, and/or any future sponsors/supporters of the study
- 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.

Blood may be stored in the laboratory of our collaborator, Dr. Katayoun Rezvani who is also in the Department of Stem Cell Transplantation and Cellular Therapy at MD Anderson Cancer Center.

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