THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

A Phase II Study of the Combination of Decitabine, Venetoclax, and Ponatinib in patients with Philadelphia Chromosome-Positive Acute Myeloid Leukemia or Myeloid Blast Phase Chronic Myelogenous Leukemia 2019-0610

Subtitle: Takeda Pharmacovigilance-MDACC Alliance

Study Chair: Nicholas Short

_____ _____
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

The goal of this clinical research study is to learn about the effectiveness of the combination of decitabine, venetoclax, and ponatinib when given to patients with acute myeloid leukemia (AML) or chronic myeloid leukemia (CML) in myeloid blast phase.

It is important to know that ponatinib may cause a blood clot to form in an artery or in a vein. Depending on the location of the clot, this could cause a heart attack, a stroke, severe damage to other tissue, or death. A blood clot may occur within 2 weeks after you start taking the drug. About 41% (about 2 in 5) of patients taking the drug form an abnormal clot. Blood clots can occur in patients that do not have other known risk factors for forming clots. If you develop a blood clot, you will need to stop taking ponatinib. In some cases, emergency surgery could be needed to remove the clot and restore blood flow.

This is an investigational study. Decitabine is FDA approved and commercially available for the treatment of myelodysplastic syndrome (MDS). Venetoclax is FDA approved and commercially available for the treatment of chronic lymphocytic leukemia (CLL) and AML. Ponatinib is FDA approved and commercially available for the treatment of certain subgroups of patients with acute lymphoblastic leukemia or CML. It is considered investigational to combine these drugs to treat AML or CML.

The study drug(s) 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. If you take part in this study, you may experience challenges related to the cost of staying in Houston, travelling to the clinic for treatment, and not being eligible for other studies or therapies.

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

You may receive up to 24 cycles of the combination of ponatinib, venetoclax, and decitabine. You will no longer be able to receive the study drugs if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

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

You may choose not to take part in this study. You may choose to receive standard treatment for AML that includes cytarabine at a different dose schedule in combination with idarubicin or daunorubicin, or a combination of commercially available drugs that have shown activity in AML (mostly based on cytarabine), such as established combinations that include venetoclax. You may choose to receive other drugs, or supportive care alone (including transfusions). There are approved treatments that have been shown to be effective in treating the disease. The study doctor will discuss the risks and benefits of the alternative treatments available to you. 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 be done within 14-28 days before your first dose of study drugs to help the doctor decide if you are eligible to take part in this study:

- You will have a physical exam.

- Blood (about 3½ tablespoons) will be drawn for routine and biomarker testing (including genetic biomarkers). Biomarkers are found in the blood/tissue and may be related to your reaction to the study drugs.
- You will have a bone marrow aspirate to check the status of the disease, including genetic testing. The genetic testing will look for genetic mutations (changes) in DNA found in the bone marrow. To collect a bone marrow aspirate, 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.
- You will have an EKG and either an echocardiogram (ECHO) or a MUGA scan to check your heart function.
- Within 7 days before the start of the study, 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.

Up to 20 participants will be enrolled in this study. All participants will take part at MD Anderson.

Study Drug Administration

If you are found to be eligible to take part in this study, you will begin receiving the study drugs in cycles. Each cycle is 28 days. However, if you have not recently received ponatinib, your first cycle will be 35 days.

Cycle 1

If you have **not received ponatinib** recently, you will take **ponatinib** by mouth on Days 1-21 of Cycle 1. Then, on Days 8-28 of Cycle 1, you will take **venetoclax** 1 time by mouth each day as instructed by your treating doctor. It is recommended that the dose of venetoclax be ramped up (slowly increased) over the first 3 days. This means you will take the lowest dose on Day 8. On Day 9, you will take a higher dose of venetoclax. On Day 10, you will take the highest dose recommended for you, which is the dose of venetoclax you will take throughout the rest of the study. On Days 8-12 of Cycle 1, you will receive **decitabine** by vein (IV) over about 60 minutes.

If you have been **recently treated with ponatinib**, you will take **ponatinib** by mouth every day during Cycle 1. On Days 1-21 of Cycle 1, you will take **venetoclax** 1 time by mouth each day as instructed by your treating doctor. Venetoclax should be taken with food. It is recommended that the dose of venetoclax be ramped up (slowly increased) over the first 3 days. This means you will take the lowest dose on Day 1. On Day 2, you will take a higher dose of venetoclax. On Day 3, you will take the highest dose recommended for you, which is the dose of venetoclax you will take throughout the rest of the study. On Days 1-5 of Cycle 1, you will receive **decitabine** by vein over about 60 minutes.

You will be hospitalized for at least the first 4 days of Cycle 1 of venetoclax therapy to be monitored for side effects. You may be hospitalized for the duration of the first 28 days or until your blood count recovers during Cycle 1 and then as needed for side effects. The study doctor will tell you more about this.

Cycles 2–24 (All participants)

- On **Days 1-28 of Cycle 2-24**, you will take **ponatinib** by mouth every day.
- On **Days 1-21 of Cycle 2-24**, you will take **venetoclax** 1 time by mouth each day.
- On **Days 1-5 of Cycle 2-24**, you will receive **decitabine** by vein over about 60 minutes.

If you are taking certain drugs (such as antifungal medicines) that may affect how your body processes the study drug, your dose of venetoclax may be lowered. Depending on how your body reacts to venetoclax, your doctor may choose a different dose for you to take for the rest of the study. This will be discussed with you.

Changes in doses of the study drugs or additional drugs, or dose schedules other than those described above, are allowed if the study doctor thinks it is in your best interest.

If you have disease taking place outside of your bone marrow, you may receive intrathecal therapy and/or radiation therapy. Your doctor will discuss this with you. You will sign a separate consent describing the intrathecal therapy and radiation therapy 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. Your participation in the study will be over after long-term follow-up.

Study Visits

On **Day 1 of each cycle:**

- You will have a physical exam.
- Blood (about 2-3 teaspoons) will be drawn for routine tests.

During Cycle 1, after each new dose of venetoclax you receive, blood (about 2-3 teaspoons) will be drawn to check electrolytes in your blood and your kidney function. This is done because venetoclax may cause a side effect called tumor lysis syndrome (TLS). TLS happens when breakdown products of cancer cells enter the blood stream and may affect your kidneys and other organs. The study doctor will monitor your kidney function while you receive venetoclax and check for signs of TLS.

At least 1 or 2 times each week during Cycle 1, and before the start of each new cycle, blood (about 2-3 teaspoons) will be drawn for routine tests. You may be able to have these blood draws done at a local clinic or lab closer to your home, if this is more convenient for you. This option will be discussed with you.

On **Day 28 of Cycle 1** (if you have been recently treated with ponatinib) **or on Days 7 and 35 of Cycle 1** (if you have not been recently treated with ponatinib) **and then every 2-3 cycles after that,** you will have a bone marrow aspiration to check the status of the disease and blood (about 3 tablespoons) will be drawn for research testing. Some of the bone marrow will be used for research tests to look for changes in the disease that may show how you respond to the drugs. If the doctor thinks the disease has come back or worsened, this procedure will be repeated.

During Cycle 3 and then every 3 months after that, you will have an EKG.

During Cycle 4 and then every 3 months after that, you will have either an echocardiogram (ECHO) or a MUGA scan.

Follow-Up
About 30 days after your last dose of study drugs and then every 6 months after that, you will be called by the study staff and asked about how you are doing. Each call should last about 5-10 minutes.

Other Information
Within 3 days before your first dose and while taking venetoclax, avoid having any grapefruit, Seville (sour) oranges, star fruit, pomegranate and products containing juices of these fruits.

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.

Venetoclax, ponatinib, and decitabine 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.

Side effects will vary from person to person, and some may occur after you have stopped receiving the study drug. 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.

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.

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**.

Decitabine Side Effects

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

Common (occurring in more than 20% of patients)

• swelling (including arm/leg) • pale skin • fever • fatigue • headache • difficulty sleeping • dizziness • high blood sugar (possible diabetes)	• 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) • nausea	• constipation • diarrhea • vomiting • loss of appetite • low blood cell counts (red, white, platelets) • shivering • cough • difficulty breathing • infection

Occasional (occurring in 5-20% of patients)

• swelling (face) • abnormal heart sound • low blood pressure (possible dizziness/fainting) • high blood pressure • fast heartbeat • chest pain • heart failure • pain • chills • confusion • anxiety/depression • numbness • skin rash/redness • itching • night sweats • hair loss (partial or total) • dry skin • hives • lymph node swelling • toothache	• mouth blisters/sores (possible difficulty swallowing) • weight loss • abdominal pain • abdominal swelling • heartburn • tongue/mouth pain • lip blisters/sores • difficulty swallowing • upset stomach • fluid in the abdomen • dehydration • hemorrhoids • difficult, painful, and/or frequent urination • bacteria in the blood • high blood platelet count (possible increased clotting) • abnormal liver tests (possible liver damage or yellowing of the skin and/or eyes)	• weakness/tenderness • muscle spasms • joint pain • walking/balance problems (possible falling) • blurry vision • abnormal kidney test (possible kidney damage) • high blood levels of uric acid (possible painful joints and/or kidney failure) • sore throat • low oxygen level in the blood (possible lightheadedness) • fluid in or around the lungs (possible difficulty breathing) • runny or stuffy nose • nosebleed • injection site swelling

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

• irregular heartbeat • enlarged heart • heart attack • heart and lung failure • bleeding around the brain • mental status change • skin condition with fever and skin lesions • blood in the urine	• kidney failure • lung inflammation • blood clots in the lung (possible failure to breathe) • stopped breathing • coughing up blood • enlarged spleen • gallbladder inflammation (possible abdominal pain)	• severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

Ponatinib Side Effects

Common (occurring in more than 20% of patients)

• high blood pressure • swelling (arm/leg) • heart attack • blood clots in an artery (possible organ damage such as stroke and/or heart attack) • blood clots in a vein (possible pain, swelling, and/or redness) • blood vessel disorder (possible tissue death) • fatigue • weakness • headache • fever • bleeding in the brain • stroke	• skin rash • dry skin • high blood sugar (possible diabetes) • low blood sugar • 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) • abdominal pain • constipation • nausea • loss of appetite • diarrhea	• vomiting • mouth blisters/sores (possible difficulty swallowing) • digestive system bleeding • abnormal digestive blood test (possible pancreas inflammation/damage) • low blood counts (white, red, platelet) • abnormal liver tests (possible liver damage) • pain (joint/muscle) • difficulty breathing • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)

Occasional (occurring in 3-20% of patients)

• fast/irregular heartbeat • heart and/or lung failure • decreased blood supply to the heart • heart and/or blood vessel disease • shock caused by heart damage • build-up of fluid in the tissue around the heart • decreased supply of blood through the arteries (possible tissue death) • difficulty sleeping • dizziness • chills • sweating • flushing • itching • hair loss (partial or total)	• weight loss • abdominal swelling • upset stomach • dry mouth • problems with urination • high blood levels of uric acid (possible painful joints and/or kidney failure) • impotence • abnormal liver tests (possible yellowing of the skin and/or eyes) • blood clots in a vein to the liver (possible liver and/or digestive system damage) • pain (arm/leg/back/bone) • muscle spasms	• blood clot inside the eye (possible blindness) • eye irritation/pain • swelling under the central part of the retina (possible vision loss) • bleeding in the eye • dry eyes • blurry vision • blood clot inside the eye (possible blindness) • abnormal kidney test (possible kidney damage) • fluid in or around the lung (possible difficulty breathing) • blockage in the lung (possible pain, shortness of breath, and/or failure to breathe) • cough

• high blood levels of fat (possible heart disease and/or stroke) • inflammation of the pancreas (possible abdominal pain)	• nerve damage (possible numbness, pain, and/or loss of motor function) • abnormal sensation (such as pins and needles)	• voice changes (possible hoarseness) • infection

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

• slow heartbeat • reduced blood supply to the arms and legs • narrowing of the arteries (possible high blood pressure, fatigue, and/or weakness) • swelling of the brain (possible headache and/or mental status changes) • temporary stroke symptoms • painful skin bumps • fluid in the abdomen	• abnormal connections or passageways between different parts of the digestive system • hole in the intestines (possibly leaking contents into the abdomen) • nerve damage (affecting the head and neck) • blindness • cataracts (clouding of the lens of the eye) • increased pressure in the eye (possible vision loss)	• inflammation of the eye and/or inside the eye (possible sores on the eye) • allergic reaction (such as a skin 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)

Frequency unknown

• severe increase in blood pressure (possible stroke) • blocked blood vessel (such as an artery in the abdomen)	• decreased blood circulation • blood clots in the heart (possible heart attack) • increased sensitivity of the senses	• liver failure • irritation in the tissue lining the eye • amputation due to tissue death • wound healing problems

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.

<u>Other Risks</u>

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

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

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 at least 3 months after your last dose of study drugs, if you are sexually active.

Birth Control Specifications: The study doctor or staff will discuss the birth control methods with you.

Males: Do not donate sperm while on study and for 3 months after your last dose of study drug. 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 will result in your removal from this study.

---

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 or Takeda Oncology for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-2933 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. Nicholas Short, at 713-792-8760) 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, you will be removed from the study drugs and asked to take part in the follow-up visits described above. 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.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, Takeda Oncology, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson. Reasons for your removal may include the study ending or not following study directions.

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 sponsored and/or supported by: Takeda Oncology

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 713-792-2933.

Future Research

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.

Before being shared for future research, every effort will be made to remove your identifying information from any data and/or 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 samples are used for future research. If this 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 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.

Future research is required for this study. You cannot take part in this study unless you allow your data and/or samples to be used for future research.

Genetic Research

Any samples collected from you as part of this study will 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.

Conflict of Interest

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:

- Dr. Elias Jabbour (Collaborator)
- Hagop Kantarjian (Collaborator)

Outside Care

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

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
- Millennium Pharmaceuticals, a wholly-owned subsidiary of Takeda Pharmaceutical Company Ltd., who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
- Any future sponsors 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.

Your data will be de-identified (all identifying information removed) during this study. The de-identified data will be stored in a password-protected, encrypted computer. The study doctor and members of the study team will have access to this data and the key linking you to your data. The data will be stored indefinitely.

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

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol 2019-0610.

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

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

_____
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

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