THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

**Informed Consent**

# INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

## Phase II Study of Dual Targeting of BCR-ABL1 by adding the Allosteric Inhibitor ABL001 in Patients with Chronic Myeloid Leukemia (CML) and Minimal Residual Disease (MRD) While on Therapy with Tyrosine Kinase Inhibitors
2019-0618

**Subtitle:** Novartis (IIR)

Study Chair: Ghayas C. Issa

_____ _____
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 study is to learn if adding asciminib (ABL001) to dasatinib or nilotinib in patients with chronic myeloid leukemia (CML) can help to control the disease.

**This is an investigational study.** ABL001 is not FDA approved or commercially available. It is currently being used for research purposes only. Dasatinib and nilotinib are types of standard of care drugs called tyrosine kinase inhibitors (TKI) and they are FDA approved and commercially available for the treatment of CML.

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.

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

You may receive therapy for up to 36 months.

ABL001 will be provided to you at no cost while you are on this study. You and/or your insurance provider will be responsible for the cost of dasatinib or nilotinib.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to continue receiving your standard TKI therapy outside of this study or you may choose to receive other forms of chemotherapy. 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 Visit**

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will be performed within **14 days** before the first dose of study drugs to help the doctor decide if you are eligible:

- You will have a physical exam.
- You will complete a disease-related symptom questionnaire. The questionnaire should take about 10 minutes to complete.
- If you can become pregnant, blood (about ½ teaspoon) or urine will be collected for a pregnancy test. To take part in this study you must not be pregnant.

**Within 30 days** before the start of therapy:

- You will have an EKG and either an echocardiogram (ECHO) or MUGA scan to check your heart function.
- Blood (about 2 tablespoons) will be drawn for routine, biomarker, and cytogenetic testing. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug. Cytogenetic testing looks at how genetic changes to cells may affect how the disease may react to the study drug.
- You will have a bone marrow aspirate and/or biopsy to check the status of the disease, as well as for cytogenetic, biomarker, and genomic testing. Genomic testing is done to learn how leukemia or immune cell genes (DNA, genetic information) may affect how the study drugs work. To collect a bone marrow biopsy/aspirate, an area of the hip or other site is numbed with anesthetic, and a small amount of bone marrow and bone is withdrawn through a large needle.

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 40 participants will be enrolled in this study. All will take part at MD Anderson.

**Study Drug Administration**

If you are found to be eligible to take part in this study, you will continue to receive the TKI (either dasatinib or nilotinib) you were receiving before enrolling in this study. You will continue to receive the same dose of TKI you have been receiving for the past 6 months.

You will take ABL001 tablets two (2) times a day, every day, with 8 ounces (about 1 cup) of water. ABL001 should be taken at least 1 hour before or 2 hours after a meal. You may drink water during this time. You should swallow the tablets whole; do not chew or crush the tablets. If you vomit during the first hour after taking the dose, you may retake the dose before the next scheduled dose. If a dose is not taken within 6 hours after the usual dosing time, that dose should be skipped and the next dose taken as scheduled.

If you respond to therapy that lasts at least 2 years, you may be able to stop taking ABL001 and/or the TKI. If the disease begins to return, you may restart one or both of the treatment agents at the same dose and schedule you were on when treatment was stopped. You will be able to receive ABL001 free of charge when restarted if not covered by your insurance. Your doctor will discuss this with you in more detail.

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 on the study will be over after the follow-up visits.

**Study Visits**

At **Weeks 1, 2, 4, 6, and 8 after starting treatment, at Month 3, 6, 12, 18 and then every 6-12 months after that:**

- You will have a physical exam. At Weeks 1 and 6, you will not have a physical exam.
- You will have an EKG (Week 1 and 4 only) and either an ECHO or MUGA scan (Week 4 only).
- You will complete a disease-related symptom questionnaire (except Weeks 1, 2, and 6).
- Blood (about 2 tablespoons) will be drawn for routine tests (except Week 1).

If your doctor agrees, instead of a physical exam, you may have a follow-up phone call with a member of the study team. This call should last about 10 minutes. Then, you may have these routine blood tests and physical exam performed by your local doctor. If you choose to have these tests performed by your local doctor, you will need

to return to MD Anderson at least every 6 months during the first 2 years then every 12 months for a physical exam, and all bone marrow aspirations and/or biopsies.

At **4 and 8 weeks after starting treatment, then at 3, 6, 9, 12 and 18 months, then every 6 months after that**, blood (about 2 teaspoons) will be drawn for biomarker and cytogenetic testing.

**Every 6 months during the first year,** then at any time the doctor thinks it is needed, you will have a bone marrow aspirate and/or biopsy to check the status of the disease and for biomarker, genomic, and cytogenetic testing.

**End-of-Treatment Visit and Follow-Up**

**At the time you stop receiving treatment:**

- You will have a physical exam
- Blood (about 4 teaspoons) will be drawn for routine, biomarker, and cytogenetic testing.
- You will have a bone marrow aspirate and/or biopsy to check the status of the disease and for biomarker and genomic testing.
- You will complete a disease-related symptom questionnaire.

**Every 4-8 weeks for the first 6 months after you stop receiving treatment and then every 3-6 months after that:**

- You will have a physical exam
- Blood (about 4 teaspoons) will be drawn for routine tests and cytogenetic testing.

**At 6 and 12 months after you stop receiving treatment:**

- Blood (about 4 teaspoons) will be drawn for biomarker and cytogenetic testing.
- You will have a bone marrow aspirate and/or biopsy to check the status of the disease and for biomarker and genomic testing.
- You will complete a disease-related symptom questionnaire.

**If you stop receiving the TKI therapy as part of your standard care,** you will have a bone marrow aspiration and/or biopsy to check the status of the disease 6 and 12 months after stopping TKI therapy.

If you have side effects related to the study drug when you stop therapy, you will receive follow-up phone calls from a member of the study team and will be asked about how you are feeling **every 2 weeks for 30 days** or until the side effects go away or improve. The phone call should take about 10 minutes.

**Other Instructions**

If you are taking dasatinib:

- Call your doctor at the first sign of diarrhea. You should keep some Loperamide (Imodium) at home, in case you have diarrhea. You should call

your doctor right away or go to the hospital if there are any signs of bleeding from your stomach (vomiting bloody or dark stomach contents) or bleeding from the intestines (dark or bloody bowel movements).
- Call your doctor right away, and go to a hospital if you have signs of heart problems such as abnormal heartbeat or chest discomfort or breathing problems.
- If anybody other than you will handle the study drugs, they should wear protective gloves when handling dasatinib.

All participants should avoid having any grapefruit, Seville 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. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. 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.

ABL001, dasatinib, and nilotinib may 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/or difficulty breathing.

Tell the study staff about any side effects you may have, even if you do not think they are related to the study product/procedures.

**ABL001 Side Effects**

**This is an early study of ABL001 in humans, so the side effects are not well known.** Based on studies in humans and animals, ABL001 may cause the following side effects:

| | | |
|---|---|---|
| • heart attack<br>• headache<br>• fatigue<br>• dizziness | • abnormal taste<br>• inflammation of the intestines (possible | • nausea<br>• diarrhea<br>• low blood cell counts (red/platelets/white) |

| | | |
|---|---|---|
| • itching<br>• skin rash<br>• skin redness and/or dryness<br>• sweating<br>• low blood levels of phosphate (possible bone damage) | diarrhea and/or abdominal pain)<br>• vomiting<br>• constipation<br>• inflammation of the pancreas (possible abdominal pain) | • liver inflammation (possible liver damage)<br>• joint pain<br>• muscle pain/spasm<br>• dry eyes<br>• allergic reaction (possible difficulty breathing) |

**<u>Dasatinib Side Effects</u>**

**Common (occurring in more than 20% of patients)**

| | | |
|---|---|---|
| • swelling<br>• headache<br>• fatigue<br>• skin rash (possible itching, blistering, shedding, irritation, and/or redness) | • diarrhea<br>• nausea<br>• low blood cell counts (red, white, platelets) | • pain<br>• build-up of fluid in and/or around the lungs (possible difficulty breathing)<br>• difficulty breathing |

**Occasional (occurring in 3-20% of patients)**

| | | |
|---|---|---|
| • irregular heartbeat<br>• build-up of fluid in the tissue around the heart<br>• decreased blood supply to the heart<br>• heart failure<br>• severe heart problems<br>• enlarged heart<br>• fever<br>• central nervous system bleeding | • itching<br>• constipation<br>• vomiting<br>• abdominal pain<br>• digestive system bleeding<br>• abnormal liver tests (possible liver damage or yellowing of the skin and/or eyes) | • muscle spasms<br>• abnormal kidney test (possible kidney damage)<br>• increased blood pressure in the lungs (possible difficulty breathing and/or heart failure)<br>• infection |

**Exact frequency unknown but occurring in between 1 and 10% of patients:**

| | | |
|---|---|---|
| • fast heartbeat<br>• chest pain<br>• flushing<br>• high blood pressure<br>• chills<br>• depression<br>• dizziness<br>• difficulty sleeping<br>• acne<br>• hair loss (partial or total)<br>• eczema (skin inflammation)<br>• dry skin<br>• sweating<br>• high blood levels of uric acid (possible painful joints and/or kidney failure) | • abdominal swelling<br>• loss of appetite<br>• upset stomach<br>• inflammation of the stomach and/or intestines<br>• mouth blisters/sores (possible difficulty swallowing)<br>• abnormal taste<br>• weight loss/gain<br>• nerve damage (possible numbness, pain, and/or loss of motor or sensory function) | • weakness<br>• blurry vision<br>• dry eyes<br>• vision problems<br>• ringing in the ears<br>• cough<br>• lung inflammation (possible difficulty breathing)<br>• severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) |

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

| | | |
|---|---|---|
| • chest pain due to heart trouble<br>• low blood pressure (possible dizziness/fainting)<br>• heart attack<br>• heart and lung failure<br>• heart inflammation<br>• inflammation of the tissue around the heart (possible chest pain)<br>• abnormal blood test (possible heart problems)<br>• stroke<br>• blood clots in a vein (possible pain, swelling, and/or redness)<br>• abnormal blood clotting<br>• seizure<br>• memory loss<br>• dementia (loss of mental capacity) | • inflammation of the thyroid gland (possible tenderness in the neck)<br>• overactive thyroid gland (possible weight loss, heart rate changes, and/or sweating)<br>• underactive thyroid gland (possible weight gain, heart failure, and/or constipation)<br>• high blood levels of fat (possible heart disease and/or stroke)<br>• low blood levels of albumin (possible swelling, weakness, and/or fatigue)<br>• diabetes | • decreased bone marrow function and inability to make red blood cells<br>• blockage of the bile tract (possible body yellowing and/or abdominal pain)<br>• liver damage<br>• paralysis of nerves controlling the head and neck<br>• bone destruction<br>• eye bleeding<br>• inflammation of an eye nerve<br>• hearing loss<br>• kidney failure<br>• breakdown of muscle tissue (possible kidney failure) |

| | | |
|---|---|---|
| • fainting<br>• difficulty walking<br>• inflammation of the fatty layer under the skin<br>• skin condition with fever and skin lesions<br>• painful skin bumps<br>• hand-foot syndrome (palms of hands/soles of feet having pain, swelling, and blistering)<br>• very severe blistering skin disease (with ulcers of the skin and digestive tract) | • fluid in the abdomen<br>• dehydration<br>• gum bleeding<br>• stomach ulcer<br>• abnormal connections or passageways between organs or vessels<br>• intestinal blockage<br>• gallbladder inflammation (possible abdominal pain)<br>• severe inflammation of the pancreas (possible sudden abdominal pain)<br>• blood in the urine<br>• uterine and/or vaginal bleeding | • difficulty breathing due to narrowing of the airways<br>• blockage in the lung (possible pain, shortness of breath, and/or failure to breathe)<br>• coughing up blood<br>• breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)<br>• allergic reaction |

Dasatinib may cause harm to a fetus if taken during pregnancy.

**<u>Nilotinib Side Effects</u>**

**Common (occurring in more than 20% of patients)**

| | | |
|---|---|---|
| • headache<br>• fatigue<br>• fever<br>• skin rash and/or itching | • night sweats<br>• nausea<br>• vomiting<br>• diarrhea<br>• constipation | • low blood cell counts (red, platelets, white)<br>• joint pain<br>• cough<br>• infection |

**Occasional (occurring in 3-20% of patients)**

| | | |
|---|---|---|
| • high blood pressure<br>• swelling (arm/leg)<br>• narrowing of the arteries (possible high blood pressure, fatigue, and/or weakness)<br>• blocked arteries in part of your body (possible decreased blood flow | • dry skin<br>• hair loss (partial or total)<br>• high blood sugar (possible diabetes)<br>• abnormal salts, minerals, and/or acids in the blood (possible weakness, | • upset stomach<br>• pain (abdomen/mouth/<br>• throat)<br>• loss of appetite<br>• abnormal liver tests (possible liver damage and/or |

| | | |
|---|---|---|
| that may result in pain, organ damage, and/or loss of limbs)<br>• stroke<br>• difficulty sleeping<br>• dizziness<br>• weakness | swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure)<br>• abnormal digestive blood test (possible inflammation of the pancreas) | yellowing of the skin and/or eyes)<br>• pain (arm/leg/muscle/ back/bone)<br>• muscle spasms<br>• difficulty breathing<br>• flu-like symptoms |

**Exact frequency unknown but occurring in 1-10% of patients:**

| | | |
|---|---|---|
| • chest pain (possibly due to heart trouble)<br>• fast/slow/extra/irregular heartbeat<br>• abnormal EKG<br>• flushing<br>• anxiety<br>• depression<br>• fatigue/lack of energy<br>• numbness<br>• dizziness<br>• acne<br>• eczema (skin inflammation)<br>• skin redness<br>• increased sweating<br>• hives | • itching<br>• non-cancerous or pre-cancerous skin lesions<br>• diabetes<br>• high blood levels of fat (possible heart disease and/or stroke)<br>• abnormal taste<br>• weight gain or loss<br>• gas<br>• abnormal blood test (possible pancreas damage)<br>• inflammation of the pancreas (possible abdominal pain) | • abdominal swelling<br>• frequent urination<br>• abnormal sensation (such as pins and needles)<br>• nerve damage (possible numbness, pain, and/or loss of motor function)<br>• neck pain<br>• dry eye<br>• painful red eyes<br>• bleeding in the eyes<br>• swelling (around the eyes)<br>• voice changes<br>• nosebleed |

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

| | | |
|---|---|---|
| • low blood pressure (possible dizziness/fainting)<br>• severe increase in blood pressure (possible stroke)<br>• heart failure<br>• heart attack<br>• enlarged heart<br>• decreased blood supply to the heart | • overactive thyroid gland (possible weight loss, heart rate changes, and/or sweating)<br>• underactive thyroid gland (possible weight gain, heart failure, and/or constipation)<br>• high hormone blood levels (possible bone | • jaundice (yellowing of skin and/or eyes)<br>• abnormal liver or bone test<br>• swelling of the eye nerve (possible vision loss)<br>• damage to the retina (possible vision loss)<br>• double vision<br>• eye irritation |

| | | |
|---|---|---|
| • inflammation of the tissue around the heart (possible chest pain)<br>• build-up of fluid in the tissue around the heart<br>• severe heart problems<br>• heart valve hardening<br>• artery hardening<br>• blood clots in a vein (possible pain, swelling, and/or redness)<br>• sudden loss of blood resulting in shock<br>• swelling (face)<br>• bleeding around the brain<br>• swelling of the brain (possible headache and/or mental status changes)<br>• memory loss<br>• fainting<br>• loss of consciousness<br>• painful skin bumps<br>• hand-foot syndrome (palms of hands/soles of feet having pain, swelling, and blistering)<br>• red, dry, scaly patches of thickened skin (psoriasis)<br>• inflammation of the thyroid gland (possible tenderness in the neck)<br>• abnormal blood test (possible heart problems) | pain, nausea, and/or kidney stones)<br>• high insulin levels (possible weight gain, weakness, and/or hunger)<br>• low insulin levels (possible anxiety and/or sweating)<br>• low blood sugar<br>• esophagus pain<br>• dehydration<br>• vomiting of blood<br>• bleeding or blood that may be tarry or coffee ground-like in the stool<br>• digestive system bleeding<br>• bleeding in the abdomen<br>• stomach ulcer<br>• hole in the intestines (possibly leaking contents into the abdomen)<br>• intestinal blockage<br>• heavy menstrual bleeding<br>• blood in the urine<br>• high blood platelet count (possible increased clotting)<br>• blockage of the bile tract (possible body yellowing and/or abdominal pain)<br>• liver damage (possibly due to inflammation)<br>• enlarged liver | • blurry vision<br>• kidney failure<br>• high blood levels of uric acid (possible painful joints and/or kidney failure)<br>• blue skin due to low oxygen supply<br>• lung inflammation (possible difficulty breathing)<br>• fluid in and/or around the lungs (possible difficulty breathing)<br>• increased blood pressure in the lungs (possible difficulty breathing and/or heart failure)<br>• allergic reaction (such as a skin reaction)<br>• severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)<br>• breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)<br>• sudden death |

If you stop taking nilotinib, the leukemia cells may start to grow again.

**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

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.

**Questionnaires** may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

**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.

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 if you are sexually active.

Birth Control Specifications: If you can become pregnant, you must use birth control pills, injections, or implanted hormonal methods for as long as you are on study. You may choose to use an intrauterine device (IUD) or intrauterine system (IUS), or other highly effective forms of hormonal birth control (for example hormone vaginal ring or birth control patch).

All males, even if you have had a vasectomy, must use a condom while on study and for at least 30 days after your last dose of study drugs.

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 will result in your removal from this study.

### Loss of Confidentiality

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.

## OPTIONAL PROCEDURES FOR THE STUDY

**Optional Procedure #1:** If you agree, a part of the bone marrow samples collected during this study will be stored in a research bank by MD Anderson for use in biomarker testing, which may include genetic biomarkers, and genomic testing. Samples will be collected from the biopsies you are having as part of the main study at the following time points: within 30 days before starting treatment, every 6 months during the first year, then every 6-12 months, and at your End-of-Treatment Visit. If you stop receiving TKI therapy as part of your standard of care, a part of the bone marrow samples collected 6 and 12 months after stopping therapy will be used for this testing.

**Optional Procedure #2:** If you agree, additional blood (about 2 teaspoons) will be drawn at 4 and 8 weeks after starting treatment, then at 3, 9, 12 and 18 months after treatment, and then every 6 months after that, and stored in a research bank by MD Anderson for use in biomarker and genomic testing. The blood drawn for this testing will be drawn at the same time as the routine blood draws during the study. If you stop receiving the TKI therapy as part of your standard care, additional blood (about 2 teaspoons) will be drawn for this testing before stopping therapy and at 6 and 12 months after stopping TKI therapy.

### Optional Procedure Risks

**Genetic research** may result in the development of beneficial treatments, devices, new drugs, or patentable procedures. There are no plans to provide you compensation from such developments. The results of any genetic tests may be put in your health records. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job.

Researchers can learn about cancer and other diseases from your **banked samples**. In the future, people who may do research with these samples may need to know more information about your health. This information may be collected from your medical record by researchers under the supervision of the study chair. Sometimes your samples may be used for genetic research about diseases that are passed on in families.

## 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 allow a part of the bone marrow sample collected at therapy start, every 6 months during the first year, then every 6-12 months, to be used for biomarker and genomic testing?

**YES** **NO**

**Optional Procedure #2:** Do you agree to allow additional blood to be drawn at 4 and 8 weeks after starting treatment, then at 3, 9, 12 and 18 months, then every 6 months after that, to be used for biomarker and genomic 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 or Novartis 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. Ghayas C. Issa, at 713-745-6798) 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, Novartis, 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 sponsored and/or supported by: Novartis.

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 Novartis 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.

**Genetic Research**
Research samples collected from you as part of this study will be used for genetic research which may include study of the genes potentially involved in causing resistance to treatment. This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment.

**Conflict of Interest**
Dr. Ghayas Issa (Study Chair) has received compensation from Novartis as a Scientific Advisor and Consultant. The financial interests are within the limits of the conflict of interest policy.

Dr. Hagop Kantarjian (Collaborator) has received compensation from Novartis as a Scientific Advisor and Consultant. The financial interests are within the limits of the conflict of interest policy.

Dr. Tapan Kadia (Collaborator) has received compensation from Novartis as a Consultant. The financial interests are within the limits of the conflict of interest policy.

Dr. Guillermo Garcia-Manero (Collaborator) has received compensation from Novartis as a Scientific Advisor. 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
- Novartis, 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.

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 **2019-0618.**

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 _____

**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