MC1785 / 17-004126

Phase II Trial of Daratumumab for Transplant-Eligible Multiple Myeloma Patients

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC1785, Phase II Trial of Daratumumab for Transplant-Eligible Multiple Myeloma Patients

IRB#: 17-004126

Principal Investigator: Sikander Ailawadhi, M.D. and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Sikander Ailawadhi, M.D.	**Phone:** (904) 953-2000 **Institution Name and Address:** Mayo Clinic Florida 4500 San Pablo Rd Jacksonville, FL 32224	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate (The RSA is independent of the Study Team)	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study
Patient Account Services	**Toll-Free:** (844) 217-9591	▪ Billing or insurance related to this research study

Other Information:

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.

A description of this clinical trial will be available on http://mayoclinic.org. This Web site will not include information that can identify you. You can search this Web site at any time.

1. Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have been diagnosed with Multiple Myeloma, received induction treatment, and are considered transplant eligible. The plan is to have about 50 people take part in this study at Mayo Clinic.

2. Why is this research study being done?

The purpose of this study is to determine the effect of daratumumab on patients with Multiple Myeloma before and after they undergo an autologous stem cell transplant.

Daratumumab is a monoclonal antibody, which works with the body's immune system to destroy tumors. Daratumumab was approved by the US Food and Drug Administration (FDA) for the treatment of patients with multiple myeloma.

3. Information you should know

Who is Funding the Study?

This study will be funded by the Mayo Clinic Division of Hematology-Oncology

Information Regarding Conflict of Interest

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

4. How long will you be in this research study?

You will be in the study for up to 3 years.

5. What will happen to you while you are in this research study?

If you agree to be in the study, you will be asked to participate in the following:

Screening Visits

During these visits, we will do some tests and procedures to see if you are eligible to take part in this research study. The Principal Investigator will review the results of these tests and procedures. If you aren't eligible, the Principal Investigator will tell you why. At this visit we will:

- Ask you about your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Draw a blood sample
- Ask you for a urine sample
- Test your [blood/urine] for pregnancy if you are a female able to become pregnant
- Bone Marrow Aspirate/Biopsy. The Bone Marrow samples will be tested to detect Multiple myeloma cells. This test is called minimal residual disease (MRD) and it will assist in understanding how much this treatment is controlling the cancer.
- Skeletal (bone) Survey. Skeletal surveys assess potential bone damage or bone deterioration caused by multiple myeloma.

Consolidation 1 (Daratumumab Therapy) – Cycles 1-2 (If stem cell transplant is delayed, you may receive 2 additional cycles of treatment)

During the Consolidation 1 portion of the trial, you will receive 16mg/kg of the Daratumumab weekly by IV infusion or 1,800 mg by subcutaneous injection during cycles 1 and 2. Clinic visits during the part of trial will also consist of the following. If your stem cell transplant is delayed, you may receive additional cycles of treatment during consolidation and maintenance. Your study doctor will let you know if these additional cycles are required:

Cycle 1, Day 1

- Blood Samples (If your labs were completed less than 14 days prior to this visit, you will not have blood collected during this visit for this study)

Cycle 1, Day 15

- Blood samples

Cycle 2 and/or 4, Day 1

- Physical exam and review of medical history
- Blood and urine samples

End of Cycle 2 and/or 4 (≤14 days prior to cycle 3)

- Physical exam and review of medical history
- Blood and urine samples
- Bone marrow aspirate/biopsy

Consolidation 2 (Autologous Stem Cell Transplant) – Cycle 3 or Cycle 5 if stem cell transplant is delayed

Cycle 3 or (Cycle 5 if stem cell transplant is delayed), Day 100

All patients enrolled in the trial after completing consolidation 1 treatment, will proceed to a Stem Cell Transplant. This portion of the study will begin within 8 weeks of completing consolidation 1 treatment. Clinic visits during this part of the trial will also consist of the following:

- Physical exam and review of medical history
- Blood and Urine Samples
- Bone marrow aspirate/biopsy

Maintenance Therapy (Cycles 4 and beyond OR Cycles 6 and beyond if stem cell transplant is delayed)

After patients complete consolidation 2 treatment, they will enter maintenance treatment within 14 days of the last consolidation 2 treatment visit. Maintenance treatment will consist of combination therapy. Patients will receive daratumumab in combination with Lenalidomide every 4 weeks for about a year and then daratumumab by itself every 3 months.

Daratumumab will be administered via 1 injection or infusion, while the Lenalidomide will be administered orally via 10mg tablets.

Clinic visits during this part of the trial will also consist of the following:

- Physical Exam and Review of Medical History
- Blood and Urine Samples
- PET Scan
- Pregnancy Test
- Bone marrow aspirate/biopsy

These exams, tests or procedures are part of regular clinical care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to the Principal Investigator.

During this period, we will also ask you to keep a pill diary for your lenalidomide tablets. Missed doses for lenalidomide are to be omitted rather than made up, unless the dose was forgotten and remembered on the same day, in which case the dose can be taken that day. Any doses missed on a particular day are not to be made up the next day. Doses that are considered to vomited are not to be made up and a mention about the time of dose and time of vomiting episode should be made in the pill diary.

Daratumumab Administration

Daratumumab can be administered via intravenous infusion or subcutaneous injection. Please discuss your options with your study doctor to determine the best method for you. Additionally, you may have the option to receive your Daratumumab treatment in your local area. Your study doctor will review this option with you as well. If you choose to be treated locally, you will still be required to return to Mayo Clinic for your study visits.

Survival Follow-Up

About 30 days after the last dose of treatment, you will be contacted by study staff to check if you have experienced any adverse events. The timing of contact may vary depending on your disease status and if you report an adverse event. Contact is as follows:

- Every 3 months until your disease progresses
- At disease progression, if applicable
- Every 6 months after disease progression
- New adverse event occurrences

After you have been enrolled in the study for 3 years, you will no longer be contacted for survival follow-up.

6. What are the possible risks or discomforts from being in this research study?

Risks Associated with Daratumumab

Likely risks of Daratumumab ***(events occurring greater than 10% of the time)***

- Infusion related reactions
- Fatigue
- Nausea
- Anemia
- Insomnia
- Anxiety
- Back pain
- Low neutrophils
- Fever
- Cough
- Low platelets
- Low lymphocytes
- Numbness/tingling of the hands, feet, or limbs
- Dizziness
- Headache
- Shortness of breath
- Nasal congestion
- Diarrhea
- Constipation
- Abdominal pain
- Decreased appetite
- Muscle spasms

- Bone pain
- Swelling of hands, feet, or limbs
- Tremor
- Weight loss
- Blurred vision
- Upper respiratory infection
- Inflammation of the airways that carry air to your lungs (bronchitis)
- Pneumonia
- Swelling of the nasal passages and the back of the throat (nasopharyngitis)
- Low potassium (hypokalemia)
- High blood sugar (hyperglycemia)

Less likely risks of Daratumumab ***(events occurring l1-10% of the time)***

- Injection site reaction
- Flu like symptoms
- Respiratory tract infection
- Shingles (Herpes Zoster)
- Sepsis (a life-threatening condition that arises when the body's response to an infection injures its own tissues and organs
- Irregular heartbeat
- Low oxygen in the body (hypoxia)
- Swelling of the throat
- Swelling of lower legs or hands (peripheral edema)
- Inflammation of lung tissue (pneumonitis)
- Fluid in lungs (pulmonary edema)
- Lung infection
- Sinusitis
- Common cold (rhinitis)
- Inflammation in the back of the throat (pharyngitis)
- Narrowing of the airways into the lungs (bronchospasm)

Rare likely risks of Daratumumab ***(events occurring less than 1% of the time)***

- Liver infection (hepatitis) in those patients who are carriers of the hepatitis B virus
- Interference with pre-transfusion blood testing
- Inflammation of the trachea (tracheitis)
- Acute sinusitis
- Bronchiolitis
- Infectious laryngitis and pharyngitis

- Rhinovirus infection
- Upper respiratory tract bacterial infection
- Infectious pneumonia
- Neutropenic sepsis (Low neutrophils that cannot fight off an infection and become septic)
- Neutropenic infections (Having an infection with low neutrophils
- Fungal infection of the mouth (oropharyngeal candidiasis)

Pregnancy Risks

The effect of daratumumab on a fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. It is not known if daratumumab passes into your breast milk. Because of these risks, women cannot take part in this study if they are pregnant or breastfeeding.

If you are a female, you must have a negative pregnancy test in order to participate in this study unless you cannot become pregnant.

Birth Control for female participants

If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below:

- Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

You must use birth control for the entire study and for at least 3 months after your last dose of study drug.

Birth Control for Male participants

If you are sexually active, and able to father a child, you must agree to use one of the birth control methods listed below:

- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Hormonal methods used by your partner, such as birth control pills, patches, injections, vaginal ring, or implants
- Intrauterine device (IUD) used by your partner
- Abstinence (no sex)

You must use birth control for the entire study and for at least 3 months after your last dose of study drug.

Infusion Related Reactions

A side effect to daratumumab may occur during or shortly after an infusion (when the medicine is given into a vein). This is called an infusion related reaction. It usually occurs with the first infusion. For the first 156 patients who were treated with the therapeutic dose of daratumumab alone about approximately half of patients (48%) had a reaction, mostly (95%) during the first infusion. Almost all of the reactions (97%) were mild or moderate, and started within 3 to 4 hours of the infusion. Tell your doctor right away if you feel dizzy, weak, nauseated, light-headed, itchy, or if you have a fever, chills, cough, throat tightening, flu-like symptoms, runny nose, sneezing, sore throat, trouble breathing, or pain (in your chest, back, abdomen, muscle or joints).

Two patients experienced a narrowing of the airways, which made it difficult to breathe, and needed to be treated at a hospital. These events happened 1 to 2 days after the second full dose infusion. These two patients had a medical history of airway problems. If you have a breathing problem now or have any history of this, or if this happens while you are on the study you should tell your study doctor right away. You may be asked to see a doctor who takes care of patients with airway diseases, and additional medicines for airway problems may be given to you. Your doctor will explain how these additional medicines should be taken.

Injection Site Reactions

Skin reactions at or near the injection site (local), including injection site reaction may occur. Symptoms may include itching, swelling, bruising, or redness of the skin. These reactions sometimes happen more than 24 hours after an injection. If this happens while you are on the study you should tell your study doctor right away.

Get emergency medical help if you have any of following: hives; wheezing; difficulty breathing; swelling of your face, lips, tongue, or throat; or pain in chest.

The manufacturer, Janssen Biotech, Inc has tried different ways of giving the infusions to lessen these reactions. The manufacturer will continue to monitor infusion-related reactions and make changes to the infusions as necessary.

In this study, the following will be done to reduce the chance of a daratumumab infusion related reaction:

- You will get medications, including steroids, acetaminophen and antihistamine, before and after the infusion
  - The infusion may be slowed down or stopped
  - At the discretion of the study doctor, you may stay overnight in hospital after the infusion so medical staff can check on you and to make sure you are monitored and managed appropriately. Your study doctor will discuss with you if an overnight stay is required.

Blood Cell Effects

Daratumumab may affect different types of blood cells.

- Low lymphocyte and monocyte levels may be seen. Lymphocytes and monocytes are types of white blood cells, which are part of the body's immune response system which fights infections. This means that while you take daratumumab, there may be a greater risk of getting an infection or getting a more severe infection. 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 include headache, fever, coughing, congestion, chest tightness, leg or arm swelling, or shortness of breath.
- Low platelet levels may be seen. Platelets help blood to clot. Low platelets may increase the risk of bleeding and bruising. No cases of bleeding have been seen so far in patients who have taken daratumumab.

Precautions (safety measures)

Allergic reactions/Anaphylaxis
Daratumumab is an antibody made from a protein. Protein drugs can cause allergic reactions (for example fever or chills, sometimes, it is very difficult to tell the difference with infusion related reactions) in some people.

Anaphylaxis is the worst type of allergic reaction, it can happen suddenly and often causes the throat to swell, an itchy rash and sometimes the blood pressure to drop. Anaphylaxis has not been seen with daratumumab so far. Your study doctor and their staff will be ready to treat such a reaction in case it happens. If this happens, you will not receive any more daratumumab infusions. You may not be able to be treated again with this type of medication. In the future, you should tell any other doctor you visit that you received daratumumab in this research study and if you had an allergic reaction.

Interference with cross-matching blood for transfusions
Daratumumab can interfere with the standard test to identify compatible blood for transfusion support for up to six months after the last infusion. The blood transfusion center needs to be

informed that you have received daratumumab so that additional steps can be taken to identify compatible blood products.

Risks Associated with Lenalidomide

Likely risks of lenalidomide *(events occurring greater than 20% of the time)*
Side effects considered serious are* ***bolded.*

- **Fatigue or feeling tired;**
- **Neutropenia** or a decrease in white blood cells that can make you more prone to infections;
- **Thrombocytopenia** or a decrease in platelets which can cause you to bruise or bleed easily and/or may require platelet transfusion;
- Constipation or difficulty moving your bowels;
- Diarrhea or loose/frequent bowel movements.

Less likely risks of lenalidomide *(events occurring less than or equal to 20% of the time)*

- **Anemia** or a decrease in red blood cells that can cause tiredness which may require red blood cell transfusion;
- Nausea;
- Loss of appetite;
- **Back pain**;
- Joint pain;
- Muscle cramps;
- Swelling of the arms and legs;
- Problems falling asleep or staying asleep;
- **Fever**;
- Cough;
- **Shortness of breath** or difficulty catching your breath;
- Upper respiratory infection**;**
- Rash;
- Itching and dry skin;
- Lack or loss of strength;
- Dizziness;
- Headache;
- Abnormal thyroid function or inflammation of thyroid gland;
- Abdominal pain and or distension;
- Gastrointestinal bleeding;
- Bowel obstruction;

- Infections involving various organs;
- Abnormalities of liver tests;
- Allergic reaction to drug;
- Abnormalities of mineral levels in blood;
- Heartburn;
- Muscle pain.

Serious side effects occurring in 1% or more of patients and not listed in bold above

- Neutropenia associated with a fever;
- Pulmonary embolism or blood clot in or around the lungs;
- Deep vein thrombosis or blood clots in a larger blood vessel;
- Atrial fibrillation or irregular heartbeat;
- Progression of the disease being studied including multiple myeloma;
- Pneumonia or an infection of the lungs;
- Sepsis or an infection of the blood;
- Dehydration;
- Kidney failure which can cause increases or decreases in the amounts of chemicals in your blood which can cause irregular heartbeats, muscle twitching, seizures, and/or death.
- Myocardial infarction (heart attack)
- Stroke (bleeding in the brain or clotting)

Rare cases of the following events have been reported:

- Angioedema- an allergic skin disease characterized by patches of swelling involving the skin and/or the lining of your nose, mouth, and gastrointestinal tract.
- Anaphylaxis- serious potentially life-threatening type of allergic reaction that may cause breathing difficulty, dizziness, low blood pressure, and loss of consciousness.
- Stevens-Johnson syndrome and toxic epidermal necrolysis- serious allergic skin reactions that begin as a rash in one area and later cover more of the body leading to detachment of the top layer of skin (could be body-wide). Medical journals have reported patients with allergic skin reaction with thalidomide who also developed the same type of reaction with lenalidomide
- Tumor lysis syndrome- metabolic complication that can occur during or without treatment of cancer. These complications are caused by the break-down products of dying cancer cells and include hyperkalemia (high potassium), hyperphosphatemia (high phosphorus), hyperuricemia and hyperuricosuria (high uric acid in blood and urine), hypocalcemia (low calcium), and consequent acute uric acid nephropathy and acute renal failure (kidney damage).

- Tumor Flare reaction- a condition that involves any of the following increase in the size of the cancerous lymph nodes, rash and slight fever.
- Rhabdomyolysis- a serious condition involving the destruction of skeletal muscle that can lead to kidney failure. Signs and symptoms include dark, red, or cola colored urine and muscle tenderness, stiffness, aching (myalgia) or weakness.
- Increase in blood levels of lipase due to inflammation of pancreas gland.
- Abnormalities of blood clotting
- Bone marrow failure
- Decrease in lymphocytes (type of white blood cells)
- Enlarged spleen
- Abnormal heart rhythms
- congestive heart failure (condition where the heart becomes weak and cannot pump enough blood to the rest of the body
- Decreased function of adrenal gland
- Decreased hearing
- Vision abnormalities
- Clotting in blood vessels of intestines
- Seizures
- Graft-versus-host disease (when transplanted donor tissue attacks the tissues of the recipient's body) - (graft vs. host disease)

Also Reported on Lenalidomide Trials But with the Relationship to Lenalidomide Still Undetermined:

- Tissue swelling - (angioedema)
- Rhabdomyolysis is a breakdown of muscle fibers. It occurs when muscle cells die and release cell contents into the blood stream. It can cause muscle pain and a number of health problems, including damage to the kidneys. If severe, this could be life threatening. - (rhabdomyolysis)

These events have the potential to be fatal.

Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking study drug. In some cases, side effects can be serious, long lasting or may never go away.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Hematological Toxicity
Lenalidomide is associated with significant neutropenia (decrease in white blood cells that help fight infection) and thrombocytopenia (decrease in platelets that help with blood clotting). You will have your blood counts checked frequently when starting treatment with lenalidomide.

Deep Vein Thrombosis and Pulmonary Embolism
Lenalidomide has demonstrated an increased risk of deep vein thrombosis (DVT, blood clot in a larger blood vessel) and pulmonary embolism (PE, a blood clot in or around the lungs) in some people with certain medical conditions. The study staff will ask you about any risk factors you may have. [If you have a history of blood clots your doctor will prescribe either heparin or coumadin for the first four months of the study treatment. The doctor may continue to prescribe the medication or aspirin for the remainder of your course of study treatment. All other patients will receive (at the discretion of the treating physician) either oral low–dose aspirin or another treatment to prevent blood clotting during study participation. Patients unable or unwilling to undergo treatment for prevention of blood clots will not be eligible to participate in this study. You will be instructed on the signs and symptoms of DVT and PE and if symptoms occur you should contact your study doctor promptly.

Second new cancers
According to researchers, patients with cancer have a higher risk of developing a second new cancer when compared to people without cancer. In clinical studies of newly diagnosed multiple myeloma, a higher number of second cancers were reported in patients treated with induction therapy (treatment as first step to reducing number of cancer cells) and/or bone marrow transplant then lenalidomide for a long period of time compared to patients treated with induction therapy and/or bone marrow transplant then placebo (a capsule containing no lenalidomide). Patients should make their doctors aware of their medical history and any concerns they may have regarding their own increased risk of other cancers.

Other Risks
If any physician other than the study doctor prescribes medication for you for another condition or you are taking any over-the-counter medications or vitamins, you must inform the study staff. This is important because the interaction of some medications may cause serious side effects.

Lenalidomide has been shown to increase the level of digoxin in the blood in some patients; please tell your doctor if you are taking digoxin.

Your condition may not get better or may become worse while you are in this study.

Risks Associated with Pregnancy

Lenalidomide is related to thalidomide. Thalidomide is a known to cause severe life-threatening human birth defects. Findings from a monkey study indicate that lenalidomide caused birth defects in the offspring of female monkeys who received the drug during pregnancy. If lenalidomide is taken during pregnancy, it may cause birth defects or death to any unborn baby. Females must not become pregnant while taking lenalidomide. You have been informed that the risk of birth defects is unknown. If you are female, you agree not to become pregnant while taking lenalidomide.

If you are sexually active and able to become pregnant, you must agree to use 2 of the birth control methods listed below:

- Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

You must use birth control or abstain from sex for 4 weeks prior to starting lenalidomide, during the entire study and for at least 4 weeks after your last dose of the drug.

Lenalidomide is detected in trace quantities in human semen according to a study. The risk to the fetus in females of child bearing potential whose male partner is receiving lenalidomide is unknown at this time. For these reasons male patients receiving lenalidomide must use a latex condom while taking lenalidomide, when temporarily stopping lenalidomide, and for 28 days after permanently stopping lenalidomide treatment during any sexual contact with a pregnant female or a female of child bearing potential even if you have undergone a successful vasectomy.

Patients should not donate blood during treatment therapy or for 56 days following discontinuation of lenalidomide.

PET Scan

For your PET scan, a radioactive drug (tracer) will be put into your body. The amount of radiation you're exposed to is small, and the risk of negative effects from it is low. But the tracer might:

- Cause a major allergic reaction, in rare instances
- Expose your unborn baby to radiation if you are pregnant
- Expose your child to radiation if you are breast-feeding

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

8. What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

9. What are the possible benefits from being in this research study?

This study may not make your health better. However, daratumumab may increase your response to the stem cell transplant. Currently the stem cell transplant is beneficial for patients with multiple myeloma but most patients eventually relapse. There is a chance daratumumab may increase your chances of having a durable remission. Durable remission is when there are no measurable signs of cancer, and there have been no signs for a reasonable length of time.

10. What alternative do you have if you choose not to participate in this research study?

You don't have to be in this study to receive treatment for your condition. Talk to the Principal Investigator or your doctor if you have any questions about any alternative treatments or procedures for your condition.

11. What tests or procedures will you need to pay for if you take part in this research study?

You and/or your insurance will need to pay for all tests and procedures that you would have as part of your clinical care. These tests and procedures are:

- The drug and drug Administration
- Routine Laboratory Tests
- Pregnancy Tests
- Bone Marrow Aspirate/Biopsy
- Physical Exams
- Imaging Procedures

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

12. Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

13. Will your information or samples be used for future research?

Your information or samples collected for this study will not be used or shared for future research studies even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

14. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. To protect the data and confidentiality of subject's data, a code will be used as an identifier. The code will be a registration number assigned specifically to the patient by Mayo Clinic. The correlating Mayo Clinic number and the patient's name for reference will be maintained in a secure database accessible by Mayo Clinic assigned research staff.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- To do the research.
- To report the results.
- To see if the research was done correctly.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts forever, unless you cancel it.

ENROLLMENT AND PERMISSION SIGNATURES

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature