The Ohio State University Consent to Participate in Research

Study Title:	**Phase I/II Study of Lenalidomide in Combination with Monoclonal Antibody MDV9300 (CT-011) in Patients with Relapsed/Refractory Multiple Myeloma**
Principal Investigator:	**Yvonne Efebera, M.D.**
Sponsor:	**The Ohio State University**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

You are being asked to take part in a research study. We are asking you to take part in this study because you have multiple myeloma (MM). There have been changes in how we treat MM, but in some patients it comes back (relapses) or it does not respond (is refractory) to treatment.

In this study, we will use a drug that is sometimes used to treat MM, lenalidomide (REVLIMID®), with an antibody, MDV9300 (previously known as CT-011), made by a drug company called Medivation Inc. Antibodies are part of your immune system; they are a type of protein that protects your body against foreign invaders, called antigens, by grabbing hold of antigens to stop them from invading. MDV9300 is a monoclonal antibody, which means that it was made in a lab; it reacts against cancer cells, including MM. We hope the MDV9300 will help your body fight MM. This antibody is a new way to treat the disease and we hope it will work with the lenalidomide to better fight the MM. In this study, we will find out if patients with your disease tolerate using lenalidomide and MDV9300 and, if so, what

the best dose is. Knowledge gained from the results of this study may help to find new types of treatment for patients with relapsed or refractory MM.

2. How many people will take part in this study?

We expect no more than 30 patients to be enrolled in the first part of the study, where we will find the maximum tolerated dose (MTD). That is the dose of the drug that has the most effect yet does not cause unacceptable side effects. Six (6) of those patients who are taking the study drug at the MTD will go on to the second part of the study, along with another 23 patients.

3. What will happen if I take part in this study?

This study only includes patients who choose to take part. You may take your time to make your decision and discuss this with your family and friends. By agreeing to take part in the study, you are agreeing to comply with the study requirements.

This study will have two parts. The purpose of the first part is to learn what the highest effective dose is for patients with the least amount of side effects. Patients who are treated at this MTD will continue into the second part of the study. The purpose of the second part of this study is to find out if there are any other side effects or risks to using MDV9300 and lenalidomide together and how effective the combination is. If your disease remains stable, you will be given the option of starting a low-dose of dexamethasone, a steroid that is commonly used by multiple myeloma patients in combination with lenalidomide.

The study calendar is organized into cycles that are 28 days long. After the first 4 cycles, or just under 4 months, your study doctor will decide whether your disease is getting better, holding steady, or getting worse. If it is getting worse, you will be removed from the study in your best health interest. This decision will happen again after 8 and 12 cycles of treatment. If your disease is stable or if it improves, you may continue study treatment for as long as your study doctor feels that it is helpful to you. You will need to come to clinic for an off-study visit at 1, 3, and 6 months after your last cycle of therapy.

Study Drugs

MDV9300

MDV9300 is an antibody that will be given to you as an infusion. This means that it will slowly be put into your body using a needle, through a vein in your arm. The first infusion may last up to 2 hours. This is so that any effects related to the infusion procedure can be controlled better. Your vital signs will be watched closely during each infusion, including temperature, blood pressure, pulse rate, and respiratory rate (a measure of your breathing). The other infusions will last about 1.25 hours each. You will have infusions every four weeks, on day 3 of the cycle. If you experience side effects related to the infusion, it may take longer than 1.25 hours to complete.

Although MDV9300 was previously thought to act via inhibition of PD-1, it has been found that this is not in fact the case.

The first three patients in the study will be given the lowest dose of MDV9300, 1.5mg/kg. If these patients tolerate the dose level, the next three patients will receive a higher dose, 3 mg/kg. If tolerated, the next group will receive 6mg/kg, the highest dose. If one patient has any unacceptable side effects from the MDV9300, the next group of three patients will receive the same dose level to determine if it is not tolerated. If it is unclear if the patients are tolerating the dose level, the same dose will be given to the next set of three patients. If two of three patients have unacceptable side effects, then the next group of patients will be dosed at a lower level. This part of the study will help us learn which dose is best for patients in that they have the least amount of side effects.

The best dose chosen from part 1 of the study will be used to treat patients in part 2 of the study. The patients who were treated on the selected dose (up to 6 in number) without their disease getting worse will continue on to the second part of the study. Another 23 patients will also participate in this second part.MDV9300MDV9300

Lenalidomide (REVLIMID®)
Lenalidomide is a capsule that you will take by mouth every day. The FDA has approved its use in combination with dexamethasone to treat MM in patients who have had at least one prior therapy. You will be given a diary to record when you take this drug. You should bring it with you to your study visits. If any dose is missed or vomited during the cycle period, it cannot be made up; instead you should skip it.

You will be given 15mg of lenalidomide on days 1-21 of the first 28-day cycle. On the first day of the second cycle, depending on how you are doing, your doctor will decide if you can move up to the next higher dose, a 5 mg increase, or if you should stay at the same level as the last cycle. This will continue for each cycle until the study doctor determines that you are not able to take a higher dose. You may remain on the same dose level or not, depending on your response to treatment.

Dexamethasone
If after 3 cycles, your disease is stable, you may be given dexamethasone, a steroid. The FDA has approved its use with lenalidomide to treat MM. This is a 40mg tablet that you will take by mouth once per week, on days 1, 8, 15, and 22 in each cycle. Based on how you tolerate the steroid, or if you are age 70 or older, your dose may be reduced to 20 mg. You will be given a diary to record when you take this drug. You should bring it with you to your study visits.

Procedures
- **Medical history:** a review of your complete medical history, including any medications you have used or are using now, and any therapies you have had
- **Physical exam:** a physical exam by your study treatment team, including vital signs
- **Status assessments:** questions about how you are feeling, to help your study doctor assess what is best for you
- **MUGA or ECHO:** an imaging test that takes pictures of your heart at specific points during each heartbeat to tell how well your heart is pumping blood

- **Electrocardiogram (ECG):** a test to measure your heart's rhythm. If the ECG shows abnormalities, the study doctor may require you to have additional ECGs through the study period.
- **Blood tests:** blood samples drawn to determine the state of your disease and later to determine how well you are responding to the study treatment.
    - Some samples will be used up during their analysis and others will be kept for longer periods of time. Blood samples will be collected every two weeks during the first two months of the study, then once a month thereafter. This will happen on the third day of each cycle, on the same day you come in for the MDV9300 infusion.
    - **Clinical laboratory evaluations (disease assessments):** blood samples that will be used to measure a protein marker in your blood to determine if your disease responds to the study drug combination
    - **Hematology and chemistry:** blood samples that will be used to measure your blood counts and blood chemistry to help determine side effects and evaluate the safety of the study drug combination. These results will be used to see if you are well enough to continue receiving the study drug combination.
- **Urine tests:** samples of urine to be collected as described. For the 24-hour urine sample, you will be provided with a collection jug to take home.
    - **Urinalysis:** a urine sample taken at the start of the study to look at substances in your urine; this measures how well your kidneys are working. Your study doctor will decide if you need to provide urine samples during the rest of the study.
    - **24 Hour urine samples:** a urine sample that will be collected over a 24-hour period of time to measure proteins in your urine
- **Bone Marrow Biopsy:** a collection of bone marrow cells from your hipbone used to measure your disease and how well it is responding to treatment. For this procedure, a numbing drug is injected into the skin over one of your hipbones. A needle is then inserted into the hipbones and a small piece of bone or fluid is removed. The procedure may be repeated to see if there are any remaining multiple myeloma cells that can be detected in the bone marrow, once you have stopped treatment, or as clinically indicated.
- **X-rays and/or Scans:**
    - **Skeletal Survey**: an X-ray will be taken of the bones of the head, spine, pelvis, arms and legs
    - **MRI and/or CT "CAT scan":** additional scans to check for signs of multiple myeloma if the results from the first scan show these are necessary. Your study doctor will decide if you need these tests during the rest of the study.
- **Patient Diary:** a paper form that you will take home to record the date, time and number of lenalidomide (capsules) and dexamethasone (tablets) taken. You should bring this with you to each visit.
- **Pregnancy Test:** a blood or urine sample will be taken to see if you are pregnant (if you are a woman who is able to become pregnant). This test will take place during the screening period and 24 hours before you are prescribed lenalidomide each time during the study. *Please read the pregnancy information in Section 6 of this consent form for more information about lenalidomide and pregnancy.*

  Lenalidomide is only available through a drug program, called REV-ASSIST. This program has requirements you must meet in order to receive a prescription for lenalidomide.

REV-ASSIST Procedures:

Females of childbearing potential:

1. You must complete two pregnancy tests before you will receive a prescription for lenalidomide. The first must be within 10-14 days of the prescription. The second must be within 24 hours of receiving it.
2. Complete and sign the REVLIMID® Patient-Physician agreement form, given to you by study staff.
3. Complete a phone survey by calling 1-888-423-5436. Completing this phone survey with authorize the study doctor to give you a prescription for lenalidomide. The survey must be completed before each and every new lenalidomide prescription during the study.
4. Agree to avoid sexual intercourse, or to use 2 different methods of birth control 4 weeks before, during, and 4 weeks after treatment with lenalidomide. You may not take lenalidomide while you are pregnant or breastfeeding.

Males:

1. You must complete and sign the REVLIMID® Patient-Physician agreement form, given to you by study staff.
2. Agree to abstinence, or to use 2 different methods of birth control 4 weeks before, during, and 4 weeks after treatment with lenalidomide, even if you have previously had a vasectomy.
3. Agree not to donate sperm 4 weeks before during, and 4 weeks after treatment.

Screening

After you have agreed to participate in the study and have signed this form, you will enter the screening part of the study, which can last up to 28 days (4 weeks) before you receive your first dose of the study drug. The following tests and procedures will be used during the screening part to determine if you are eligible to be in the study:

- Medical history, physical exam
- Medication review
- Pregnancy test (if applicable)
- MUGA or ECHO
- ECG
- Blood test
- Urine tests
- Bone marrow biopsy
- Skeletal survey
- Lenalidomide prescription: *REV-ASSIST procedures are required*

Treatment

Once it has been determined that you are able to participate in this study, you will be enrolled and begin treatment. During treatment, you will begin to take the study drug combination.

This study is split up into cycles, with each cycle lasting 28 days. The tests and evaluations during treatment are similar to those that happen during screening, but not all of them will be performed on study days. Please refer to the study treatment calendar, which can be found at the back of this consent form.

During each cycle, you will receive:

- **MDV9300** through an infusion on day 3 of the cycle, at a dose your study doctor will discuss with you. Before the infusion you will be given pain relief medication, such as Tylenol or ibuprofen, and an antihistamine, such as Benadryl, to help prevent an allergic reaction to MDV9300.
- **Lenalidomide** on days 1-21 of the cycle, at a dose your study doctor will discuss with you
- **Dexamethasone** weekly, at a dose of 40 mg, unless the study doctor decides that 20 mg is a better dose for you. Dexamethasone will be added only if your disease is stable after 3 cycles.

The following are the procedures that will occur during the first cycle of the study. The time points (days) in the study may vary by +/- 4 days to accommodate weekends, holidays, and your schedule. After the first cycle, labs will be done once with subsequent cycles. These may change slightly if the study doctor feels it is in your best interest.

Day 3: You will have a review of medical history, physical exam by the study doctor, medication review, and be evaluated for any adverse events. You will have blood tests, and a urinalysis. You will receive the first MDV9300 infusion of the cycle.

Days 4, 6, 10: You will have blood samples. You will be asked how you are feeling and if you are taking any new medications.

Day 17: You will have blood samples drawn and be asked about how you are feeling and if you are taking any new medications; provide a urine sample for urinalysis. You will also be given a new prescription for lenalidomide. Females able to have children will be required to have a pregnancy test with negative results prior to receiving this prescription.

Post-Treatment/Follow-up: Your overall response to study treatment will be evaluated at the end of 4, 8, and 12 study cycles. If your disease has progressed at any of these time points, study therapy will be stopped and you will resume treatment that is standard of care, and clinically indicated, for multiple myeloma. At the end of study treatment, you will be followed by research staff for 30 days to be monitored for any side effects.

You will have an "off-study" visit, which includes a physical exam with medical history, medication review, and questions about side effects. You will get another skeletal survey (or MRI or CT); blood and urine tests; and a bone marrow biopsy. Females who are able to become pregnant will be required to complete another pregnancy test.

If you have side effects that require you to stop being in the study, you will be monitored by study staff until the side effects go away.

The study doctor may determine that it is in your best interest, based on blood tests or side effects during a cycle, not to continue into the next cycle. In this event, you will be monitored weekly with relevant tests and procedures, until the study doctor determines that it is safe for you to proceed into the next cycle of the study.

4. How long will I be in the study?

The study may last less than 56 days (total longest time of screening period and first cycle). If your disease does not get worse, your study doctor may continue your treatment on study until he or she determines that it is not good for you. The length of time you will be in the study depends on how your body responds to the treatment, the study doctor's evaluation of the best interest of your health, and your willingness to continue with the study.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University. If you decide to stop being in the study, you will resume clinically appropriate standard of care. You will no longer receive the study medication, MDV9300. You must inform the study doctor, Dr. Efebera, or the study coordinator if you wish to stop participating in this study.

6. What risks, side effects or discomforts can I expect from being in the study?

This study is a phase I and II study, which means that we are trying to find out how this drug/antibody combination will affect people. While on this study, you are at risk for the side effects outlines below. Risks are possible side effects of study medication or another medicine, and those related to any of the study procedures. You should discuss these risks with your study doctor. In addition, if you think you may be allergic to anything or the medicines taken concurrently during the study, please inform your study doctor. Lenalidomide contains lactose, a type of natural sugar found in milk and dairy products. When a person has difficulty digesting lactose, they have lactose intolerance. Tell the study doctor if you are lactose intolerant, or not sure whether you are lactose intolerant or not.

If any discomforts or risks occur, you must tell the study doctor or study staff, even if you don't think they are related to the study drug.

Unexpected side effects may occur which have not been reported. Your study doctor will be paying particular attention to those side effects that may be more severe or occur in greater frequency as a result of the combination of the study treatment you receive. Your study doctor may decide to discontinue treatment without your agreement if the treatment is too toxic or harmful. Based on the safety information from patients already treated with MDV9300 alone or in combination with other medicines, known side effects may include, but are not limited to:

Possible Risks and Side Effects of MDV9300

These risks and side effects were reported in clinical studies involving 286 patients. Not all possible risks and side effects are known at this time. MDV9300The study doctor will inform you as soon as possible when there are new known risks of MDV9300.

Most common side effects (occurring in more than 20% of patients):

- Fatigue, feeling tired and/or weak
- Anemia, a decrease in the number of red blood cells, can lead to tiredness, weakness, or shortness of breath
- Thrombocytopenia, a decrease in the number of blood platelets that help blood clot, can lead to an increased risk of bleeding
- Respiratory infection
- Decrease in the number of white blood cells, making you more likely to get infections (bacterial, fungal, viral)
- Dry mouth
- Diarrhea

Less common side effects (occurring in less than 20% of patients):

- Pain of the extremities (in muscle in your arms, legs, feet, or hands)
- Nausea
- Edema, or swelling of the extremities (arms, legs, feet, hands)
- Sweating
- Neuropathy, or nerve damage that can cause pain
- Cough
- Difficulty breathing
- Hypotension, or low blood pressure
- Itchy skin, or rash
- Decreased hunger
- Vitiligo (patches of the skin losing their pigment)

Additional Risks of the Infusion of MDV9300:

- Shivering, shaking, or chills
- Fever
- Vomiting
- Chest pain or discomfort
- Flushing, or redness of the face
- A feeling of burning at the infusion site
- Full body rash

Possible Risks and Side Effects of Lenalidomide and Dexamethasone

Your study doctor will discuss with you the possible risks involved with the other medicines that you are required to take in this study, lenalidomide and dexamethasone, as they are commonly used to treat your type of cancer. The risks and side effects below pertain to patients who have multiple myeloma.

Dexamethasone

Most common side effects (occurring in 10-15% of patients):

- Increased appetite
- Weight gain
- Sleep disturbance
- High blood pressure
- Fluid retention
- Ankle swelling
- Bruising
- Infection
- Mood changes
- Slow wound healing
- Depression

- Hyperglycemia, or high blood sugar, which can lead to fatigue, weight loss, excessive thirst, and frequent urination

Less common side effects (occurring in 1-9% of patients):

- Loss of appetite
- Muscle twitching
- Increased thirst
- Frequent urination
- Increased perspiration
- Diarrhea
- Nausea
- Headache
- Bone thinning
- Spinal fracture, or fracture of bones
- Rapid heartbeat
- Fungal infections

Rare side effects (occurring in less than 1% of patients):

- Blurred vision
- Personality changes
- Stomach ulcers that may cause blood in vomit
- Blood in stool
- Abdominal pain

<u>Lenalidomide</u>

Most common side effects (occurring in more than 20% of patients):

- Anemia, or decrease in red blood cells, which can lead to fatigue or shortness of breath
- Constipation
- Diarrhea
- Feeling tired or weak
- Decrease in the number of white blood cells, making you more likely to get infections (fungal, bacterial, viral)
- Thrombocytopenia, or decrease in the number of blood platelets that help blood clot, can lead to an increased risk of bleeding

Less common side effects (occurring in less than 20% of patients):

- Vomiting
- Nausea, or feeling that you will vomit
- Chills
- Swelling of your hands, arms, legs, or feet (extremities)
- Fever
- Chills
- Infection
- Loss of appetite, or decrease in hunger
- Pain in your joints
- Pain in your back
- Cramps or spasms in your muscles
- Pain in your muscles
- Dizziness, or a sensation of lightheadedness, unsteadiness, or giddiness
- Headache, or pain in your head
- Difficulty sleeping or trouble falling asleep
- Cough
- Shortness of breath
- Sweating more than is usual for you
- Itchy skin
- A rash on your skin
- Sores on your skin
- Forming clumps of blood, or clots, in your bloodstream, which can break and move to other organs in your body where they can block the supply of blood and oxygen

Rare side effects (occurring in less than 1% of patients):

- Swelling and redness of the pancreas
- An allergic reaction, which can consist of swelling of the throat, difficulty breathing, extremely low blood pressure, or lack of consciousness
- Rapid killing of tumor cells which may cause abnormal electrolytes or kidney damage (called tumor lysis syndrome)
- Swelling/inflammation of the pancreas, which can lead to abdominal pain, nausea, vomiting, decreased appetite, fever, diarrhea, fast heartbeat, or difficulty breathing
- Inflammation of the lung
- Skin reaction that leads to damage and shedding of the top layer of skin with ulcers and lesions in the mucous membranes (called Stevens Johnson Syndrome)
- A more severe form of Stevens Johnson Syndrome, which can be life-threatening (called Toxic Epidermal Necrolysis Hypersensitivity)
- Swelling below the skin surface, which may include pain, itching, or welts (called angioedema)
- Liver damage or failure (called hepatotoxicity)
- Second cancers from chemotherapy treatment
- Intestinal perforation (a hole in the wall of the intestine)

Pregnancy Contraindication

Lenalidomide can cause severe and life-threatening birth defects to an embryo or fetus. If pregnancy occurs during treatment, tell the study doctor as soon as possible. If you are male and you believe your sexual partner may have become or is pregnant while you are in treatment, tell the study doctor as soon as possible. It is not known if lenalidomide is excreted in breast milk and it may have adverse effects to nursing infants.

Females of reproductive potential enrolled in this study must agree to abstain from sexual intercourse, or to use two methods of approved birth control at the same time. Approved birth control methods include tubal ligation, intra-uterine device, or hormonal (birth control pills, injections, hormonal patches, vaginal rings, or implants). If you have sexual contact with a male that has had a vasectomy, choose one other form of contraception that is considered effective, such as male latex or synthetic condoms, a diaphragm, or cervical cap.

Females enrolled in this study must also have two negative pregnancy tests prior to starting treatment with lenalidomide. The first test should be performed within 10-14 days of starting treatment. The second test should occur within/before 24 hours of starting lenalidomide treatment. Pregnancy testing will also occur each time your lenalidomide prescription is refilled by the study doctor. If you miss your menstrual cycle while on treatment or if your menstrual cycle is irregular, inform the study doctor. You will need to complete a pregnancy test.

Males enrolled in the study must agree to always use a synthetic or latex condom during any sexual contact with females of reproductive potential, even if you have had a vasectomy. Males enrolled in the study must also agree not to donate sperm, as lenalidomide will be present in semen.

Pregnancy precautions must begin at least 4 weeks prior to treatment with lenalidomide, during treatment, during dose interruptions, and 4 weeks following discontinuation of therapy. **By signing the consent form, you agree to the requirements in this section, and to the REV-ASSIST Procedures in Section 3 of this consent form.**

Female sexual partners of male study participants: Your male partner is offered to participate in a clinical research study. As a prerequisite to participate in this study your partner must agree to use a condom during intercourse. This is important because test results of the study treatment in pregnant animals indicated that the medicine could harm an unborn baby through the sperm. At the same time it is also important that you do not become pregnant while your partner is taking the medication. Therefore, you should use a highly effective method of contraception during the time your male partner receives the study treatment and thereafter for another 4 weeks. Highly effective methods of contraception are those methods of birth control that have less than 1% of unwanted pregnancy during one year, if used appropriately according to the instructions of the manufacturer.

Methods of highly effective birth control include oral, injected or implanted hormonal methods of contraception, or an intrauterine device (IUD) or intrauterine system (IUS). Intrauterine means that these birth control methods work inside of the uterus to prevent contraception.

For details on the most appropriate contraception you may talk to your regular doctor or (if your male partner agrees) with the study doctor. If you get pregnant despite taking the birth control precautions, please ask your partner to inform the study doctor as soon as possible. The study doctor will ask your permission to collect information about you, your pregnancy and your child.

Other Risks and Inconveniences

Obtaining blood samples may cause some discomfort, pain, bruising, bleeding and or puncture into the vein and the formation of a blood clot. You may feel lightheaded or faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. The amount of blood drawn is not considered to be a significant amount, and is not expected to have any significant risk to you.

The risk of a CT scan or a MRI is as follows:

- There is a slight risk of developing an allergic reaction to the contrast material. Contrast material is a substance that allows doctors to see organs and tissues inside of your body, which can help them see how your body is responding to treatment. The reaction can be mild (itching, rash) or severe (difficulty breathing or sudden shock). Death resulting from an allergic reaction is rare. Most reactions can be controlled using medication. Be sure to tell your study doctor if you have allergies of any kind, such as hay fever, iodine allergy, eczema, hives, or food allergies.
- The contrast material used during CT scanning can cause water loss or damage to the kidneys that may lead to kidney failure. This is a concern if you are dehydrated or have poor kidney function. If you have a history of kidney problems, blood tests (creatinine,

blood urea nitrogen) may be done before the CT scan to check that your kidneys are functioning properly.

- If contrast material is used, you may be at risk for kidney problems if you have diabetes, especially if you take metformin (Glucophage). You will need to stop taking metformin for a period of time before the test and resume taking it as directed by your study doctor or the radiologist.
- There is always a slight risk of damage from being exposed to any radiation, including the low levels of X-rays used for a CT scan. However, the risk of damage from the X-rays is usually very low compared with the potential benefits of the test.

With a chest X-ray, there is a slight risk of damaging cells or tissue from being exposed to radiation. However, the levels of radiation are low in a chest X-ray.

Complications related to bone marrow biopsies may include bleeding (inside or outside of the body), pain or bruising at the biopsy site, blood clots, or infection. Care will be taken to avoid these complications.

There are many drugs (prescription and over the counter medications) and dietary supplements (including what are sometimes called "complementary" or "alternative" medicines), which may interact with the experimental drugs. The study doctor will review all of the medications and supplements you are currently taking before starting these.

7. What benefits can I expect from being in the study?

There is no guarantee that this treatment will benefit you. This treatment regimen may also be harmful to you. However, the benefits could be an easing of symptoms; decrease in the amount of cancer suggestive of improvement in your cancer, prolonged disease-free remission and/or survival or increased knowledge about this cancer treatment in patients with multiple myeloma. This could benefit patients in the future.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. If you choose not to participate in this trial, other treatments you qualify for will be discussed with you. If you choose not to take part in any of those treatment options, you have the right to choose supportive care. Supportive care is when you decide not to treat your cancer, but instead decide to treat your symptoms in a manner that will keep you as comfortable as possible.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies involved in this research

- U.S. Food and Drug Administration, FDA
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices
- The sponsor supporting the study, or their agents or study monitors
- Your insurance company (if charges are billed to insurance)

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form, because the study involves the use of your protected health information.

10. What are the costs of taking part in this study?

You will receive the MDV9300 antibody free of charge. It will be supplied by the manufacturer, Medivation Inc. However, your insurance will be billed for the lenalidomide and dexamethasone you receive, and you may be responsible for the costs that your insurance company will not pay for.

You or your insurance company will be responsible for paying for procedures, tests and medications that are part of standard care for patients with your type of cancer. Specifically, ECHO scans will be billed to you or your insurance company. This is a painless test that will be used to evaluate how well your heart is working. You are responsible for any co-pays, co-insurance, and deductibles as required by your insurance company or charges your insurance company does not pay.

Participating in this research study may lead to additional costs to you. Your insurance company may not pay for costs associated with research studies like this one. Please contact your insurance company to review benefits provided by your insurance policy.

If you become sick as a result of this study, any medical care that you require will be billed to your insurance company, and you may have to pay for any medical care, including hospitalization that your insurance company does not pay for.

11. Will I be paid for taking part in this study?

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

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, notify the researcher or study doctor immediately. They will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study. Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study. You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subject research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

The study doctor may remove you from this study for any reason. Any new information about the study medicine will be given to you so you may decide to continue in the study or leave it.

You may be taken out of the study if:

1. Staying in the study would be harmful.
2. You need treatment not allowed in this study.
3. You fail to follow instructions.
4. You become pregnant.
5. The study is cancelled.

If you should decide to leave the study you should tell the study doctor or study staff. They will make sure that proper procedures are followed and a final visit is made for your safety.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact **the study doctor:**

Yvonne Efebera, M.D.
Ohio State University Wexner Medical Center
Starling Loving A346
320 West 10th Avenue
Columbus, OH 43210

614-293-3196 (during office hours)
614-293-8000 (24 hours**)**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact **Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251**. If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **the study doctor, Dr. Yvonne Efebera.**

STUDY TREATMENT CALENDAR

Study Activity	Time Point										
	Screening	Cycle1 Day3[a]	Cycle1 Day4[a]	Cycle1 Day6[a]	Cycle1 Day10[a]	Cycle1 Day17	Cycle2 Day3[a]	Cycle3 Day3[a]	Cycle5 Day3[a]	Cycle*x* Day3[a]	Off Study[b]
History, physical examination, medication review	X	X					X	X		X	X
Sign Informed Consent Form	X										
Disease evaluation by your study doctor	X										
CT or MRI[c]	X										X
MUGA or ECHO scan	X										
Pregnancy test[d]	X										
Evaluation for side effects	X	X					X	X		X	X
Blood Draw	X	X	X	X	X	X	X	X	X	X	X
12-lead Echocardiogram ECG[e]	X							X			
24hr urine test[f]	X	X[f]					X[f]	X[f]		X[f]	X[f]
Bone Marrow biopsy, one-sided[g]	X								X[g]		X[g]
MDV9300 Given		X					X	X	X	X	
Lenalidomide prescribed	X										
Pregnancy test[h]	X										
Correlative studies[i]		X	X	X	X	X	X	X	X	X	X
MDV9300 testing		X	X	X	X	X	X				

a. Timepoints have a +/- 4 day window to accommodate weekends, holidays, and for patient convenience.
b. Testing and evaluation by the study doctor will be done at 1,3,and 6 months after removal from study

c. Scans will be done at baseline and may be done if your disease progresses.
d. Females of childbearing potential must have a negative pregnancy test. This is required by the RevAssist program, to receive a prescription for lenalidomide.
e. Baseline and periodic ECGs will occur during the study. If you have an abnormal ECG, this will occur at more frequent intervals.
f. 24hr urine test will occur at screening and as required to evaluate your disease.
g. One-sided bone marrow (BM) biopsy will be done at baseline and at end of 4th cycle. If you have non-secretory multiple myeloma, it will be completed if your disease progresses.
h. Lenalidomide and dexamethsone will start on day 1 of each cycle and does not require you to be in clinic. Lenalidomide will be ordered for the next cycle. A pregnancy test will also occur at this time, in order to order more Lenalidomide through RevAssist.
i. Blood samples will be collected before, during, and after infusions to measure levels of drug in your body
j. Samples will be collected to determine how your body is responding to the study drug. This will be done within 30 minutes of the study drug infusion.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time