Study Title: A Phase II Study to Evaluate the Safety and Efficacy of Rigosertib (ON 01910) plus Pembrolizumab in Patients with Unresectable or Metastatic Melanoma Refractory to Immune Checkpoint Blockade
Version Date: 16Feb2023
PI: Douglas Johnson, M.D., M.S.C.I. NCT05764395

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
You are being asked to participate in this research study because you have a type of skin cancer called melanoma, which cannot be removed by surgery (unresectable) or which has spread to other areas of your body (metastatic). For this condition, you have previously received a type of treatment called immunotherapy (using anti-PD-1 or anti-PD-L1 antibodies) but your disease got worse (progressed) during this previous treatment.

In this study, you study doctor feels you may possibly benefit from investigational treatment with an antibody called pembrolizumab in combination with a drug called rigosertib.

Investigational means the combination of pembrolizumab and rigosertib is being tested in research studies and is not approved as a standard treatment by regulatory health authorities, such as the U.S. Food and Drug Administration (FDA).

Pembrolizumab (also known as KEYTRUDA®) is an anti-PD-1 antibody currently approved by the FDA for treatment of melanoma as well as certain types of several other cancers. Pembrolizumab increases the activity of cells (T cells) in the body's immune system. This happens when the pembrolizumab antibody binds to and blocks a protein receptor (called PD-1) located on the surface of T cells.

Rigosertib is an investigational drug that is being tested in research studies. It is hoped that rigosertib may help against cancer by interfering with the cellular signaling pathways that cancer cells need to grow and divide. Rigosertib is a medicine that may change the immune system to make immunotherapy more

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effective. The combination of rigosertib with pembrolizumab may be a promising treatment. Either alone or in combination with other drugs (including pembrolizumab), rigosertib has not been approved as a standard treatment by the FDA. The safetyand initial possible benefit of rigosertibis currently under investigation in early studies in humans.

It is unknown if this study will help you. You may have side effects from the drugs and feel worse. Your disease may or may not respond to this investigational study treatment.

It is hoped the investigational combination of pembrolizumab and rigosertib will increase the ability of your immune system to fight your disease.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Rigosertib is an oral drug. You will take pills (tablets) of rigosertib by mouth on a daily schedule. Pembrolizumab is an intravenous medication which you will receive once every six weeks by intravenous (IV) infusion into your vein.

The length of time you receive treatment on this study will depend on the side effects you may experience, and how your disease does or does not respond to the study treatment. It is anticipated you may receive study treatment until you have intolerable side effects, until your disease gets worse, or for up to about 2 years of treatment on this study. You also may withdraw from the study at any time.

If you have side effects, your study doctor may require you to reduce your dose of oral rigosertib, or temporarily stop taking rigosertib and/or pembrolizumab . If you have serious side effects, you may be required to permanently stop one the drugs, or stop all study treatment and discontinue participation in the study.

This study receives financial support from Onconova Therapeutics, Inc. (the pharmaceutical company that makes rigosertib) and drug supply from Merck & Co., Inc. (the pharmaceutical company that makes pembrolizumab).

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Up to about 29 patients are anticipated to enroll in this study at Vanderbilt.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may significantly affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

All patients in this study are scheduled to receive pembrolizumab in combination with rigosertib in treatment cycles lasting 28 days per cycle.

Pembrolizumab is scheduled for administration once every 6 weeks by a 30 minute intravenous infusion into a vein.

Rigosertib pills (tablets) are scheduled to be taken twice each day (2 tablets in the morning and 2 tablets in the afternoon), on Days 1 to 21 of each 28-day cycle, followed by 1 week of rest without rigosertib (on Days 22 to 28). You will take rigosertib in a fasting state (without food on an empty stomach), twice daily as follows:

- Morning dose after an overnight fast, on an empty stomach, and wait 1 hour after dosing to have breakfast.
- Afternoon dose at approximately 3 PM (±1 hour) at least 2 hours after lunch, on an empty stomach, and wait 1 hour before the next meal.

Water is permitted during the fasting period. Any vomited dose will be reported as a missed dose. Good hydration (at least 2 liters of water per day) is recommended for all patients. Your study team will have more information about taking rigosertib, and you will likely need to maintain a paper drug diary provided to you, in order to document your rigosertib dosing.

The maximum duration of treatment you could receive in this study is considered to be about 2 years, including up to 18 infusions of pembrolizumab (once every 6 weeks), plus up to 24 twenty-eight day cycles of rigosertib.

If you decide you would like to take part in the study and you sign this informed consent form, you will have screening tests and procedures done to make sure you are eligible to participate.

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STUDY PHASES

This study has three phases: the Screening phase, the Treatment Phase and the Follow up Phase.

Screening

You will have the following done (within 28 days prior to your first dose of treatment in the study unless otherwise noted), in order to determine if you are a good candidate for the study. The information and samples collected as part of these screening activities will be kept and used like the rest of the study results. These tests are sometimes part of regular medical care. They may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This is up to the study doctor.

- **Informed Consent**: Discussion of this study and review and signing of this Informed Consent Form
- **Medical history:** You will be asked about your health and any illnesses you may have or had in the past. You will be asked about medicines you are taking (including over-the-counter medicine, vitamins or herbal treatments).
- **Physical examination:** You will receive a complete physical examination including measurement of height and weight. Your performance status (your ability to carry out your daily activities) will be assessed.
- **Vital signs:** Your temperature, breathing, blood pressure, and heart rate will all be checked.
- **Concomitant medications:** You will be asked what medicines you are taking.
- **Pregnancy Test:** If you are a woman capable of becoming pregnant, you will have a blood or urine test to be sure you are not pregnant.
- **Blood tests (about 1-2 tablespoons):**
  - **Blood tests to check your health:** A small amount of your blood will be drawn from a vein for lab tests (including blood counts and blood chemistry, levels of magnesium and phosphorus, troponin level to check your heart, thyroid level, and lactate dehydrogenase [LDH] level to help check your disease).

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- **Blood test for pregnancy:** If a urine pregnancy test result cannot be confirmed as negative, a blood pregnancy test will be performed.
- **Blood tests for communicable diseases:** As part of this study, you may be tested for communicable diseases e.g. HIV, Hepatitis C. If results show that you are positive for a communicable disease the study staff will tell you the results. We will talk with you before and after testing, and your test result will be given to you only in person. You should know that the study staff may be required to give your name to the Tennessee Department of Health if you test positive because this is the law. It is important to seek medical care if you have a communicable disease. If you need a referral, please let the study staff know.
- **Blood test for correlative labs:** A small amount of your blood will be drawn from a vein for genetic lab tests, which are optional.

- **Urine tests** (about ¼ cup): to check your kidney function and overall health.
- **Computed tomography (CT) or magnetic resonance imaging (MRI)** performed within 30days prior to your first dose of study drug will be reviewed to check the current state of your disease.
  - The MRI scan will take about 60 minutes. An MRI scan is taken in a large machine that is shaped like a tunnel. This scan does not use x-rays. Instead, they use a strong magnet and radio waves, like those used in an AM/FM radio to make pictures of your body.
  - You may not be able to have this scan if you have a device in your body such as aneurysm clips in the brain, heart pacemakers or defibrillators, and cochlear implants. Also, you may not be able to have this scan if you have an iron-based tattoos, pieces of metal (bullet, BB, shrapnel) close to or in an important organ (such as the eye).
  - Certain metal objects like watches, credit cards, hairpins, writing pens, etc. may be damaged by the machine or may be pulled away from the body being scanned. For these reasons, you will be asked to remove these objects before going into the room for the scan.
  - You will hear "hammering", clicking or squealing noises during the scan. You will be given earplugs to reduce the noise. You will also be told how to alert the staff if you need them.
  - During the scan, the MRI staff is able to hear and talk to you. You will also be able to hear the staff. They will be talking to you during your scan and may ask you to hold your breath, not move, or other simple tasks. You may be asked to lie very still throughout the scan.

- **Archival or fresh tumor tissue:**
  - Each patient in this study must provide a sample of tumor tissue from a biopsy, surgery or procedure. Required before starting study treatment, this tumor tissue must not have received radiation and can be a sample that is either old (archival) or new (recently obtained within 3 months prior to enrollment in this study).
  - Please note there is a chance you may need a new biopsy during screening, if you do not already have an existing tumor sample available, suitable and sufficient for testing.
  - Additionally, at least 10 of 29 patients enrolled in this study will each be required to have up to 3 fresh biopsies. These biopsies are intended to occur during Screening prior to starting study treatment; and after starting study treatment on Cycle 3, Day 1 (approximately during study Week 8) and on Cycle 5, Day 1 (approximately during study Week 16). Your study doctor will tell you more about this, including the intention that the fresh biopsies are obtained only from patients who have an easily accessible tumor (such as a lesion located on the surface of the skin, or just before the skin surface).
  - The purpose of these tumor samples is to perform research testing on how the rigosertib and pembrolizumab study treatment is interacting with your immune system (in particular your T cells).

Treatment, End-of-Treatment Visit, and Follow-Up Phases

Cycle 1, Day 1 (Week 0)
If you are eligible for the study, you will return to clinic to start the study treatment; the following things will be done:

- Physical exam, vital signs, body weight, and questions about your level of activity.
- Questions about any changes to your health and to your medications.
- Collection of about ¼ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, and levels of magnesium and phosphorus).
- Collection of about ⅔ tablespoon of blood for genetic research (optional).
- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test (unless already completed during screening ≤ 72 hours prior to your first dose of study treatment).
- Collection of up to about ⅔ tablespoon of blood for research.
- **Rigosertib** oral drug supplied for Cycle 1.
- **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.

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Cycle 1, Day 15 (Approximately Week 2)

- Physical exam, vital signs, body weight, and questions about your level of activity.
- Questions about any side effects you are experiencing and any changes to your medications.
- Collection of about ¼ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, and levels of magnesium and phosphorus).
- Collection of about ⅔ tablespoon of blood for genetic research (optional).

Cycle 2, Day 1 (Approximately Week 4)

- Physical exam, vital signs, body weight, and questions about your level of activity.
- Questions about any side effects you are experiencing and any changes to your medications.
- Collection of about ¼ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, and levels of magnesium and phosphorus).
- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- Collection of about ⅔ tablespoon of blood for genetic research (optional). **Rigosertib** oral drug reconciled (counted) and refilled for new cycle if not already done.

Cycle 2, Day 15 (Approximately Week 6)

- Physical exam, vital signs, body weight, and questions about your level of activity.
- Questions about any side effects you are experiencing and any changes to your medications.
- Collection of about ¼ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, and levels of magnesium and phosphorus).
- Collection of about ⅔ tablespoon of blood for genetic research (optional).
- **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.

Cycle 3, Day 1 (Approximately Week 8)

- Physical exam, vital signs, body weight, and questions about your level of activity.
- Questions about any side effects you are experiencing and any changes to your medications.
- Collection of about ½ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, magnesium and phosphorus levels, troponin level to check your heart, and thyroid level).
- Collection of about ⅔ tablespoon of blood for genetic research (optional).

- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- Fresh tumor biopsy: At least 10 of 29 patients enrolled in this study will each be required to have up to 3 fresh biopsies. These biopsies are intended to occur during Screening prior to starting study treatment; and after starting study treatment on Cycle 3, Day 1 (approximately during study Week 8) and on Cycle 5, Day 1 (approximately during study Week 16). Your study doctor will tell you more about this, including the intention that the fresh biopsies are obtained only from patients who have an easily accessible tumor (such as a lesion located on the surface of the skin, or just before the skin surface).
- Computed tomography (CT) or magnetic resonance imaging (MRI) to check your disease. Scanning will be done every 8 weeks, starting at Week 8 through Week 24. After Week 24, at the discretion of your study doctor, tumor imaging may be performed approximately every 12 weeks (Weeks 36, 48, etc.) or whenever clinically indicated while you remain on study treatment. Also, if scans at some point initially indicate that your disease either is or is not responding to the study treatment, then you will likely have repeat scans done at least 4 weeks after the initial scans, in order to confirm treatment response or disease progression.
- **Rigosertib** oral drug reconciled and refilled for new cycle if not already done.

Cycle 3, Day 15 (Approximately Week 10)

- Physical exam, vital signs, body weight, and questions about your level of activity.
- Questions about any side effects you are experiencing and any changes to your medications.
- Collection of about $^{1}/_{10}$ tablespoon of your blood for routine laboratory testing (including blood chemistry and levels of magnesium and phosphorus).

Cycle 4, Day 1 (Approximately Week 12)

- Physical exam, vital signs, body weight, and questions about your level of activity.
- Questions about any side effects you are experiencing and any changes to your medications.
- Collection of about ¼ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, and levels of magnesium and phosphorus).
- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test. Subsequently, additional pregnancy testing will be performed every 4 months while you receive study treatment, and also when you stop the study.
- Collection of about ⅔ tablespoon of blood for genetic research (optional).
- **Rigosertib** oral drug reconciled and refilled for new cycle if not already done.
- **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.

Cycle 4, Day 15 (Approximately Week 14)

- Physical exam, vital signs, body weight, and questions about your level of activity.
- Questions about any side effects you are experiencing and any changes to your medications.
- Collection of about $^{1}/_{10}$ tablespoon of your blood for routine laboratory testing (including blood chemistry and levels of magnesium and phosphorus).

Cycle 5, Day 1 (Approximately Week 16)

- Fresh tumor biopsy: At least 10 of 29 patients enrolled in this study will each be required to have up to 3 fresh biopsies. These biopsies are intended to occur during Screening prior to starting study treatment; and after starting study treatment on Cycle 3, Day 1 (approximately during study Week 8) and on Cycle 5, Day 1 (approximately during study Week 16). Your study doctor will tell you more about this, including the intention that the fresh biopsies are obtained only from patients who have an easily accessible tumor (such as a lesion located on the surface of the skin, or just before the skin surface).
- Computed tomography (CT) or magnetic resonance imaging (MRI) to check your disease. Scanning will be done every 8 weeks, starting at Week 8 through Week 24. After Week 24, at the discretion of your study doctor, tumor imaging may be done approximately every 12 weeks (Weeks 36, 48, etc.) or whenever clinically indicated while you remain on study treatment.
- **Rigosertib** oral drug reconciled and refilled for new cycle if not already done.

Cycle 5, Day 15 (Approximately Week 18)

- Physical exam, vital signs, body weight, and questions about your level of activity.
- Questions about any side effects you are experiencing and any changes to your medications.
- Collection of about ½ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, magnesium and phosphorus levels, and thyroid level).
- Collection of about ⅔ tablespoon of blood for genetic research (optional).
- **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.

Cycle 6, Day 1 (Approximately Week 20)

- **Rigosertib** oral drug reconciled and refilled for new cycle if not already done.

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Day 1 of ODD Cycles 7, 9, 11, 13, 15, 17, 19, 21, and 23
(Approximately Weeks 24, 32, 40, 48, 56, 64, 72, 80, and 88)

- Day 1 each Cycle: **Rigosertib** oral drug reconciled and refilled for new cycle if not already done.
- Cycle 7, Day 1:
  - Physical exam, vital signs, body weight, and questions about your level of activity.
  - Questions about any side effects and any changes to your medications.
  - Collection of about ¼ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, and levels of magnesium and phosphorus).
  - Urine test to check your kidney function and overall health (about ¼ cup of urine).
  - Collection of about ⅔ tablespoon of blood for genetic research (optional).
  - Computed tomography (CT) or magnetic resonance imaging (MRI) to check your disease. Scanning will be done every 8 weeks, starting at Week 8 through Week 24. After Week 24, at the discretion of your study doctor, tumor imaging may be performed approximately every 12 weeks (Weeks 36, 48, etc.) or whenever clinically indicated while you remain on study treatment.
  - **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.
- Cycle 13, Day 1:
  - Computed tomography (CT) or magnetic resonance imaging (MRI) to check your disease.
  - Questions about any side effects you are experiencing.
  - **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.
- Cycle 19, Day 1:
  - Computed tomography (CT) or magnetic resonance imaging (MRI) to check your disease.
  - Questions about any side effects you are experiencing.
  - **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.

Day 15 of ODD Cycles 11, 17 and 23
(Approximately Weeks 42, 66 and 90)

- Cycle 11, Day 15:
  - Physical exam, vital signs, body weight, and questions about your level of activity.
  - Questions about any side effects you are experiencing and any changes to your medications.
  - Collection of about ½ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, levels of magnesium and phosphorus, and thyroid level).
  - Collection of about ⅔ tablespoon of blood for genetic research (optional).
  - **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.

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- Cycle 17, Day 15:
  - __ Questions about any side effects you are experiencing.
  - — **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.

- Cycle 23, Day 15:
  - — Questions about any side effects you are experiencing.
  - — **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.

Day 1 of EVEN Cycles 8, 10, 12, 14, 16, 18, 20, 22, and 24
(Approximately Weeks 28, 36, 44, 52, 60, 68, 76, 84, and 92)

- Day 1 each Cycle: **Rigosertib** oral drug reconciled and refilled for new cycle if not already done.
- Cycle 8, Day 1: If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.
- Cycle 10, Day 1:
  - — Physical exam, vital signs, body weight, and questions about your level of activity.
  - — Questions about any side effects you are experiencing and any changes to your medications.
  - — Collection of about ¼ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, and levels of magnesium and phosphorus).
  - — Urine test to check your kidney function and overall health (about ¼ cup of urine).
  - — Collection of about ⅔ tablespoon of blood for genetic research (optional).
  - — Computed tomography (CT) or magnetic resonance imaging (MRI) to check your disease. Scanning will be done every 8 weeks, starting at Week 8 through Week 24. After Week 24, at the discretion of your study doctor, tumor imaging may be performed approximately every 12 weeks (Weeks 36, 48, etc.) or whenever clinically indicated while you remain on study treatment.
  - — **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.
- Cycle 12, Day 1: If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.
- Cycle 14, Day 1: Questions about any side effects you are experiencing.
- Cycle 16, Day 1:
  - — Computed tomography (CT) or magnetic resonance imaging (MRI) to check your disease.
  - — If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.
  - — Questions about any side effects you are experiencing.
  - — **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.

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- Cycle 20, Day 1:
  - If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.
  - Questions about any side effects you are experiencing.
- Cycle 22, Day 1:
  - Computed tomography (CT) or magnetic resonance imaging (MRI) to check your disease.
  - Questions about any side effects you are experiencing.
  - **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.

Day 15 of EVEN Cycles 8, 14, 20, and 22
(Approximately Weeks 30, 54, 78, and 86)

- Cycle 8, Day 15:
  - Physical exam, vital signs, body weight, and questions about your level of activity.
  - Questions about any side effects you are experiencing and any changes to your medications.
  - Collection of about ½ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, levels of magnesium and phosphorus, and thyroid level).
  - Collection of about ⅔ tablespoon of blood for genetic research (optional).
  - **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.
- Cycle 14 Day 15:
  - Questions about any side effects you are experiencing.
  - **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.
- Cycle 20, Day 15:
  - Questions about any side effects you are experiencing.
  - **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes.
- Cycle 22, Day 15: Questions about any side effects you are experiencing.

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End of Treatment

In general, you may continue this study for up to approximately 2 years of study treatment, as long as you do not have serious side effects, and as long as your disease does not get worse. The maximum duration of treatment you could receive in this study, considered to be about 2 years, includes up to 18 infusions of pembrolizumab (once every 6 weeks), plus up to 24 twenty-eight day cycles of rigosertib. In order to safely stop the study, you will have the following things done when you permanently stop the study treatment:

- Physical exam, vital signs, body weight, and questions about your level of activity.
- Questions about any side effects you are experiencing, and about any changes to your medications and any new anti-cancer therapy you may have started.
- Collection of about ½ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, levels of magnesium and phosphorus, thyroid level, and lactate dehydrogenase [LDH] level to help check your disease).
- If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.

30-Day Follow-Up

Approximately 30 days after your final treatment in this study (or earlier if you begin new anti-cancer treatment after this study), you will have the following things done as part of follow-up:

- Questions about any side effects you are experiencing, and about any new anti-cancer therapy you may have started.
- Collection of about ⅓ tablespoon of your blood for routine laboratory testing (including levels of magnesium and phosphorus, thyroid level, and lactate dehydrogenase [LDH] level to help check your disease).

Long-term Follow-Up

About every 3 months (12 weeks) after your 30-Day follow-up visit in this study, you and/or your doctor's office may be contacted, for example by telephone or a clinic visit, to check on how you are doing and to learn about any new anti-cancer therapy you may have started. This will continue until one of the following occurs (whichever occurs first): study ends, you withdraw your consent, your death, or until 3 years after your final dose of treatment in this study. Additional follow-up beyond one year may occur if deemed medically necessary by your study physician.

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Side effects and risks that you can expect if you take part in this study:

You may have side effects while on this study. Everyone participating in the study will be watched carefully for any side effects. However, study doctors don't know all the side effects that may happen. You should tell your study doctor or study nurse right away about any possible side effects that you experience.

Side effects may be mild or very serious. Some side effects could begin soon after you begin the study treatment. Other side effects could be delayed and occur later in the study, or even after you stop the study treatment. Your health care team may give you medicines to help decrease the frequency or severity of side effects. In some cases, side effects can be serious, long lasting, or may never go away. There is also a risk of death.

You should talk to your study doctor about any side effects you have while participating in this study. You also need to discuss other medications you are currently taking, in order to avoid some side effects when combining rigosertib with other drugs, such as warfarin (an anticoagulant or blood thinner, typically used to prevent blood clots), or phenytoin (an anticonvulsant, often used to prevent seizures and to treat epilepsy).

Risks of Rigosertib

In general, based on studies of rigosertib administered to patients either by mouth or by intravenous IV infusion, the most common side effects of rigosertib include:

- **Low white blood cells** (increased risk of infection)
- **Low platelets** (increased risk of bleeding)
- **Bladder inflammation** (cystitis)
- **Painful urination** (dysuria)
- **Blood in urine** (hematuria)
- **Fatigue**.

Urinary symptoms associated with rigosertib have been reduced by changing the timing of rigosertib administration to avoid the drug settling in the bladder at night.

In this study, all patients will receive oral rigosertib by mouth. In other clinical trials, oral rigosertib has been administered to patients with myelodysplastic syndrome (MDS, a type of blood cancer) or other hematologic cancers of the blood. Additional information listed below about potential risks of rigosertib is based on information from these studies.

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Very Common Side Effects Of Rigosertib, Some May Be Serious
In 100 people receiving oral rigosertib, at least 10 may have:

- **Diarrhea** (frequent, loose watery stools)
- **Dysuria** (difficult and/or painful urination)
- **Fatigue** (feeling tired, tiredness, weakness)
- **Hematuria** (blood in the urine)
- **Micturition urgency** (frequent urination)
- **Nausea** (feeling sick to the stomach)
- **Pollakiuria** (frequent urination)
- **Urinary tract pain** (pain from the kidneys, ureters, bladder, urethra)

Very Common Side Effects Of Rigosertib, Some May Be Serious
In 100 people receiving oral rigosertib, from 1 to 9 may have:

- **Abdominal discomfort** (abdominal pain)
- **Abdominal distension** (feeling of fullness and tightness in the abdomen, bloating)
- **Abdominal pain** (pain in the belly area)
- **Abdominal pain upper** pain in the upper belly area)
- **Alanine aminotransferase increased** (above normal level of liver enzyme lab test)
- **Anemia** (low number of red blood cells that can cause tiredness and shortness of breath
- **Aspartate aminotransferase increased** (above normal level of liver enzyme lab test)
- **Asthenia** (feeling weakness and having less energy)
- **Constipation** (difficulty passing stool or hard stool)
- **Cystitis** (inflammation or infection of the bladder)
- **Cystitis noninfective** (inflammation of the bladder)
- **Decreased appetite** (desire to eat is reduced not due to a mental health issue)
- **Dehydration** (too little fluid in the body)
- **Dizziness** (sensation of losing balance)
- **Dry mouth** (reduced saliva flow; mouth feeling dry)
- **Dysgeusia** (taste changes that may affect the way foods normally taste)
- **Dyspepsia** (indigestion, "heartburn", upset stomach)
- **Dyspnea** (shortness of breath)
- **Headache** (continuous or throbbing pain in the head)
- **Hyponatremia** (decreased levels of sodium in the blood)
- **Insomnia** (difficulty sleeping or falling asleep)
- **Leukopenia** (white blood cells circulating in the blood are abnormally low)
- **Muscle spasms** (involuntary contraction or movement of muscle, cramp)
- **Neutropenia** (decreased number of neutrophils, a type of white blood cell, can cause infection)
- **Nocturia** (urination at night)

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- **Edema peripheral** (swelling in the arms or legs)
- **Proteinuria** (excessive protein in the urine)
- **Pruritus** (itching)
- **Pyrexia** (elevated body temperature)
- **Rash** (area of skin redness or raised bumps)
- **Stomatitis** (swelling of mouth or lips)
- **Thrombocytopenia** (low number of platelets in blood; increased risk of bleeding)
- **Urinary incontinence** (loss of bladder control)
- **Urinary retention** (difficulty emptying the bladder, inability to urinate)
- **Urinary tract infection** (infection in the kidneys, ureters, bladder, urethra)
- **Vomiting** (ejection of something from the stomach through the mouth)
- **Weight decreased** (loss of weight due to reduced tissue, mass, fluid, or fat).

Risks of Pembrolizumab (also known as KEYTRUDA®)

Pembrolizumab can cause serious side effects. Pembrolizumab is a medicine that may treat certain cancers by working with your immune system. Pembrolizumab can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work.
These problems can sometimes become severe or life-threatening and can lead to death.

You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your study doctor right away if you develop any new or worsening signs or symptoms, including:

Lung problems
- cough
- shortness of breath
- chest pain.

Intestinal problems
- diarrhea (loose stools) or more frequent bowel movements than usual
- stools that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdomen) pain or tenderness.

Liver problems
- yellowing of your skin or the whites of your eyes
- severe nausea or vomiting
- pain on the right side of your stomach area (abdomen)
- dark urine (tea colored)
- bleeding or bruising more easily than normal.

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Hormone gland problems

- headaches that will not go away or unusual headaches
- eye sensitivity to light
- eye problems
- rapid heartbeat
- increased sweating
- extreme tiredness
- weight gain or weight loss
- feeling more hungry or thirsty than usual
- urinating more often than usual
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- dizziness or fainting
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- hypothyroidism

Kidney problems

- decrease in your amount of urine
- blood in your urine
- swelling of your ankles
- loss of appetite.

Skin problems

- rash
- itching
- skin blistering or peeling
- painful sores or ulcers in your mouth or in your nose, throat, or genital area
- fever or flu-like symptoms
- swollen lymph nodes.

Additionally, since pembrolizumab was approved in September 2014, the following side effect has been reported by people receiving pembrolizumab. The side effect was voluntarily reported from a group of people of unknown size. It is not possible to estimate the frequency of this side effect.

Inflammation or swelling of the nerve fibers of the eye which send visual information from your eye to your brain. This health condition often has a sudden onset of vision loss, loss of color vision, pain when

moving your eyes, and/or loss of peripheral vision. It may affect one or both eyes at the same time (optic neuritis).

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with pembrolizumab. Call or see your study doctor right away for any new or worsening signs or symptoms, which may include:

- chest pain, irregular heartbeat, shortness of breath, swelling of ankles
- confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- persistent or severe muscle pain or weakness, muscle cramps
- low red blood cells, bruising.

Infusion reactions that can sometimes be severe or life-threatening. Signs and symptoms of infusion reactions may include:

- chills or shaking
- dizziness
- itching or rash
- feeling like passing out
- flushing
- fever
- shortness of breath or wheezing
- back pain.

Common side effects of pembrolizumab when used alone include:

- feeling tired
- pain, including pain in muscles, bones or joints and stomach-area (abdominal) pain
- rash
- diarrhea
- fever
- cough
- decreased appetite
- itching
- shortness of breath
- constipation
- nausea
- low levels of thyroid hormone.

Side effects of pembrolizumab when used alone that are more common in children than in adults include:

- fever
- vomiting
- upper respiratory tract infection
- headache
- low levels of white blood cells
- low levels of red blood cells (anemia).

Common side effects of pembrolizumab when given with certain chemotherapy medicines include:

- feeling tired or weak
- nausea
- constipation
- diarrhea
- decreased appetite
- rash
- vomiting
- cough
- trouble breathing
- fever
- hair loss
- inflammation of the nerves that may cause pain, weakness, and paralysis in the arms and legs
- swelling of the lining of the mouth, nose, eyes, throat, intestines, or vagina
- mouth sores
- headache
- weight loss
- stomach-area (abdominal) pain
- joint and muscle pain
- trouble sleeping.

Before receiving pembrolizumab, tell your study doctor about all of your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-

Barré syndrome

- are pregnant or plan to become pregnant.

Reproductive Health/Sexual Activity and Pregnancy

Some medications have the potential to cause side effects in the reproductive system of women or men that could cause harm, including birth defects, during pregnancy. Rigosertib is known to be harmful to a developing embryo and fetus. Pembrolizumab can harm an unborn baby. There has not been enough study of rigosertib in combination with pembrolizumab to fully predict the risks to pregnant women, the developing fetus, or to the breast-feeding child.

If sexually active with the ability to become pregnant or to cause pregnancy, both women and men participating in this study must agree to use effective birth control as discussed with and directed by their study doctor during treatment with these medicines and for 180 days after completing study treatment.

In the event of pregnancy, the study team may request additional information about the pregnancy or the outcome of the pregnancy in an effort to better understand the effects of study treatment on a pregnancy and/or the fetus.

Information for Women who could become pregnant (Women of Child-bearing Potential):

- Before starting treatment in this study, tell your study doctor if you are pregnant or plan to become pregnant.
- You will have a pregnancy test before starting treatment in this study.
- Together with your partner, you must use effective birth control during and for at least 120 days for women and 90 days for men after your final dose of rigosertib or pembrolizumab (whichever dose occurs last). Talk to your study doctor about birth control methods you can use during this time.
- Tell your study doctor right away if you think you may be pregnant, or if you become pregnant during treatment in this study.
- Tell your study doctor if you are breastfeeding or plan to breastfeed. It is not known if the study treatment passes into your breast milk. Do not breastfeed during study treatment and for at least 120 days after your final dose of study treatment.

Information for Men with sexual partners who could become pregnant (Partners of Childbearing Potential):

From the time you start study drug treatment until at least 90 days after your final dose of rigosertib or pembrolizumab (whichever dose occurs last) you must:

- Tell your sexual partner about your participation in this clinical trial. Together with your partner, you must use effective birth control during and for at least 90 days after your final dose of rigosertib or pembrolizumab (whichever dose occurs last). Talk to your study doctor about birth control methods you can use during this time.
- Tell your study doctor immediately if your partner becomes pregnant during this clinical trial.
- Do not donate sperm for at least 90 days after your final dose of study treatment.

Risks of Procedures

Blood Collection

Risks of taking blood include pain, a bruise at the point where blood is taken, redness and swelling of the vein, infection, and a rare risk of fainting.

Intravenous (IV) Catheter

Prior to beginning pembrolizumab, an intravenous (IV) catheter will be inserted for the delivery of pembrolizumab and to take blood samples. IV catheters can usually be placed in a hand, arm, or leg. These are known as "peripheral" IVs. IVs placed in the central circulation, like the internal jugular vein (neck) or subclavian vein (just beneath the collar bone), are known as "central lines." You should discuss this with your study doctor. For both types of intravenous catheter, the area will be numbed (with an anesthetic) before the catheter is inserted. During the insertion, you could feel a pinch and shortly thereafter bleeding, redness, or a bruise could develop. Rarely, an infection could occur if not kept clean. For central catheters, although rare, they can sometimes cause collapse of a lung or cause bleeding. Lung collapse is usually treated by putting a tube into your chest for a few days to allow your lung to expand. Pressure is placed on any area that might bleed.

Tumor Biopsy

A tumor tissue biopsy is a procedure that involves removing samples of tumor surgically or percutaneously (through the skin) often using a hollow "core" needle. To undergo a biopsy, you will be given medication to help numb the area and reduce pain. A small cut may then be made in the skin. Biopsy risks can include:

- Pain and discomfort. The amount of pain and discomfort will vary, depending on the location of the biopsy site. These risks can be discussed with the study doctor.
- Minor bleeding at the biopsy site.
- Tenderness at the biopsy site.
- Scarring at the biopsy site.
- Rarely, an infection at the biopsy site.
- You may receive an injection of lidocaine to numb the area of the biopsy site. Lidocaine, a numbing drug, may burn or cause a rash, redness, or soreness where you get the shot. There is a risk that this drug may cause problems with heart rhythm.
- Uncommonly, complications from biopsies can be life threatening. As with any interventional procedure, other potentially serious complications from bleeding or organ damage may occur.

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These might require additional surgical intervention.

Computed Tomography (CT)

A CT scan uses radiation (x-rays) guided by a computer to take pictures of your internal organs. The contrast solution that may be given for a CT scan may cause an allergic reaction (rare). Severe allergic reactions can be life threatening. CT contrast solution can cause kidney damage, especially if you are diabetic, dehydrated (lost body water) or elderly. CT contrast is used in scans to highlight specific parts of the body.

During CT scans, you will lie still on a table that slides into a tunnel slightly wider than your body. People who feel anxiety in confined spaces (claustrophobia) may feel uncomfortable in the narrow cylinder. If you feel uncomfortable in confined spaces, please tell your study doctor and the imaging team performing your scans. They may give you a medication in an effort to make you feel more comfortable in a confined space.

Radiation Risks:

This research study may involve exposure to radiation from up to 1 CT Head scan and 1 CT Chest, Abdomen, Pelvis (CAP) with contrast. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you may receive by participating in this study is equal to your body receiving 55 months (4.6 years) of radiation from your natural surroundings, or about or about 27% of the amount allowed in a year for people who are exposed to radiation as part of their work.

Magnetic Resonance Imaging (MRI)

There are no known major risks with an MRI scan. But it is possible that harmful effects could be found out in the future. Even though the tunnel is open, it may bother you to be placed in a tight space (claustrophobia), and to hear the noise made by the magnet during the scan. You will be given earplugs to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan. It may be hard to lie on the table during the scan. If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs.

If you use a transdermal patch (medicated patches applied to the skin), you may need to take it off during the MRI scan. Transdermal patches slowly deliver medicines through the skin. Some patches have metal in the layer of the patch that is not in contact with the skin (the backing). You may not be able to see the metal in the backing of these patches. Patches that contain metal can overheat during an MRI scan and cause skin burns in the immediate area of the patch. Tell the study doctor that you are using a patch and why you are using it (such as, for pain, smoking cessation, hormones). Ask your doctor for guidance about removing and disposing of the patch before having an MRI scan and replacing it after the procedure. Tell the MRI facility that you are using a patch. You should do this when making your

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appointment and during the health history questions you are asked when you arrive for your appointment.

Risks that are not known:
Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: Participating in this study may help patients with cancer get better care in the future.

The benefits you might get from being in this study: Participating in this study may or may not have direct medical benefit for you. Rigosertib is an investigational product. Rigosertib in combination with pembrolizumab is an investigational combination. You may or may not receive therapeutic benefit from participation in this study. Your condition may get better but it could stay the same or get worse.

Payments for your time spent taking part in this study or expenses:
You will not be paid for your participation in this study.

Costs to you if you take part in this study:
If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

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Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Douglas Johnson at [redacted]. If you cannot reach the research staff, please page the study doctor at [redacted]

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
Your study doctor might take you out of the study for reasons such as:

- You are unable to tolerate the treatment, or you have a side effect and the study doctor feels should end the treatment.
- Your disease spreads or gets worse (progresses).
- You have another serious illness or need major surgery.
- You do not follow the study doctor's instructions.
- Your health changes or new information becomes available and the study doctor feels it is no longer in your best interest for you to continue in the study, or decides to stop the study.

If you are removed from the study, the reason will be explained to you.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

If you decide to not participate in this study, your doctor will discuss other options, such as:

- You may choose to have standard treatment for your disease outside of a clinical trial.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated for your disease.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your disease.

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

Clinical Trials Reporting Program.
Vanderbilt's NCI-Designated Cancer Center or the Sponsor registers National Cancer Institute (NCI)-supported clinical trials with NCI though their Clinical Trials Reporting Program (CTRP) to provide study related information. The data provided will include the following identifiable information that may

identify you: birth month/year and five-digit zip code. NCI uses the data to manage and enhance the nation's investment in cancer research.

Confidentiality:
All efforts within reason will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Your information and samples will be given a code. Dr. Johnson, his staff, and other authorized people will be the only people who know your personal information.

Study data will be recorded in a Vanderbilt electronic database which is maintained by a research coordinator and data manager at Vanderbilt. The electronic database is password protected in order to help protect your identity. Your study records will be locked up in the clinical trials office.
Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Johnson and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

At any time, you may ask to have your sample destroyed. You should contact Dr. Johnson to have your sample destroyed and no longer used for research. His mailing address is:

[redacted]

We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.
There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

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Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include Vanderbilt University Medical Center and its agents or contractors, study safety monitors and auditors, data managers and other agents and contractors used by the study team, researchers and study team members. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. Also, your records may be seen by people from regulatory authorities (such as the U.S. Food and Drug Administration [FDA]), auditors, and the Institutional Review Board [IRB]). By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include any funders of the study and their agents or contractors, outside providers, study safety monitors, government agencies, and other sites in the study. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let him know by using the contact information provided in this consent form. Dr. Johnson's mailing address is:

[redacted]

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Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Signature of Legal Representative _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____

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Consent for Genetic Research

A purpose of this study is to look at genes (DNA) and related genetic information (RNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

Patients with similar diseases do not always obtain the same benefit from the same treatment. Therefore, a goal is to help understand why patients respond differently to treatment, and to then develop treatment that provides maximum benefit for individual patients.

As part of the study, your tumor biopsy tissue, blood and/or fluid samples will be collected to better understand your disease. It is possible that genetic testing may be conducted on some or all of this material. You are being asked for your permission to allow this.

It is possible that genetic testing on these samples could help to learn more about:

- The effect of treatment on your body
- Why some people respond to treatment and others do not
- Why some people have side effects
- The causes of the disease.

What we learn about you from research on your samples is unlikely to be put in your health record. No one else (like a relative, boss, or insurance company) will be given your test results.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job. To help prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Dr. Johnson and his staff helping with the study will have access to your name.

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 comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample may be used to make DNA and/or RNA that will be kept for an unknown length of time (maybe years) for future research. Samples will be destroyed when no longer needed. Your samples may be used to make new products, tests or findings. These may have value and may be developed and

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owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact Dr. Johnson to have your sample destroyed and no longer used for research. His mailing address is:

[redacted]

We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them. There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue/fluid samples may be used for current gene research in cancer related to rigosertib and/or pembrolizumab:

☐ Yes ☐ No

My blood/tissue/fluid samples may be stored/shared for future gene research in cancer:

☐ Yes ☐ No

My blood/tissue/fluid samples may be stored/shared for future gene research for other health problems (such as arthritis, heart disease, etc):

☐ Yes ☐ No

Signature: _____ Date: _____