MC1884 / 18-003574

Phase II Trial of Sequential Treatment of Multiple Myeloma with Antibody Therapy

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC1884: Phase II Trial of Sequential Treatment of Multiple Myeloma with Antibody Therapy

IRB#: 18-003574

Principal Investigator: Dr. Sikander Ailawadhi 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
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.

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, previously treated with daratumumab as part of their standard of care, and are considered eligible to participate. The plan is to have about 41 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 combining the drugs elotuzumab, pomalidomide and dexamethasone in patients who do not respond to daratumumab based treatment. Everyone in this study will receive the combination of elotuzumab, pomalidomide, and dexamethasone which is still experimental and isn't approved by the U.S. Food and Drug Administration (FDA). However, the FDA has allowed the use of this drug combination in this research study. We hope the information from this study will help us improve treatment for 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 Visit
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 and/or urine for pregnancy if you are a female able to become pregnant
- Bone Marrow Aspirate/Biopsy.
- PET/CT scan

Day 1 of Every Cycle (Each cycle = 28 days)

- Physical Exam
- Draw a blood sample
- Ask you for a urine sample
- Test your blood and/or urine for pregnancy if you are a female able to become pregnant
- Bone Marrow Aspirate/Biopsy (if clinically necessary)
- PET/CT scan (if clinically necessary)

Day 15 for Cycles 1-2 only

- Draw a blood sample
- Ask you for a urine sample
- PET/CT scan (if clinically necessary)

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 dexamethasone and pomalidomide tablets. Pomalidomide should be taken without food (at least 2 hours before or 2 hours after a meal). Do not open or crush capsules. Missed doses 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 be 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.

End of Treatment

- Physical Exam
- Draw a blood sample
- Ask you for a urine sample
- Test your blood and/or urine for pregnancy if you are a female able to become pregnant
- Bone Marrow Aspirate/Biopsy
- PET/CT Scan

Follow-up

After you have completed the end of treatment visit, you will be contacted by study staff to check if you have experienced any adverse events and to confirm your disease status. 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 events occurrences

After you have been followed for 3 years from the date you entered the study, no further follow-up will be required; therefore, the study staff will no longer contact you.

Treatment (Cycles 1-2)
Elotuzumab and dexamethasone will be administered by IV on Days 1, 8, 15, and 22 of Cycles 1 and 2. Each infusion may take between 45-90 minutes each. You will also take pomalidomide (oral capsule) during days 1-21 of Cycles 1-2.

Treatment (Cycles 3 and beyond)
Elotuzumab and dexamethasone will be administered by IV on Day 1 during Cycles 3 and beyond. Each infusion may take between 45-90 minutes each. In addition to receiving dexamethasone infusions, you will take an oral capsule on Days 8, 15, and 22. You will also take pomalidomide (oral capsule) during days 1-21 of Cycle 3 and beyond.

You must return to Mayo Clinic for treatment while participating in this study as administration of these drugs by any other doctor or medical facility is not allowed. In order to obtain pomalidomide, your name, address, phone, date of birth and the fact that you are participating in this trial will be disclosed to Celgene and its agents or vendors that supply pomalidomide and administer the POMALYST REMS™ program. By signing this consent form you agree to this disclosure.

Management of Infusion Reactions
In order to prevent infusion reactions, you may receive the following medications 45-90 minutes prior to your infusion:

- Acetaminophen
- Diphenhydramine
- Famotidine

You will be monitored for infusion reactions by trained study staff after each infusion. If a reaction is suspected, your infusion may be interrupted and appropriate medical measures will be taken such as administration of antiemetics, antihistamines, analgesics, corticosteroids, oxygen, ephinephrine, or any other measure deemed necessary by the study team.

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

Risks associated with Dexamethasone

Likely risks of Dexamethasone for Oral and IV Administration (DXM)

- Fluid and electrolyte disturbances

- Congestive heart failure in susceptible persons
- High blood pressure (hypertension)
- Heightened or exaggerated sense of happiness or well-being (euphoria)
- Personality changes
- Inability to remain or fall asleep (insomnia)
- Exacerbation of infection
- Exacerbation or symptoms of diabetes
- Experiencing anxiety, become paranoid, hear voices, become agitated or disoriented (psychosis)
- Muscle weakness
- Thinning of the bones and reducing bone mass (osteoporosis)
- Vertebral compression fractures
- Inflammation of the pancreas (pancreatitis)
- Inflammation of the esophagus (esophagitis)
- Ulcer in the stomach or esophagus (peptic ulcer)
- Changes in the skin (dermatologic disturbances)
- Seizures (convulsions)
- Feeling of dizziness or spinning (vertigo)
- Headache
- Endocrine abnormalities
- Changes in the eye (ophthalmic changes)
- Metabolic changes
- Itching
- Hypersensitivity reactions (allergic reaction)
- Life-threatening allergic reaction -such as difficulty breathing, low blood pressure, and/or organ failure (anaphylactic reaction)
- Withdrawal from prolonged therapy may result in symptoms including fever, myalgia and pain in joints (arthralgia).

You may experience easy bruising while using dexamethasone. If you experience frequent, unrelenting headaches or visual changes while taking dexamethasone, please let the study doctor or know as soon as possible.

<u>Risks associated with Elotuzumab</u>

Likely risks of Elotuzumab *(events occurring greater than 20% of the time)*

- Fever associated with dangerously low levels of a type of white blood cell (neutrophils)

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

- Reaction that can occur during or following the infusion of the drug. The reaction may include fever, chills, rash, low blood pressure and difficulty breathing.
- Taste changes
- Infection of the air tube from the windpipe to the lungs
- Infection in the mouth
- Change in liver or kidney function
- Lung infection
- Sinus infection
- Blood infection
- Urinary tract infection
- Skin infection
- Infection in the stomach or intestines
- Changes in the amounts of salts and minerals in the blood
- Uncontrolled trembling or shaking movements in one or more parts of your body
- Hiccups
- Feeling of sadness, worthlessness, thoughts of suicide or death (depression)
- Increased blood sugar level
- Voice changes
- Hives
- Tiredness (fatigue)
- Inability to sleep

Rare but serious risks of Elotuzumab *(events occurring less than 2-3% of the time)*

- Fast or slow heartbeat
- Chest pain due to heart problems
- Abnormal heart rhythm
- Unpleasant sensation of irregular and/or forceful beating of the heart
- Dry eyes
- Cloudiness of the eye (cataract)
- Excess gas or bloating
- Infection caused by a virus
- Neck or jaw pain
- Toothache
- Sleepiness, the state of feeling drowsy, ready to fall asleep
- Sudden severe confusion and rapid changes in brain function that occur with physical or mental illness
- Irritability; Agitation or restlessness

- Memory loss
- Inability to control the flow of urine from the bladder
- Stuffy nose
- Inflammation (swelling and redness) of the skin
- Loss of bladder control
- Formation of a blood clot that plugs the blood vessel; blood clots may break loose and travel to another place, such as the lung

Other Risks

It is also possible that your immune system could make antibodies against elotuzumab, which would limit how well it works against the myeloma.

Risks associated with Pomalidomide

Likely risks pomalidomide (greater than 10% chance this may happen):

- Decrease in the number of platelets that help your blood to clot (thrombocytopenia)
- Changes in bowel movement (constipation, diarrhea)
- Cough
- Decrease in the cells carrying oxygen to your body (anemia)
- Decreased appetite
- Fever (pyrexia)
- Low number of white blood cells (leukopenia, neutropenia)
- Muscle cramp (muscle spasms)
- Nausea
- Bone pain
- Pneumonia
- Shortness of breath (dyspnea)
- Swelling including arms and legs (edema peripheral)
- Tiredness (fatigue)

Less likely risks of pomalidomide (between a 1-10% chance that this may happen):

- Infection (bronchitis, upper respiratory tract infection, respiratory tract infection, neutropenic sepsis)
- Dizziness (vertigo)
- Vomiting
- Rash
- Abnormal shaking (tremor) changes in sensations including decreased sense of touch, burning sensation, or tingling (neuropathy peripheral)

- Sore throat (nasopharyngitis)
- Kidney not working well (renal failure)
- Confusion (confusional state)
- Abnormal blood test results (hyperkalemia, hyponatremia)
- Abnormal liver lab test (alanine aminotransferase increased)
- Less alert (depressed level of consciousness)
- Blood clots in legs or lungs (pulmonary embolism, deep vein thrombosis)
- Difficulty in passing urine (urinary retention)
- Itching (pruritus)
- Abnormally low number of red and white blood cells, as well as platelets (pancytopenia)
- Low number of white blood cells with a fever (febrile neutropenia)
- Pelvic pain).

Rare but serious risks of pomalidomide (Between 0.1-1% chance that this may happen):

- Abnormal blood test results (Hyperbilirubinemia)

Risk with Intravenous (IV) Drug Administration

Temporary irritation and bruising may occur at the infusion site. There may also be discomfort, pain, or bruising from the needle puncture. In rare cases, an infection may also occur at the site of the needle stick.

Herpes Zoster Prophylaxis

You may be at an increased risk of infection including reactivation of herpes zoster and herpes simplex viruses. For this reason, you may receive acyclovir while during study treatment and 3 months after stopping treatment.

Pregnancy Risk-Fetus or Breast Feeding

The effect of these drugs on a fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. 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 Requirements for Female participants

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)
- Partner's vasectomy (2nd method should be one of the barrier methods listed above)

You must use birth control 4 weeks prior to your first treatment, during the entire study, and for at least 4 week after your last dose of study drugs. Please do not donate any tissue or blood during this time. If you miss a period, or think you might be pregnant during the study, you must tell the Principal Investigator immediately.

Birth Control Requirements for Male participants
If you are sexually active, and able to father a child, you must agree to use the birth control method listed below:

- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)

Pomalidomide is known to appear in semen; therefore, only barrier methods (listed above) are acceptable and must be used during any sexual contact with females. You must use birth control during the entire study and for at least 4 weeks after your last dose of study drugs, even if you have undergone a success vasectomy. Please do not donate blood, tissue, or semen during this time.

If your partner thinks she might have become pregnant while you are in the study or 4 weeks afterwards, you must tell the Principal Investigator immediately. The Principal Investigator may ask for your partner's permission to collect information about the outcome of her pregnancy and her newborn. You won't have to stop taking the study drug or stop taking part in the study if your partner becomes pregnant.

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?

There are limited standard of care options available for the treatment of your disease. This study may not make your health better; however, the combination of pomalidomide, elotuzumab and dexamethasone may help to improve your disease and provide better standard of care treatment options in the future, if proven effective.

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. Your other choices include carfilzomib, ixazomib, panobinistat, or other treatments your doctor may feel is appropriate for your disease. Talk to the Principal Investigator or your doctor if you have any questions about any of these treatments or procedures.

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:

- Drugs and drug administration
- Routine Laboratory tests (blood and urine)
- Pregnancy tests
- Bone Marrow Aspirate/Biopsy
- Physical Exams
- PET/CT scans

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. 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.

Health information may be collected about you from:

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

Why will this information be used and/or given to others?

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

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- 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
201 Building 4-60
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 until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

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