THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

An Open-label Phase IB/II Study of Magrolimab in Combination with Azacitidine and Venetoclax for the Treatment of Patients with Acute Myeloid Leukemia (AML)
2020-0027

Study Chair: Naval Daver

_____ _____
Participant's Name Medical Record Number

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

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

STUDY SUMMARY

There are 2 parts to this clinical research study: Part 1 (dose evaluation) and Part 2 (dose expansion).

The goal of Part 1 of this clinical research study is to find a recommended dose of magrolimab (previously known as Hu5F9-G4) that can be given in combination with azacitidine and venetoclax to patients with acute myeloid leukemia (AML).

The goal of Part 2 of this clinical research study is to learn if the recommended dose of the drug combination found in Part 1 can help to control the disease.

The safety of this drug combination will be studied in both parts.

This is an investigational study. Venetoclax in combination with azacitidine is FDA approved and commercially available for the treatment of AML. Magrolimab is not FDA approved or commercially available for the treatment of any disease. It is

currently being used for research purposes only. The study doctor can explain how the drugs are designed to work.

The study drugs may help to control the disease. Future patients may benefit from what is learned. There may be no benefits for you in this study.
Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. Possible reasons you may not want to take part in this study include prolonged stay out of town (if you need to travel to get to study visits), the fact that this is the first time this drug combination has been studied in humans, and/or the potential risk of side effects (listed below) and/or hospitalization.

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

You may continue taking the study drug(s) for as long as the doctor thinks it is in your best interest.

Magrolimab and venetoclax will be provided to you at no cost while you are on study. You and/or your insurance provider will be responsible for the cost of azacitidine.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive only venetoclax with azacitidine. You may choose to receive other standard treatment for AML. The study doctor will discuss the possible risks and benefits of these treatments. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

1. STUDY DETAILS

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

- You will have a physical exam.
- Blood (about 8 teaspoons) will be drawn for routine tests, pharmacodynamic (PD) testing, red blood cell (RBC) genotyping, and biomarker testing. PD testing measures how the level of study drug in your body may affect the disease. RBC genotyping is testing related to how your red blood cells may respond to the study drug and helps identify the kind of red blood cells that may be needed for transfusions during the study. Biomarkers are found in the blood and tissue and may be related to your reaction to the study drug.
- Urine will be collected for routine tests.
- You will have an EKG to check your heart function.

- If you have not had one in the previous 28 days, you will have a bone marrow aspirate and biopsy to check the status of the disease. To collect a bone marrow aspirate and biopsy, an area of the hip or other site is numbed with anesthetic, and a small amount of bone marrow is withdrawn through a large needle.
- If you can become pregnant, blood (about 1 teaspoon) or urine will be collected 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 to be eligible to take part in this study, you will be assigned to a study group based on when you join this study. Up to 18 participants will be enrolled in Part 1 of the study, and up to 120 participants will be enrolled in Part 2.

If you are enrolled in Phase 1, the dose of magrolimab you receive will depend on when you join this study. If intolerable side effects are seen in the first group of patients, the dose will be lowered for the next group.

If you are enrolled in Phase 2, you will receive magrolimab at the recommended dose that was found in Phase 1.

All participants will receive the same dose levels of azacitidine and venetoclax.

Up to 138 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration

Each study cycle will be 28 days long.

You will need to be admitted to the hospital during the first 14 days of Cycle 1 so you can be closely monitored for side effects.

On Days 1-7 of each cycle, you will receive azacitidine either as an injection under the skin or by vein over 30-60 minutes. You may be able to receive it on a different schedule if needed, but you will always receive it over 7 days in each cycle. The study doctor will tell you if another schedule is an option.

You will take venetoclax by mouth 1 time each day on Days 1-28 of each cycle. The doctor will let you know if there are any changes recommended to the number of days of venetoclax you need to take in each cycle. Take the dose with about a cup (8 ounces) of water within 30 minutes after a meal, preferably breakfast. If you miss or vomit a dose, the next dose should not be increased to account for missing a dose. You should just take the next regular dose at the regularly scheduled time.

You will receive magrolimab by vein on Days 1, 4, 8, 11, 15, and 22 of Cycle 1. During Cycle 1, the dose will be increased on Days 4, 8 and 11. The doctor will let you know if there are any changes recommended to dosing of magrolimab in each cycle. During Cycle 2, you will take magrolimab every week (Days 1, 8, 15, and 22). Starting with Cycle 3, you will take the drug every 2 weeks (Days 1 and 15).

Study Visits

On **Day 1 of each cycle**, you will have a physical exam.

Blood (about 6 teaspoons) will be drawn for routine tests **2 times each week during Cycles 1-3, then 1-2 times during each cycle after that**. This schedule can be reduced after Cycle 6 if the study doctor thinks it is appropriate to do so.

Blood (about 2 teaspoons) will be drawn to check for tumor lysis syndrome (TLS) before your dose of venetoclax and 6-8 hours after the dose on **Days 1-3 of Cycle 1**. TLS is a side effect in which breakdown products of the cancer cells enter the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage).

You will have a bone marrow aspiration to check the status of the disease on **Day 21 of Cycle 1, then at the end of every 3 cycles (Cycles 3, 6, and so on)**. You will also have one if at any time the disease gets worse.

If you take the study drugs for more than 6 months, your study visit schedule may change (for example, bone marrow aspirations may be reduced to every 6-12 months and blood tests may be reduced to 1 time each month).

The doctor will inform you if there are any changes to the study visit schedule.

End-of-Treatment Visit

After you stop taking the study drugs:

- You will have a physical exam.
- Blood will be drawn for routine tests.
- If the study doctor thinks it is needed, you will have a bone marrow aspiration.

Follow-Up

You will be called every 30 days during the 100 days after you stop taking the study drugs and asked about how you are doing. Each call should last about 5 minutes.

Then, 100 days after the last dose, you will have a physical exam, and blood (about 6 teaspoons) will be drawn for routine tests. If you cannot make it to MD Anderson for this visit, the required follow-up treatment procedures may be done with a local doctor and the records forwarded to MD Anderson.

Other Instructions

Tell the study staff about any drugs you are taking during the study. This includes prescription drugs, over-the-counter drugs, natural or herbal medicines, alternative medicines, and vitamins. Do not have any vaccines (live attenuated) during the study except for the flu vaccine. If you need to have any vaccines while on study, tell the study staff right away.

You should avoid illegal drugs, herbal remedies, self-prescribed drugs, tobacco products, and excessive alcohol consumption during the study.

You should not consume grapefruit or grapefruit products, Seville oranges, or Star fruit within the 3-day period before to the first venetoclax administration and until the last dose of venetoclax.

MAGROLIMAB RESULTS IN MYELODYSPLASTIC SYNDROME:

A study named ENHANCE was completed to test the effect of magrolimab in people who have myelodysplastic syndrome which is a type of blood cancer. In the ENHANCE study, people were treated with either magrolimab and azacitidine or azacitidine by itself. The study was ended early because it showed that people treated with magrolimab and azacitidine were not having better outcomes compared to people treated with azacitidine alone. People treated with magrolimab and azacitidine lived an average of 15 months after starting the study while people treated with azacitidine alone lived an average of 18.2 months. People treated with the two-drug combination of magrolimab and azacitidine were more likely to experience serious side effects, including side effects which may lead to death. The common side effects seen in the study such as anemia, infusion related reactions, serious infection and severe neutropenia are discussed in detail below. While the ENHANCE study tested a different treatment combination in people with a different disease than ENHANCE-3, the information learned from the ENHANCE study about the safety of magrolimab is important to anyone who may be treated with magrolimab.

2. POSSIBLE 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.

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.

Magrolimab, azacitidine, and venetoclax 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, fatigue/lack of energy, pale skin, low blood pressure, and/or fast heartbeat. 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.

Magrolimab Side Effects

Occurring in more than 10% of patients:

• low blood pressure (possible dizziness or fainting) • fatigue • fever • chills • headache •	• nausea/vomiting • diarrhea • abdominal pain • loss of appetite • low blood cell counts (red, white, platelets) • infusion reaction (possible fever, headache, chills, skin rash, swelling, and/or nausea/vomiting)	• difficulty breathing • cough

Occurring in 1-10% of patients:

• destruction of red blood cells • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)

Magrolimab attaches itself to your red blood cells which may cause older cells to die (causing anemia), especially at the beginning of the treatment. In a few patients treated with magrolimab, anemia or the effects of anemia have been life-threatening or fatal. Sudden deaths have occurred during or shortly after initial treatment doses. The study doctor will test your blood for anemia before each magrolimab infusion and a few hours after you start the first and second infusion of magrolimab. Your blood may be tested more often if the study doctor thinks it is needed. If you experience severe anemia, the study doctor may recommend a blood transfusion to increase the number

of your red blood cells before and/or after receiving magrolimab. The study doctor may also stop treatment altogether with magrolimab.

It is important that you tell the study doctor about any past known or suspected cardiovascular (heart) disease and any related symptoms, including but not limited to, chest pain, difficulty breathing, and swelling of the lower limbs before participating in the study. These conditions may increase your risk of side effects from anemia.

The study drug can also make the red blood cells "sticky." In severe cases, the blood becoming sticky could cause kidney and/or lung failure, headaches, changes in vision, changes in mental status, or multi-organ failure.

Magrolimab may affect some of the tests used to determine your blood type. This may require that special additional testing be performed on your blood if you were to need a blood transfusion for any reason. For any non-emergency blood transfusion, you will be required to come to MD Anderson where the appropriate testing can be performed. In the event of an emergency and you are taken to another hospital, the emergency doctors should contact the magrolimab study doctor right away. It is possible that the study drug may change the blood type test, which means you could receive the wrong type of blood during a transfusion. This could result in a serious, life-threatening reaction.

Azacitidine Side Effects

The following side effects have been reported when azacitidine is given either by vein or as an injection under the skin:

Common (occurring in more than 20% of patients)

• fever • fatigue/lack of energy • headache • nausea • vomiting	• diarrhea • constipation • loss of appetite • low blood cell counts (red, platelets, white) • weakness	• pain • shivering • cough • difficulty breathing • injection site redness and/or pain

Occasional (occurring in 5-20% of patients)

• chest pain • pale skin • swelling (arm/leg) • abnormal heart sound • fast heartbeat • low blood pressure (possible dizziness/ fainting)	• dry skin and/or itching • sweating • low blood levels of potassium (possible weakness/or muscle cramps) • weight loss • abdominal pain,	• difficulty swallowing • difficult and/or painful urination • blood in the urine • sore throat • muscle cramps • nosebleed • stuffy and/or runny

• high blood pressure • fainting • dizziness • anxiety • depression • difficulty sleeping • numbness • hives and/or skin redness • skin bump/sores/rash	tenderness, and/or swelling • bleeding gums • tongue sores • bleeding in the mouth • mouth blisters and/or sores (possible difficulty swallowing) • upset stomach • hemorrhoids	nose • abnormal breath sounds • wheezing • build-up of fluid around the lungs • lymph node swelling • infection • hardened tissue/inflammation/skin discoloration at the injection site • injection site swelling, itching, and/or rash • increased risk of bleeding after a procedure/surgery • reaction to a blood transfusion

Rare but serious (occurring in fewer than 5% of patients)

• irregular heartbeat • heart failure • bleeding in and/or around the brain • seizure • skin condition with fever and skin lesions • decay of body tissue • lesions due to skin infection • abnormal blood acid/base balance (possible organ damage) • dehydration • gallbladder inflammation (possible abdominal pain) • digestive system bleeding	• tarry stool • enlarged spleen • bone marrow failure • liver failure • kidney failure • build-up of bodily waste products in the blood (possible kidney problems) • coughing up blood • lung inflammation (possible difficulty breathing) • tissue death at the injection site caused by drug leakage • bleeding in the eye • catheter site bleeding • infection at the injection site	• allergic reaction, which may be life-threatening (such as difficulty breathing, low blood pressure, and/or organ failure) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)

Azacitidine may cause you to develop another type of cancer (such as

leukemia, a type of blood cancer).

Venetoclax Side Effects

Common (occurring in more than 20% of patients)

• fatigue • diarrhea	• nausea • low blood counts (red, platelets, white)	• upper respiratory tract infection

Occasional (occurring in 3-20% of patients)

• swelling (arm/leg) • fever • headache • 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)	• vomiting • constipation • back pain • high blood levels of uric acid (possible painful joints and/or kidney failure)	• pneumonia • cough • 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)

TLS is a problem that can occur when cancer cells break down rapidly and the body has to get rid of the broken up cell parts. Sometimes your body, especially the kidneys, cannot remove the cell parts quickly enough, so the level of some of these cell products in your blood, such as salts and acids, can rise. This can happen especially in participants with large tumors or a high number of cancerous white cells in the blood. TLS can lead to serious problems, such as effects on your kidneys and heart (including abnormal heart rhythms), seizures, or even death.

If you develop TLS, your urine may look dark, thick, or cloudy. You may have fever, chills, nausea/vomiting, diarrhea, confusion, shortness of breath, irregular heartbeat, fatigue, muscle pain, joint discomfort, and/or seizure. If you notice any of these, tell your doctor or nurse right away. Your study doctor will closely watch and treat you as needed to lower the risk of any serious changes in your blood or other complications of TLS. You may need to have extra blood tests or EKGs to check for signs of TLS.

You should wear ear plugs or other hearing protection when involved in a loud activity.

Based on studies in animals, venetoclax may cause the following side effects:

• swelling and itching of the head, ears, arms and/or legs	• hair color change • gallbladder damage	• decrease in sperm

Based on studies in animals, venetoclax may cause of loss of weight or the premature loss (miscarriage) of a developing baby. This has not been seen in humans at this time.

If you notice any rash, hives, itching, or other signs of an allergic reaction such as swelling, wheezing, or you are having a hard time breathing, tell your doctor right away.

At this time, there are no known serious side effects that occur in **fewer than 3% of patients.**

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

Other Risks

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

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

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

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks
If Both: Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study and for 3 months (males) or

4 months (females) after the dose if you are sexually active.

Appropriate methods of birth control include sterilization of you or your partners, or a combination of any 2 of the following (a+b or a+c or b+c)

a. Use of oral, injected or implanted hormonal methods of birth control or other forms of hormonal birth control with a failure rate under 1%, such as a hormone vaginal ring or birth control patch
b. Placement of an intrauterine device (IUD) or intrauterine system (IUS)
c. Barrier methods of birth control: condom or occlusive cap (diaphragm or cervical/vault caps) with spermicidal foam/gel/film/cream/ vaginal suppository

In case of use of oral birth control, women should have been stable on the same pill before taking study treatment. Oral birth control is allowed but should be used along with a barrier method of birth control, to avoid any unknown drug interactions.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

Females: 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.

Getting pregnant may result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedures #1 and 2: If you agree, additional samples will be collected for research tests of the immune system at your screening visit, on Day 21 of Cycle 1, at the end of Cycles 3, 6, and 9, and then at any time that the disease appears to get worse:

- If you agree, bone marrow that is already being removed as part of the scheduled study procedures will be used for these tests.
- If you agree, extra blood (about 8 teaspoons) will be drawn for these tests.

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. There will be no cost to you for taking part in the optional procedures.

Optional Procedure Risks

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

Having **bone marrow biopsies/aspirations** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the

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

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 additional bone marrow collected for immune system testing?

YES **NO**

Optional Procedure #2: Do you agree to have additional blood samples drawn for immune system testing?

YES **NO**

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson, Forty-Seven Inc., or Genentech for this injury. You may also contact the Chair of MD Anderson's 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.

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

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

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

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

Additional Information

4. You may ask the study chair (Dr. Naval Daver, at 713-794-4392) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson. The study staff may ask if they can continue collecting the results of routine care from your medical record.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, supporting agencies including Forty-Seven Inc. and/or Genentech, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

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

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

9. This study is supported by: Forty-Seven and Genentech.

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

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and Forty-Seven and Genentech and/or shared with other researchers and/or institutions for use in future research.

Samples

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research.

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

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

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

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

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

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

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

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

Outside Care

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

Conflict of Interest

Dr. Naval Daver (Study Chair) has received compensation from Forty-Seven as a Scientific Advisor and Genentech as a Consultant. The financial interests are within the limits of the conflict of interest policy.

Dr. Marina Konopleva (Study Co-Chair) has received compensation from Forty-Seven as a Scientific Advisor and Genentech as a Consultant. The financial interests are within the limits of the conflict of interest policy.

Dr. Nitin Jain (Collaborator) has received compensation from Genentech, Inc. as a Consultant. The financial interests are within the limits of the conflict of interest policy.

Dr. Elias Jabbour (Collaborator) has received compensation from Genentech, Inc. as a Consultant. The financial interests are within the limits of the conflict of interest policy.

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

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

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's

contracts require sponsors/supporters to protect this information and limit how they may use it.

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

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

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

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

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

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

CONSENT/AUTHORIZATION

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

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

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

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION