Informed Consent/Authorization for Participation in Research

TITLE: A Phase II trial of Mosunetuzumab, Polatuzumab, Tafasitamab, and Lenalidomide in Patients with Relapsed B-cell NHL

PROTOCOL NO.: 2022-0459

SPONSOR: MD Anderson Cancer Center

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STUDY-RELATED PHONE NUMBER(S): 713-792-3750
713-792-2121 (24 hours)

_____ _____
Participant's Name Medical Record Number

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

Key Information

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

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

You are invited to take part in a research study because you have relapsed (has returned after treatment) or refractory (has not responded to treatment) diffuse large B-cell lymphoma (DLBCL).

What should I know about a research study?

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

Why is this research being done?

The goal of this clinical research study is to learn if giving mosunetuzumab in combination with polatuzumab vedotin, tafasitamab, and lenalidomide can help to control relapsed/refractory DLBCL. Researchers also want to learn about the safety of the study drug combination.

This is an investigational study. Mosunetuzumab is not Food and Drug Administration (FDA) approved or commercially available. It is being used in this study for research purposes only. Polatuzumab vedotin, tafasitamab, and lenalidomide are all FDA approved for the treatment of certain types of lymphoma. It is considered investigational to give these drugs in combination with mosunetuzumab to treat DLBCL. The study doctor can explain how the study drugs are designed to work.

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

You are expected to receive mosunetuzumab, polatuzumab vedotin, tafasitamab, and lenalidomide for up to 6 cycles. Depending on your response to the study drugs, you may continue to receive tafasitamab and lenalidomide, with or without mosunetuzumab, for up to 1 year after the first 6 cycles. You will be in follow-up for about 2 years after your first dose of study drugs.

You will be asked to receive the study drugs and come to the clinic regularly for routine and research tests, which may include physical exams, heart function tests, imaging scans, bone marrow aspirates/biopsies, tumor biopsies, and blood draws.

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

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

Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. If you take part in this study, you may experience side effects from the study drug, some of which may be severe or life threatening.

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

Will being in this study help me in any way?

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

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

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

Instead of being in this research study, you may choose to receive the standard treatment for the disease, which may include R-CHOP chemotherapy, currently approved drugs such as polatuzumab vedotin, tafasitamab, and lenalidomide, and/or a combination or chemotherapy and other drugs. You may choose to receive other investigational therapy, if available. These alternative treatments have risks and benefits that may be the same or different than those in this research study. The study doctor can discuss these alternative treatments, including their risks and benefits with you. You may choose not to receive treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

If you decide that you don't want any more active treatment, one of your options is called "comfort care." Comfort care includes pain medication and other support. It aims to maintain your comfort and dignity rather than cure disease. Usually, this care can be provided at home.

If you think you might prefer comfort care, please discuss this with your family, friends and your doctor.

Detailed Information

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

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

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the study chair, Dr. Jason Westin, at 713-792-2933, 713-792-3750, or 713-792-2121 (24 hours).

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

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.

- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected about 36 people will be enrolled in this research study. All will take part at MD Anderson.

What happens if I agree to be in this research?

Screening Tests

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

- You will have a physical exam, including a neurological exam (tests to check the functioning of your nerves, including tests of your balance and reflexes).
- Blood (about 5 tablespoons) will be drawn for routine tests, immune system tests, and tests to check for viruses such as hepatitis B and C and HIV (the AIDS virus). State law requires positive test results for certain communicable diseases, including HIV and hepatitis, to be reported to a local health agency. This study involves these tests. The study doctor can discuss this with you.
- Urine will be collected for routine tests.
- You will have an electrocardiogram (EKG) and either an echocardiogram (ECHO) or a multiple gated acquisition (MUGA) scan to check your heart function.
- You will have imaging scans computed tomography (CT) scans, positron emission tomography (PET)/CT scans, and/or chest x-rays) to check the status of the disease.
- You will have a tumor biopsy for biomarker testing. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drugs. The study doctor will tell you what kind of biopsy you will have and its risks.
- If the study doctor thinks the disease is in your bone marrow, you will have a bone marrow aspirate/biopsy to check the status of the disease. To collect a bone marrow aspirate, an area of the hip or other site is numbed with local anesthetic, and a small amount of bone marrow is withdrawn through a large needle.
- If the study doctor thinks it is needed, you may have a spinal tap to check for disease in the spinal cord. A spinal tap (also called a lumbar puncture) is when fluid surrounding the spinal cord is removed by inserting a needle into the lower back. The affected area is numbed with local anesthetic during the procedure.
- If you can become pregnant, part of the above blood sample will be used for a pregnancy test. To take part in this study, you must not be pregnant.

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

Study Groups

If you are found eligible to take part in this study, you will be assigned to 1 of 2 parts based on when you join the study and what disease you have: the Safety Run-In part or the Dose Expansion part. Up to 6 patients will be enrolled in the safety run-in and up to 30 will be enrolled in the dose expansion.

If you are enrolled in the safety run-in, the dose level of study drugs you receive may depend on when you join the study. During the safety run-in, the study team will first test a recommended dose of mosunetuzumab, polatuzumab vedotin, tafasitamab, and lenalidomide in 3 patients with DLBCL. If no intolerable side effects are seen, they will test the recommended dose in 3 more patients with DLBCL. If intolerable side effects *are* seen with the recommended dose level, they will test a lower dose level of mosunetuzumab, polatuzumab, tafasitamab, and lenalidomide for safety.

If you are enrolled in the dose expansion, you will receive mosunetuzumab, polatuzumab vedotin, tafasitamab, and lenalidomide at the dose level that was found tolerated in the safety run-in.

Study Drug Administration
Each cycle is 28 days.

You will first receive the study drugs for 6 cycles. This will include:

- Mosunetuzumab by vein on **Days 1, 8, and 15 of Cycle 1 and Day 1 of Cycles 2-6.** The first infusion will be given over about 4 hours. If you tolerate it well, the rest of the doses may be given over about 2 hours.
- Polatuzumab vedotin by vein on **Day 1 of Cycles 1-6**. The first infusion will be given over about 90 minutes. If you tolerate it well, the rest of the doses may be given over about 30 minutes.
- Tafasitamab by vein over on **Days 16 and 22 of Cycle 1, Days 1, 8, 15, and 22 of Cycle 2 and 3, and Days 1 and 15 of Cycles 4-6.** The first infusion will be given over about 1 ½ - 2 ½ hours. If you tolerate it well, the rest of the doses may be given over about 1 ½ - 2 hours.
- Lenalidomide by mouth 1 time a day on **Days 9-18 of Cycle 1 and Days 1-14 of Cycles 2-6**

After 6 cycles, the study doctor will check the status of the disease. If you have a complete response (the disease completely goes away), you may continue to receive tafasitamab and lenalidomide as described above for up to 1 year. If you have a partial response or the disease is stable, you may continue to receive tafasitamab, lenalidomide, and mosunetuzumab as described above for up to 1 year.

You may also receive standard drugs to help reduce the risk of side effects, such as acetaminophen, aspirin or other anticoagulants (blood thinners), diphenhydramine, corticosteroids, and granulocyte-colony stimulating factor (G-CSF). You may also receive drugs to relieve side effects, such as allopurinol, rasburicase, or tocilizumab. Please ask the study doctor about these standard drugs and their risks.

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

Study Visits

About 3 days before each cycle (including before Cycle 1), blood (about 5 tablespoons) will be drawn for circulating tumor deoxyribonucleic acid (ctDNA) testing. ctDNA testing measures the amount of tumor DNA (genetic information) in your blood.

On **Days 1, 8, 15 and 22 of Cycle 1**:

- You will have a physical exam.
- Blood (about 1 tablespoon) will be drawn for routine tests.
- Blood (about 5 tablespoons) will be drawn for ctDNA testing (Day 1 only).

On **Day 1, 8, 15, and 22 of Cycles 2-3**:

- You will have a physical exam (Days 1 and 15 only).
- Blood (about 1 tablespoon) will be drawn for routine tests.
- Blood (about 5 tablespoons) will be drawn for ctDNA testing (Day 1 only)
- If you can become pregnant, part of the above blood sample will be used for a pregnancy test (Day 1 only).

At the end of **Cycle 3**, you will have a PET-CT scan to check the status of the disease.

On **Day 1 of Cycles 4-6**:

- You will have a physical exam.
- Blood (about 5-6 tablespoons) will be drawn for routine tests and ctDNA testing.
- If you can become pregnant, part of the above blood sample will be used for a pregnancy test.

On **Day 15 of Cycles 4-6**, blood (about 1 tablespoon) will be drawn for routine tests.

At the end of **Cycle 6**, you will have a PET-CT scan to check the status of the disease. If these scans show a complete response, you will continue to have PET-CT scans every 3 months for 1 year, then every 4 months for 1 year after that unless the disease gets worse. If the Cycle 6 scans do not show a complete response, you will continue to have PET-CT scans every 3 months for 2 years or until the disease gets worse. If you later achieve a complete response, you will be put on the complete response PET-CT schedule instead.

On **Day 1 of Cycles 7-12**:

- You will have a physical exam.
- Blood (about 5-6 tablespoons) will be drawn for routine tests and ctDNA testing.
- If you can become pregnant, part of the above blood sample will be used for a pregnancy test.

On **Day 15 of Cycles 7-12**:

- Blood (about 1 tablespoon) will be drawn for routine tests.

Any time the study doctor thinks it is needed:

- You will have an EKG to check your heart function.

End-of-Dosing Visit

Within **3 weeks** after the start of your final cycle of study drugs:

- You will have a physical exam.
- Blood (up to 8 tablespoons) will be drawn for routine, immune system, and ctDNA tests.
- You will have an EKG to check your heart function.
- You will have a PET/CT scan to check the status of the disease.
- If the study doctor thinks it is needed, you will have a bone marrow biopsy/aspirate to check the status of the disease.
- If you can become pregnant, part of the above blood sample will be used for a pregnancy test.

Follow-Up

Every 3 months for 1 year, then every 4 months for 1 year after that:

- You will have a physical exam.
- Blood (about up to 8 tablespoons) will be drawn for routine tests and ctDNA testing
- You will have a PET/CT scan to check the status of the disease.

After 2 years of follow-up, you will continue to have tests and procedures to check on your health as part of your standard of care. The study team may continue to collect information about your health and the status of the disease from your medical record during this time.

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

If you take part in this research, you will be responsible for the following:

- Tell the study doctor/study staff about all medications that you are taking or plan to take, including prescription and over-the-counter medications, supplements, vitamins, and herbal remedies.
- If you visit or receive medical care from another doctor, tell them that you are in another investigational research study.

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

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

You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study

at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor who can then decide if you need to have any visits or tests to check on your health. If you withdraw from this study, you can still choose to be treated at MD Anderson.

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

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

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

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

Mosunetuzumab, polatuzumab vedotin, tafasitamab, and lenalidomide may each cause low blood cell counts (red blood cells, platelets, and/or white blood cells):

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

<u>Mosunetuzumab Side Effects</u>

Very Common Side Effects (occurring in more than 10% of patients)

- low white blood cell count
- cytokine release syndrome (CRS)—This involves a release of a large amount of proteins into the blood stream. This may cause changes in blood pressure and heartbeat, low blood oxygen levels, headache and flu–like symptoms (nausea, fever, and chills), and/or affect your lung/liver/kidney function. It may also cause certain

brain–related symptoms, such as dizziness, weakness, confusion, difficulty speaking, and/or decreased brain function (possible paralysis and/or coma).

The majority of cases of CRS are mild, causing a fever that does not require medical intervention. There is a chance that high cytokine (protein) levels could lead to hospitalization, life-threatening circumstances, or even death, even though this study has been specifically designed to minimize the risk of excessive production of cytokines.

Common Side Effects (occurring in 1-10% of patients)

• headaches • dizziness • tremors • seizures • confusion • difficulty speaking • progressive multifocal leukoencephalopathy (PML – a disease with brain damage that may likely result in paralysis and/or coma, which may be permanent, or death)	• low platelet blood cell count • inflammation of the liver (possible liver damage) • reactivation of hepatitis B infection (liver damage) • liver damage • body-wide inflammation • immune system reaction (possible fever, jaundice, liver/spleen enlargement, irritability, and/or seizures)	• infection/worsening of an existing infection • tumor flare (inflammation/pain at the tumor site, shortness of breath, low blood oxygen levels, abnormal liver tests, and/or intestinal inflammation) • enlarged tumor (possible difficulty breathing and/or damage to organs near the tumor)

Mosunetuzumab may cause your immune system to develop antibodies (proteins made in the body that respond to a substance that is foreign to the body) to the drug. If you develop these antibodies, it may affect your body's ability to respond to mosunetuzumab in the future. Blood samples will be drawn to monitor for the development of these antibodies during study treatment and at your end of treatment visit.

Uncommon (occurring in less than 1% of patients)

• tumor lysis syndrome (TLS)—breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)

<u>Polatuzumab Vedotin Side Effects</u>

Common (occurring in more than 20% of patients)

• fever • abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood	• abnormal digestive blood test (possible damage/inflammation of the pancreas) • diarrhea	• abnormal liver tests (possible liver damage) • abnormal kidney tests (possible kidney damage)

pressure, organ failure, heart problems, changes in mental status, and/or seizure)	• loss of appetite • low blood cell counts (red, white, platelets)	• nerve damage (possible numbness, pain, and/or loss of motor function)

Occasional (occurring in 3-20% of patients)

• dizziness • weight loss • vomiting • joint/bone pain	• lung inflammation (possible difficulty breathing) • infusion reaction (possible chills and/or hives)	• immune response (possible loss of drug function) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)

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

• progressive multifocal leukoencephalopathy (PML – a disease with brain damage that may likely result in paralysis and/or coma, which may be permanent, or death)	• liver damage	• abnormal liver tests (possible yellowing of the skin and/or eyes) • infection (CMV, herpes, pneumonia)

<u>Tafasitamab Side Effects</u>

As of July 2024, 1092 patients have received tafasitamab in Incyte-sponsored clinical studies; 147 of the study participants received tafasitamab monotherapy (by itself). The following side effects were frequently reported in these 147 participants:

Very Common (may occur in more than or equal to 1 in 10 patients)

- Infusion-related reactions*
- Fatigue
- Diarrhea
- Headache
- Neutropenia/Neutrophil count decreased (low cell count of neutrophils, a type of white blood cells which are important for fighting off infections)
- Constipation
- Nausea (feeling sick)
- Upper respiratory tract infection
- Pyrexia (fever)

- Thrombocytopenia/platelet count decreased (low number of blood platelets, increasing risk of bleeding and bruising)
- Anemia (low red blood cell counts, may cause difficulty breathing and/or fatigue)
- Insomnia (difficulty sleeping)

*Infusion-related reactions with symptoms of shortness of breath, feeling warm, facial flushing, nausea, vomiting and dizziness, chills, headache, hypotension. To prevent this reaction, you will be given preventative medication prior to the infusion of tafasitamab. More severe reactions may occur.

Common (may occur in more than or equal to 1 in 100 patients but fewer than 1 in 10 patients)

- Chills
- Rash
- Increased ALT and AST levels (liver enzymes, only detectable in blood testing)
- Febrile Neutropenia (low number of white blood cells with fever)
- Bronchitis (inflammation of bronchi, airways, to the lungs)
- Pneumonia (lung infection)
- Neutrophil count decreased (a decrease in the number of a type of white blood cell, increased risk of infection)
- Platelet count decreased (a decrease in the number of platelets, increased risk of bleeding and bruising)

Serious side effects that may occur with study treatment include: Infusion-related reaction, febrile neutropenia (low number of white blood cells with fever), tumor lysis syndrome, and pneumonia (lung infection).

Lenalidomide Side Effects

Common (occurring in more than 20% of patients)

• swelling (arm/leg) • fatigue • fever • dizziness • skin rash/itching	• inflammation of the stomach and/or intestines • diarrhea/constipation • nausea • low blood cell counts (red, platelets, white)	• muscle cramps/spasms • weakness • pain • lung inflammation • cough • infection (including upper respiratory tract, nose, sinuses, and/or throat)

Occasional (occurring in 3-20% of patients)

• swelling • high blood pressure	• sweating • skin redness • dry skin	• kidney failure • kidney stones • runny nose

• low blood pressure (possible dizziness/ fainting) • chest pain (possibly due to heart trouble) • irregular heartbeat • blood clots in a vein (possible pain, swelling, and/or redness) • chills/shivering • headache • difficulty sleeping • abnormal sensation (such as pins and needles) • abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure)	• underactive thyroid gland (possible weight gain, heart failure, and/or constipation) • abnormal taste • dry mouth • dehydration • vomiting • weight loss • loss of appetite • abdominal pain • difficult and/or painful urination • increased risk of bleeding • numbness • nerve damage (possible loss of motor or sensory function) • abnormal liver tests (possible liver damage)	• blockage in the lung (possible pain, shortness of breath, and/or failure to breathe) • build-up of fluid around the lungs • flu-like illness • nosebleed • sore throat • pain and/or inflammation at the tumor site • allergic reaction • breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)

Lenalidomide may occasionally cause you to develop another type of cancer (such as leukemia [blood cancer], lymphoma [cancer of the lymph nodes], skin cancer, lung cancer, prostate cancer, or other solid tumors).

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

• tissue swelling • stroke • very severe blistering skin disease (with ulcers of the skin and digestive tract) • very severe blistering skin disease (loss of large portion of skin) • skin rash (possible fever/lymph node swelling/inflammation of internal	• low blood levels of sodium (possible headache, confusion, seizures, and/or coma) • inflammation of the bile tract (possible blockage) • abnormal blood test (possible heart problems) • bacteria in the blood • liver damage • reactivation of hepatitis B infection (possible liver	• low oxygen level in the blood (possible lightheadedness) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • graft-versus-host disease (when transplanted donor tissue attacks the tissues of the recipient's body) • organ transplant rejection

organs/abnormal blood cell counts) • overactive thyroid gland (possible weight loss, heart rate changes, and/or sweating)	damage) and/or herpes zoster • abnormal liver tests (possible yellowing of the skin and/or eyes)	

Lenalidomide may rarely cause problems with collecting your own stem cells which may cause you to be unable to receive certain types of stem cell transplants.

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

• fast/slow heartbeat • heart failure or other severe heart problems • shock (possibly caused by heart damage) • heart attack • decreased supply of blood to a body part (such as the heart) • enlarged heart • bleeding around the brain • abnormal blood clotting • difficulty forming or speaking words • migraine • temporary stroke symptoms • confusion • depression • loss of alertness • skin condition with fever and skin lesions • skin bump • immune response that causes an overactive thyroid gland (possible fast heartbeat, sweating, weight loss, nervousness, and/or eye bulging) • low blood sugar	• inflammation of the colon (possible abdominal pain and/or diarrhea) • digestive system bleeding • difficulty swallowing • chronic heartburn and indigestion • intestinal blockage • hole in the intestines (possibly leaking contents into the abdomen) • decreased blood flow to part of the bowel or other body part (possibly causing tissue death) • bleeding or blood in stool • pockets of pus in or near the anus • death of spleen tissue • gallbladder inflammation (possible abdominal pain) • tarry stool • blood in the urine • destruction of red blood cells (possible anemia)	• bleeding after procedures • liver failure • blockage of the bile tract (possible body yellowing and/or abdominal pain) • difficulty walking • falling • painful joint inflammation • pelvic pain • broken bones (such as leg, pelvis, hip, rib, collapsed spine bones) • build-up of bone-like crystals (calcium phosphate) in different parts of the body (possible pain and/or decreased organ function) • build-up of bodily waste products in the blood (possible kidney damage) • kidney damage • abnormal kidney tests (possible kidney damage) • abnormal growth in the kidneys • difficulty breathing, possibly due to lung damage or fluid in the lung • wheezing • worsening of disease

• inflammation of the pancreas (possible abdominal pain)		

Lenalidomide may cause serious side effects, including:

Possible birth defects (deformed babies) or death of an unborn baby.
Females who are pregnant or who plan to become pregnant must not take lenalidomide. Lenalidomide is also present in human semen at extremely low levels during treatment.

Lenalidomide is structurally related to thalidomide which is known to cause severe life-threatening birth defects. If lenalidomide is taken during pregnancy, a birth defect or the death of the unborn baby is expected.

Reactivation of viral infections:
Following treatment with lenalidomide, in patients previously infected with hepatitis B virus (HBV) and herpes zoster virus, reactivation was reported:

- Some cases of HBV reactivation progressed to acute liver failure and resulted in death. For this reason, you will be sent to a physician with expertise in the treatment of hepatitis B if you are tested positive for occult HBV infection prior to the start of study treatment. You may also be treated preventatively with antiviral medications.
- Reactivation of shingles (herpes zoster infection) led in some cases to a widespread infection with the virus, acute inflammation of the brain or eye necessitating antiviral treatment and the permanent discontinuation or temporary interruption of treatment with lenalidomide.

Second new cancers:
In clinical trials in patients with newly diagnosed multiple myeloma, an increased rate of second new cancers have been observed in patients receiving lenalidomide compared with patients not receiving lenalidomide. These new cancers included acute leukemia (blood cancers), lymph node cancers, and solid tumors and were observed in patients receiving lenalidomide together with melphalan or immediately after high dose melphalan and stem cell transplantation. An increase of blood and lymph node cancers was also seen in clinical trials in which patients received lenalidomide after stem cell transplantation. When lenalidomide is given with the corticosteroid dexamethasone, a higher number of skin cancers and solid tumors have been reported. Your study doctor will be checking you for any possible new cancers that may develop during your treatment.

Progressive multifocal leukoencephalopathy:
Cases of a serious and potentially fatal brain condition (with symptoms like blurred vision, loss of vision or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion) known as progressive multifocal leukoencephalopathy (PML) have been reported with

lenalidomide. PML has been reported several months to several years after starting the treatment with lenalidomide. Cases have generally been reported in patients taking dexamethasone and lenalidomide at the same time or in patients who had prior treatment with other immunosuppressive chemotherapy. Your study doctor will be checking you for new or worsening neurological symptoms, cognitive or behavioral signs or symptoms. You are advised to inform your partner or caregivers about your treatment, since they may notice symptoms that you may not be aware of.

If PML is suspected, further dosing will be suspended until PML has been excluded. If PML is confirmed, lenalidomide will be permanently discontinued.

For additional information on risks and side effects with lenalidomide, including frequency of side effects, please refer to the product inserts and speak to your study doctor.

Study Drug Combination Side Effects

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

Side Effects of Tafasitamab in Combination with Lenalidomide
As of July 2024, 1092 patients have received tafasitamab in Incyte-sponsored clinical studies; 244 of these 1092 study participants received tafasitamab in combination with lenalidomide. The following side effects were frequently reported in these 244 participants:

Very Common (may occur in more than or equal to 1 in 10 patients)

- Neutropenia (low cell count of neutrophils, a type of white blood cells which are important for fighting off infections)
- Anemia (low red blood cell counts)
- Diarrhea
- Cough
- Thrombocytopenia (low number of blood platelets, increasing risk of bleeding and bruising)
- Pyrexia (fever)
- Decreased appetite
- Hypokalemia (low blood potassium levels, possible weakness and/or muscle cramps)
- Constipation
- Nausea (feeling sick)
- Muscle spasms

Common (may occur in more than or equal to 1 in 100 patients but fewer than 1 in 10 patients)

- Pruritus (itching of the skin)
- Leukopenia (low cell count of leukocytes, a type of white blood cells which are important for fighting off infections)
- Peripheral edema (swelling of hands, arms, legs, and/or feet)
- Rash
- Back pain
- Fatigue
- Blood creatinine increased (abnormal kidney test, possible kidney damage)
- Vomiting
- Urinary tract infection
- C-reactive protein levels increased
- Dyspnea (difficulty breathing)
- Nasopharyngitis
- Upper respiratory tract infection
- Alanine aminotransferase increased (abnormal liver test, possible liver damage)
- Bronchitis (lung inflammation)
- Neutrophil count decreased (neutrophils decreased compared with previous value; neutrophils are a type of white blood cells which are important for fighting off infections)
- Lymphopenia (low lymphocyte counts, increased risk of infection)
- Infusion-related reaction*
- Aspartate aminotransferase increased (abnormal liver test, possible liver damage)
- Febrile neutropenia (low number of white blood cells with a fever)
- Hypertension (high blood pressure)

*Infusion-related reactions include flushing, skin reactions, itching; chest tightness; difficulty in breathing; fever or chills; severe allergic reaction; or low blood pressure. More severe reactions may occur.

Serious side effects that may occur with treatment include fever with low number of neutrophils, pneumonia, bronchitis, and lower respiratory tract infections.

Serious infections, including infections that can cause death, can occur during treatment with tafasitamab. Inform your study doctor if fever or other evidence of potential infection such as chills, cough or pain on urination.

A serious and potentially fatal brain condition (with symptoms like blurred vision, loss of vision or double vision, difficulty speaking, weakness in an arm or a leg, change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion) known as progressive multifocal leukoencephalopathy (PML) has been reported during combination therapy with tafasitamab. Your study doctor will be checking you for new or worsening neurological symptoms, including cognitive or behavioral signs and symptoms. If any

signs of PML are observed or PML is confirmed, your study doctor will initiate appropriate management.

Premedication Side Effects

Allopurinol may cause an allergic reaction, kidney failure, blood in urine, kidney stones, eye irritation, joint pain, liver damage, blistering/peeling skin rash, low white blood cells (risk of infection), low red cells (risk of fatigue, weakness, shortness of breath), or low platelets (risk of bleeding or bruising).

Rasburicase may cause nausea, vomiting, constipation, diarrhea, stomach pain, mouth sores, throat pain, fever, headache, anxiety, join pain, swelling of the hands, feet, ankles, or lower legs, pain, redness, swelling, or tenderness at the injection site. Severe or life-threatening allergies are possible.

Anticoagulants (blood thinners) may cause in short-term use, increased bleeding or bruising, swelling, increased blood pressure, and stomach upset for oral blood thinners like aspirin or pain at injection site for injected blood thinners like heparin. Serious allergic reactions are possible.

Acetaminophen may cause, rarely, nausea, vomiting, loss of appetite, rash, itching, or liver injury especially if combined with alcohol.

Corticosteroids (such as Dexamethasone and methylprednisolone) are steroids with many possible side effects that occur after prolonged use. In short term use, the more likely side effects are high blood sugar, worsening of stomach ulcers, difficulty sleeping, fluid retention and mood changes.

Diphenhydramine may cause dizziness, drowsiness, loss of coordination, dry mouth/nose/throat, upset stomach, constipation, dry eyes, blurred vision, or day-time drowsiness.

G-CSF can cause an allergic reaction, kidney problems, lung or breathing problems, dark urine, chest pain or pressure, fast heartbeat, dizziness or passing out, sweating, fast breathing, coughing up blood, purple spots or redness of the skin, swelling, numbness or tingling, bone/muscle/joint pain, headache, feeling tired or weak, hair loss, diarrhea, upset stomach, or throwing up. Enlarged or ruptured spleens have occurred with this drug. Ruptured spleens can be deadly. Call your doctor if you have left upper stomach or left shoulder pain. Swelling of the main blood vessel that comes out of the heart (aorta) has happened with this drug. Call your doctor right away if you feel very tired or weak. Call your doctor if you have fever, stomach pain, or back pain. A bone marrow problem called myelodysplastic syndrome (MDS) and a type of leukemia have happened with this drug in people who were born with low white blood cell counts. This has also happened in people with breast or lung cancer who are getting chemo or radiation. Call your doctor right away if you have a fever, feel very tired, or have unexplained bruising or bleeding.

Other Side Effects

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

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

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

MUGA scans may cause allergic reactions to the radioactive tracer, injection site soreness, and/or swelling. They may cause damage to cells or tissue from being exposed to the radiation used in the scan. These side effects may occur in less than 10% of patients.

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

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

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

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

Spinal taps may cause headaches, sensitivity of the eyes to light, nausea, vomiting, confusion, drowsiness and/or pain at the injection site. They may cause fever, infection,

and/or bleeding. Spinal taps may cause inflammation/bleeding around the brain and/or the covering of the spinal cord, which can lead to nerve damage. In rare instances, spinal taps may cause seizures, leakage of spinal fluid, and/or blockage of spinal fluid, which can lead to brain swelling. Severe infections of the spinal fluid or bleeding within the brain can result in coma and/or death. Repeated spinal taps may result in learning or memory difficulties.

Pregnancy Related Risks

Taking part in this study can result in known and unknown risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study.

Females: If you can become pregnant, you must use two (2) methods of birth control, such as birth control pills, intrauterine device (IUD), or a barrier method (such as a condom, diaphragm, or cervical cap) combined with spermicidal jelly for at least 12 months after your last dose of study drugs. You must also agree not to donate eggs during this period.

If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away. The sponsor will ask for information about the pregnancy.

Getting pregnant will result in your removal from this study.

Males: If you can father a child (even if you have had a successful vasectomy), you must use a barrier method of birth control (such as a condom) for 60 days after your last dose of mosunetuzumab, 6 months after your last dose of polatuzumab vedotin, and 3 months after your last dose of tafasitamab, and 60 days after your last dose of tocilizumab, if your partner can have a child or your partner is currently pregnant. Your partner must also use an additional birth control method, such as birth control pills, intrauterine device (IUD), barrier method, or spermicidal jelly. You must also agree not to donate sperm during this period.

Tell the doctor right away if your partner becomes pregnant or suspects pregnancy. If your partner/spouse becomes pregnant while you are on this study or within 6 months after your last dose of study drug, the sponsor would like to collect information about the pregnancy. The study sponsor's contact information will be made available so that, if you and your partner wish to, you can share information about the outcome of the pregnancy with the sponsor. If you and/or your partner choose not to share this information, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

Please note there are also additional precautions for all patients taking lenalidomide during this study. If lenalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Because of this risk, all patients taking

lenalidomide must read the following statements that apply to them according to gender and menopausal status.

FOR FEMALES WHO ARE ABLE TO BECOME PREGNANT*
*(Sexually mature female who: 1) has not undergone a hysterectomy (the surgical removal of the uterus) or bilateral oophorectomy (the surgical removal of both ovaries) or 2) has not been naturally postmenopausal for at least 24 consecutive months)

Please read thoroughly and initial each space provided if you understand each statement

_____: I understand that birth defects may occur with the use of lenalidomide. I have been warned by my doctor that my unborn baby may have birth defects and can even die, if I am pregnant or become pregnant while I am taking lenalidomide.

_____: I understand that I must NOT take lenalidomide if I am pregnant, breast-feeding a baby or able to get pregnant and not using 2 reliable methods of birth control.

_____: If I am having sexual relations with a man, my uterus and/or both ovaries have not been removed, I have had at least one menstrual period in the past 24 months and/or my menses stopped due to treatment of my disease, I understand that I am able to become pregnant. I must use one highly effective method of birth control plus one additional effective method of birth control (contraception) at the SAME TIME.

Highly Effective Methods	Additional Effective Methods
Intrauterine device (IUD)	Latex condom
Hormonal (birth control pills, injections, implants)	Diaphragm
Tubal ligation	Cervical Cap
Partner's vasectomy	

_____: These birth control methods must be used during the following time periods related to this study: 1) for at least 28 days before starting lenalidomide therapy; 2) while participating in the study; during interruptions in therapy and 3) for at least 28 days after lenalidomide has been stopped. I must use these methods unless I completely abstain from heterosexual sexual contact. If a hormone (birth control pill, injection, patch, or implant) or IUD method is not medically possible for me, I may use another highly effective method or two barrier methods AT THE SAME TIME.

_____: I know I must have a pregnancy test done by my doctor within 10 – 14 days and 24 hours prior to starting lenalidomide therapy, even if I have not had my menses due to treatment of my disease or had as little as one menstrual period in the past 24 months. If I have regular or no menstrual cycles, I will then have pregnancy tests every week for the first 28 days, then every 28 days while I am taking lenalidomide, again when I have been taken off of lenalidomide therapy and then 28 days after I have stopped taking lenalidomide. If I have irregular menstrual cycles, I will have pregnancy tests every week for the first 28 days, then every 14 days while I am taking lenalidomide, again when I have been taken off of lenalidomide therapy, and then 14 days and 28 days after I have stopped taking lenalidomide.

_____: I know I must immediately stop taking lenalidomide and inform my doctor, if I become pregnant while taking the drug, if I miss my menstrual period or have unusual menstrual bleeding, if I stop using 2 reliable forms of birth control, or if I think for any reason that I may be pregnant. I must talk to my doctor before changing any birth control methods.

_____: I am not now pregnant, nor will I try to become pregnant for at least 28 days after I have completely finished taking lenalidomide.

_____: I understand that lenalidomide will be prescribed only for me. I must not share it with ANYONE, even someone that has similar symptoms to mine. It must be kept out of reach of children and should never be given to females who are pregnant or able to have children.

_____: I agree any unused drug supply will be returned to the research site at each visit.

_____: I know that I cannot donate blood while taking lenalidomide and for 28 days after stopping lenalidomide.
Study patients who become pregnant will be monitored throughout the pregnancy and will continue to be monitored for 30 days after delivery (premature delivery, aborted fetus, full-term pregnancy, or no longer pregnant).

FOR ALL MALES
Please read thoroughly and initial each space provided if you understand each statement:

_____: I understand that birth defects may occur with the use of lenalidomide. I have been warned by my doctor that an unborn baby may have birth defects and can even die, if a female is pregnant or becomes pregnant while taking lenalidomide.

_____: I have been told by my doctor that I must NEVER have unprotected sexual contact with a female who can become pregnant. Because it is known that lenalidomide is present in semen, my doctor has explained that I must completely abstain from sexual contact with females who are pregnant or able to become pregnant, or I must use a latex condom every time I engage in any sexual contact with females who are pregnant or may become pregnant. I must do this while I am taking lenalidomide and for 28 days after I stop taking lenalidomide, even if I have had a successful vasectomy.

_____: I know I must inform my doctor if I have unprotected sexual contact with a female who is pregnant or can become pregnant or if I think, for ANY REASON, that my sexual partner may be pregnant. Female partners of male patients taking lenalidomide should be advised to call their own physician immediately if they get pregnant.

_____: I understand that lenalidomide will be prescribed only for me. I must not share it with ANYONE, even someone that has similar symptoms to mine. It must be kept out of reach of children and should never be given to females who are able to have children.

_____: I agree any unused drug supply will be returned to the research site at each visit.

_____: I know that I cannot donate blood, sperm, or semen while taking lenalidomide and for 28 days after stopping lenalidomide.

FOR FEMALES WHO ARE NOT ABLE TO BECOME PREGNANT
Please read thoroughly and initial each space provided if you understand each statement.

_____: I understand that birth defects may occur with the use of lenalidomide. I have been warned by my doctor that an unborn baby may have birth defects and can even die, if a female is pregnant or becomes pregnant while taking lenalidomide.

_____: I certify that I am not now pregnant, nor am I of child bearing potential as I have been in a natural menopause for at least 24 months (been through the change in life without even 1 menstrual period for the past 24 months); or I had my uterus removed (hysterectomy) or had both my ovaries removed (bilateral oophorectomy).

_____: I understand that lenalidomide will be prescribed only for me. I must not share it with ANYONE, even someone that has similar symptoms to mine. It must be kept out of reach of children and should never be given to females who are pregnant or able to have children.

_____: I agree any unused drug supply will be returned to the research site at each visit.

_____: I know that I cannot donate blood while taking lenalidomide and for 28 days after stopping lenalidomide.

ALL PATIENTS
You will be counseled at least every 28 days about not sharing lenalidomide (and other study drugs), the potential risks of fetal exposure, abstaining from blood and other donations, the risk of changes in blood counts and blood clots, and you will be reminded not to break, chew or open lenalidomide capsules. You will be provided with the "Lenalidomide Information Sheet for Patients Enrolled in Clinical Research Studies" with each new supply of lenalidomide as a reminder of these safety issues. You must receive counseling and complete phone surveys as required by the Revlimid risk evaluation mitigation strategies (REMS) program.

Pregnant females or females that are able to become pregnant should not handle or administer lenalidomide unless they are wearing gloves.

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

Tafasitamab, polatuzumab, and mosunetuzumab will be provided at no cost to you during this study. You and/or your insurance provider will be responsible for the cost of lenalidomide.

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

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

What happens to the information collected for the research?

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

A participant study number will be assigned to you once you have been enrolled in the study. This participant study number will be used to identify your data in the study report and when reporting any data from the study.

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

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

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

Will my data or samples be used for future research?

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

In some cases, all of your identifying information may not be removed before your data is used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

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

Your samples will not be used in future research.

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

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if the disease gets worse, if intolerable side effects occur, if you become pregnant, or if you are unable to follow study directions.

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

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

- call your personal doctor right away (or in an emergency, call 911)
- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form)

If you suffer a study-related injury, you may contact the Chair of the study, Dr. Jason Westin, at 713-792-2860, or 713-792-2121 (24-hours) with any questions you may have. By signing this consent form, you are not giving up any of your legal rights.

The sponsor may pay for the treatment you received because you were hurt or sick during the study if the study drug was improperly manufactured. MD Anderson does not know at this time what you may be reimbursed for. A financial counselor will be made available to you after the injury or illness is reported. If the sponsor pays any of your medical expenses, they may need to be given your name, date of birth, and Medicare ID or social security number.

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

What else do I need to know?

This research is being funded by Roche/Genentech and Incyte.

Outside relationships are disclosed to and approved by the Conflict of Interest Committee, which reviews these relationships for compliance with institutional policy. This review helps the IRB to assure that financial relationships do not have an impact on the conduct of this study. The following members of the study staff have disclosed compensation from the funding source(s) of this study:

- Jason Westin (PI)

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

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

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

This research study involves genetic testing. The Genetic Information Nondiscrimination Act (GINA) prohibits health insurers or health plan administrators from requesting or requiring genetic information of you or your family members, or using such information for decisions regarding your eligibility for insurance or your premiums. However, this law does not provide the same protection for disability, life insurance, or long-term care insurance. GINA also prohibits most employers (with 15 employees or more) from using genetic information when making decisions on your employment, including decisions related to hiring, firing, promotion, pay, and job assignments. Please contact the study doctor if you would like more information about GINA and how it protects you from genetic discrimination.

Despite measures to protect the privacy of your genetic data, the sponsor cannot promise that your genetic information could never be linked to you.

Part of your care may be provided outside of MD Anderson by your home doctor(s).

Optional Procedures for the Study

You do not have to agree to the optional procedure(s) in order to take part in this study. There are no benefits to you for taking part in the optional procedures. Future patients may benefit from what is learned. You may stop taking part at any time.

Optional Procedure #1: If you agree, you will have a core biopsy and fine needle aspirate of one of your accessible lymph nodes within 28 days before your first dose of study drugs and at 1 point during your treatment with the study drugs and at your End-of-Dosing visit. To perform a core biopsy, a sample of tissue is removed using a hollow core needle that has a cutting edge. To collect a fine needle aspirate, a small amount of tissue is withdrawn through a needle. This sample will be used for immune system testing. Please note that biopsies are part of standard of care and will thus be billed to you or your insurance provider.

Optional Procedure #2: If you agree, blood (about 4 tablespoons each time) will be drawn for research tests of the immune system and to measure lymphoma levels in the blood. These samples will be drawn weekly during Cycle 1, on Days 1 and 15 of Cycles 2 and 3, on Day 1 of all additional cycles, and at end of treatment visit. Any blood samples leftover after this testing will be sent to the Lymphoma Tissue Bank at MD Anderson for use in future research related to cancer. There will be no cost to you for taking part in Optional Procedure #2.

Samples collected from optional procedures will be stored under the tissue banking study 2005-0656 (A Collection of Blood and Tissue Samples from Patients with Lymphoma and/or Amyloidosis and/or Monoclonal Gammopathies and Normal Donors). If you agree to Optional Procedure #1 and/or #2, you will also be given a separate consent form for study 2005-0656, and it will be discussed with you.

Optional Procedure Risks:

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

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to have a core biopsy and fine needle aspirate of one of your accessible lymph nodes 1 time before and 1 time during treatment with the study drugs?

YES NO

Optional Procedure #2: Do you agree to have blood drawn for research tests described above?

YES NO

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

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

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

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

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

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

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

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

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

   You will be told about any new information that might change your decision to be in this study.

CONSENT/AUTHORIZATION

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

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

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

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

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

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

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

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT