PRINCIPAL INVESTIGATOR: Steven Pavletic, MD

STUDY TITLE: A Phase I/II Trial of BMS-986253 in Myelodysplastic Syndromes

STUDY SITE: NIH Clinical Center

Cohort: *Affected Patient, Treatment*

Consent Version: *7/5/2023*

WHO DO YOU CONTACT ABOUT THIS STUDY?

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KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. Taking part in research at the NIH is your choice.

You are being asked to take part in this study because you have been diagnosed with Myelodysplastic Syndromes (MDS). In addition, you completed the screening evaluation and were found to be eligible to take part in this research study.

The purpose of this research study is to determine if BMS-986253 is a safe and effective treatment for Myelodysplastic Syndromes (MDS). The first phase of this research study will determine the largest dose of BMS-986253 that can be safely given to patients with MDS. The second phase of this research study will determine how well patients with MDS respond to BMS-986253.

The use of BMS-986253 in this study is considered investigational, which means that is has not been approved by the U.S. Food and Drug Administration (FDA) to treat MDS. However, the FDA has given us permission to use BMS-986253 in this study.

If you have high risk MDS you will receive a DNA methyltransferase inhibitors (DNMTi) per standard of care practice in combination with the study drug. This FDA-approved DNMTi (decitabine and cedazuridine) therapy will be administered orally by the NIH doctors.

There are other drugs that may be used to treat your disease, and these can be prescribed/given by your regular doctor, even if you are not in this study. Some examples include: other DNMTi therapy such as azacitidine or decitabine, other oral treatments such as lenalidomide, or drugs

that would not treat the disease directly but may help improve your blood counts and overall symptoms, such as erythropoietin stimulating agents.

If you decide to join this study, here are some of the most important things you should know:

- You will be seen regularly during the study and will continue to receive study therapy until your disease gets worse or you have unacceptable side effects.
- You will have clinical, laboratory, and other testing, including bone marrow biopsies to see how you are doing and to assess your disease.
- You may experience side effects from taking part in this study. Some can be mild or very serious, temporary, or long-lasting, or permanent, and may include death. Side effects may include nausea, fatigue, rash, and decreased appetite.
- You may not father children or become pregnant during your participation in this study.
- If you are sexually active capable of becoming pregnant or are a male with a partner capable of becoming pregnant you must agree to using adequate contraception (hormonal or barrier method of birth control; abstinence prior to study enrollment and up to 6 months after treatment.

Just as we do not know what side effects you might have; we cannot know if you may benefit from taking part in this study. If you do not benefit, this study and the results of our research will help others in the future.

We will cover the cost for some of your expenses, such as travel and a portion of lodging, and/or meals. Someone will work with you to review your cost of taking part and what we will support.

You are free to stop taking part in the trail at any time. If you decide to stop, the study doctor may ask you to agree to certain tests to make sure it is safe for you to stop.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

The purpose of the phase I portion of this study is to test the safety of BMS-986253 at different doses to find out what effects, if any, it has on participants with MDS to determine the recommended dose for the phase 2 part of the trial. The purpose of the phase II portion of the study is to determine the response rate to BMS-986253.

WHAT WILL HAPPEN DURING THE STUDY?

If you decide to take part in this study, you will be asked to:

- Be willing and able to follow study directions and procedures, which are described below.
- Come to all study visits
- Take the study drugs as prescribed
- Tell the study staff about any side effects or problems
- Ask questions as you think of them
- Tell the study staff if you change your mind about staying in the study
- Tell the study doctor about any prescribed and non-prescribed medicine you are using before and during the study.

You must not take part in other research studies at the same time as you are taking part in this study.

You will receive the study drug as long as your doctor feels that it is safe, you are receiving benefit, and you agree to be in the study.

If you have bad side effects or the MDS gets worse, you or your doctor might decide to stop you from continuing the study.

The study is divided into 2 main periods that are known as Treatment and Follow-up. Each period is described below.

During the study

BMS-986253 will be tested at different dose levels to see which dose is safe and well tolerated when given once every two weeks. Based on this information we will determine the dose for the phase II part of the study.

Treatment Period

The treatment period will consist of treatment cycles. These cycles will each be 28 days long. If you are participating in phase I of the trial and have low risk MDS you will receive BMS-986253 alone on days 1 and 15 of each cycle. If you are participating in phase I of the trial and have high risk MDS you will receive BMS-986253 on days 1 and 15 of each cycle and an oral DNA methyltransferase inhibitors (DNMTi) per standard of care practice on days 2-6.

Once the largest dose of BMS-986253 that is safe to give is established we will move to Phase II of the study. If you are participating in phase II of the trial and have low risk MDS you will receive BMS-986253 alone on days 1 and 15 of each cycle. If you are participating in phase II of the trial and have high risk MDS you will receive BMS-986253 on days 1 and 15 of each cycle and DNA methyltransferase inhibitors (DNMTi) per standard of care practice on days 2-6.

The DNMTi therapy will be administered by your NIH study doctors.

Study Assessments:

During the study, we will perform tests to determine whether you are having side effects or if you are responding to the study therapy. These are listed below under required study procedures section.

Pre-treatment required tests:

Before receiving your first dose of study drug you will have the following assessments performed:

- Visit the NIH Clinical Center to answer questions about your medical history.
- Answer questions about how well you are able to take care of yourself.
- List any prescriptions or non-prescription medicines you have taken.
- Discuss the history of you MDS and any other medicines you have taken for the MDS.
- Have a physical exam (including height and weight).
- Have your temperature, blood pressure, breathing rate, and heart rate monitored.
- Have an electrocardiogram (ECG), a test to show how well your heart is working.
- Have blood samples taken to check your blood counts, blood minerals, liver and kidney function, and for certain virus that might be present (approximately 3 tablespoons).
- Have a bone marrow biopsy sample taken (if not already completed at screening within 30 days prior to treatment).
- If you are a female who can have children, a urine and/or blood pregnancy test will be done. If urine test if positive, it will be confirmed with a blood test (less than 1 teaspoon). The results of the blood test must be negative for you be allowed in the study.
- Functional status assessments and questionnaires, including questions about your ability to function in your daily activities and psychological assessment (questionnaires are only required if you are able to read English).

Study Drug and Required Evaluations:

Each dose of BMS-986253 will be given at the NIH. If you are also receiving DNMTi therapy it will be given also by your NIH doctors.

For both phase I and phase II the following assessments will be performed:

Day 1:

- Visit the NIH Clinical Center to answer questions about your medical history.
- Answer questions about how well you are able to take care of yourself.
- List any prescriptions or non-prescription medicines you have taken.
- Discuss the history of your MDS and any other medicines you have taken for the MDS.
- Have a physical exam (including height and weight)
- Have your temperature, blood pressure, breathing rate, and heart rate monitored.
- Have blood samples taken to check your blood counts, blood minerals, liver and kidney function, and for certain virus that might be present (approximately 3 tablespoons).
- A urine sample will be obtained
- If you are a female who can have children, a urine and/or blood pregnancy test will be done. If urine test if positive, it will be confirmed with a blood test (less than 1 teaspoon). The results of the blood test must be negative for you be allowed in the study.

- Blood samples for pharmacokinetics (PK) and pharmacodynamics (PD) (approximately 5 teaspoons)
- For Phase I patients only Research blood samples (approximately 3 tablespoons)
- BMS-986253 administration

Day 2:

- Have a physical exam (including weight)
- Have your temperature, blood pressure, breathing rate, and heart rate monitored
- Blood samples for 24-hour PK/PD timepoint (approximately 2 teaspoons)

Days 2-6:

For patients with high risk MDS only

DNMTi to be given by your NIH doctors as standard of care.

Day 15 (also day 8 and day 22 during the first cycle where indicated by*):

- Visit the NIH Clinical Center to answer questions about your medical history*
- Answer questions about how well you are able to take care of yourself*
- List any prescriptions or non-prescription medicines you have taken*
- Discuss the history of you MDS and any other medicines you have taken for the MDS*
- Have a physical exam (including height and weight)*
- Have your temperature, blood pressure, breathing rate, and heart rate monitored*
- Have blood samples taken to check your blood counts, blood minerals, liver and kidney function,* and for certain virus that might be present (approximately 3 tablespoons).
- A urine sample will be obtained*
- If you are a female who can have children, a urine and/or blood pregnancy test will be done. If urine test if positive, it will be confirmed with a blood test (less than 1 teaspoon). The results of the blood test must be negative for you be allowed in the study.
- Blood samples for pharmacokinetics (PK) and pharmacodynamics (PD) (approximately 5 teaspoons)
    - For Phase I patients only
- BMS-986253 administration

Days 16:

- Have a physical exam (including height and weight)
- Have your temperature, blood pressure, breathing rate, and heart rate monitored
- Blood samples for 24-hour PK timepoint (approximately 2 teaspoons)

Day 28:

Have a bone marrow biopsy taken at the following timepoint

- Phase I post cycle 1
- Phase II post cycle 2
- Phase II post cycle 6

- With development of treatment-related aplasia or concern that your disease is getting worse
- If your study doctor feels it is indicated.
- Research blood sample (approximately 6 teaspoons)

End of treatment visit: This will be done approximately 30 days from the end of the last cycle of therapy you received.

- Visit the NIH Clinical Center to answer questions about your medical history
- Answer questions about how well you are able to take care of yourself
- List any prescriptions or non-prescription medicines you have taken
- Discuss the history of you MDS and any other medicines you have taken for the MDS.
- Have a physical exam (including height and weight)
- Have your temperature, blood pressure, breathing rate, and heart rate monitored
- Have blood samples taken to check your blood counts, blood minerals, liver and kidney function, and for certain virus that might be present.
- Research blood samples (approximately 3 tablespoons)
- Questionnaires (questionnaires are only required if you are able to read English)

Follow-up Period

About 30 days from the end of the last cycle on therapy you will return to the clinic to have tests performed to see how you are doing. After the 1st follow up visit, follow up will occur via phone call every 3 months for first 24 months, then every 6 months to at least 5 years post enrollment to see how you are doing. Outside medical records will be requested at the time of the first follow-up phone call only.

Additional Research Testing

All of your samples collected for research purposes on this study (such as the cancer cells from peripheral blood/bone marrow samples and normal tissue) may be used to look for specific changes in the DNA in tumors that could be used to develop new ways of diagnosing and treating cancer. DNA (also called deoxyribonucleic acid) in the cells carries genetic information and passes it from one generation of cells to the next – like an instruction manual. Normal tissue contains the DNA that you were born with, DNA in cancer cells has changed – or mutated – and we think that change in the DNA is what causes tumors to form and to grow.

To look at your DNA, we may do what is called "whole genome sequencing." This where we will do special tests in the lab to look at the entire sequence, or order, of how your DNA is put together. This is what makes you unique.

To determine which parts of the DNA have mutated, we will compare DNA in your cancer cells to DNA from your normal cells. We will then analyze the results from similar cancers to see if there are any changes in the samples that are common to a particular type of tumor. To examine the tumor and normal tissue we may use several different techniques depending on the type of tissue we collect. These could include growing cell lines (cells which keep dividing and growing in the laboratory, sometimes for years allowing us to continually study those cells), xenograft

studies (placing or growing cells in another animal, such as mice), and looking in detail at the parts of the genes that produce specific proteins.

However, you should know that the analyses that we perform in our laboratory are for research purposes only; they are not nearly as sensitive as the tests that are performed in a laboratory that is certified to perform genetic testing or testing for routine clinical care. For this reason, in most cases we will not give you the results of the research tests done on your research samples. There may be exceptions to what we share with you and this is described later in this consent form in the section for "**Error! Reference source not found.**."

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study, your involvement is expected to last for as long as you are responding to the therapy and do not have an unacceptable side effect. We will also continue to follow you by phone call after you complete therapy for at least 5 years.

- You will be seen every 2 weeks to receive the study drug BMS-986253. You will also be seen prior to the start of each cycle of therapy.
- Each infusion will last approximately 1-2 hours.
- Some treatment visits will require an overnight admission for blood draws.
- Most treatments will be given in the Outpatient Day Hospital and will take approximately 2-4 hours total time

After a treatment cycle is completed, we will continue to follow you to reassess your disease and whether additional cycles of treatment are recommended for you or refer you back to your doctor for continued care if other treatment options are needed. You may decide to stop participating at any time.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

Not everyone screened for the study will be eligible to receive study therapy. It is expected that up to 93 people may receive study therapy in this study.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

In a clinical study like this one, every risk or side effect cannot be predicted. Each person's reaction to a study drug, device or procedure may be different. You may have a side effect or be at risk for symptoms, illnesses and/or complications that could not be predicted by your study doctor or the sponsor of this clinical study. If such side effects occur, you must inform your study doctor immediately.

The study doctor will be testing your blood and will let you know if changes occur that may affect your health. Below we list the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

BMS-986253

BMS-986253 used in this study, in rare cases, may affect how different parts of your body work including your blood counts, bone marrow, heart, brain, kidney, liver, and skin.

Common side effects (occurring in more than 5% of patients):

- Nausea
- Fatigue
- Decreased appetite
- Itching
- Joint pain

Occasional side effects (occurring in less than 5% of patients):

- Localized infusion reactions
- Fever, chills, weakness
- Diarrhea, vomiting
- Anemia
- Abnormal liver test (possible liver damage)
- Swelling of the hands and feet
- Headache
- Rash
- Dry mouth
- Cytokine release - patients may experience systemic effects such as myalgia, arthralgia, headache, sweats, fever, nausea, and skin rashes. These symptoms are typically observed after the first dose and are usually transient. Rarely, bronchospasm/chest tightness and hypotension or hypertension may be seen.
- Anaphylaxis
- Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activating Syndrome (MAS): HLH/MAS is a rare immune system disease. It can be caused by infections, cancer, certain drugs, and autoimmune diseases. If you develop HLH, your body's immune system does not work normally. Some white blood cells called histiocytes and lymphocytes attack your other blood cells. Abnormal blood cells then build up in your spleen and liver. This causes your spleen and liver to enlarge. HLH is a life-threatening condition. It can cause death in weeks or months even if treated. HLH has been reported in very rare instances in patients with certain advanced cancers that have been treated with this study drug in combination with other drugs but never with BMS-986253 alone.

Decitabine and Cedazuridine:

Side effects include low blood counts (symptoms include fever, anemia, or bleeding) and increased risk of infection.

The most common side effects reported, include:

- Fatigue
- Constipation
- Hemorrhage
- Myalgia
- Mucositis
- Arthralgia
- Nausea
- Dyspnea
- Diarrhea
- Rash
- Dizziness
- Febrile neutropenia

- Edema
- Headache
- Cough
- Decreased appetite
- Upper respiratory tract infection
- Pneumonia
- Transaminase increased

Other side effects linked to medical procedures during the trial:

Blood samples

Side effects of repeated blood sampling depend in part on how the blood is drawn. If blood is drawn through a needle into your skin, side-effects could include pain and bruising in the area where the blood was drawn. Other side-effects can include bruising, redness, discomfort or bleeding at the site of the needle stick, and possible lightheadedness, or rarely, fainting. If you have too much blood taken over a prolonged period, your red blood cell count may drop (this is called "anemia"). As a precaution, we will check your red blood cell level, and give you iron treatment or a blood transfusion if needed. If blood is drawn through a central intravenous catheter, risks include contamination of the catheter which could result in a serious blood stream infection, requiring admission to the hospital and giving you antibiotics through the vein. Up to approximately 10 teaspoons of blood will be collected during one visit and no more than 20 tablespoons will be collected over an 8-week period.

Bone Marrow Aspiration/Biopsy

The bone marrow aspiration and biopsy may cause pain, bruising, bleeding and infection. Soreness near the site may last for a couple of days after the procedure. You may have more pain, risk of bleeding and bruising if you complete both aspiration and biopsy rather than just the aspiration. If your pain is severe or you develop a fever following the procedure, please contact the study team immediately.

Electrocardiogram

Other than possibly experiencing some minor skin irritation from the electrodes there are no anticipated risks related to complete the electrocardiogram and/or the echocardiogram.

Intravenous Catheter

The risks of IV insertion include temporary pain and bleeding or bruising at the site where the IV enters the skin. Sometimes the IV catheter can become displaced, and if this happens there is a small chance of fluid leaking into the tissue surrounding the IV, which may cause some swelling and discomfort. Rarely, the IV site may become infected, which might require treatment with antibiotics.

Questionnaires

Some of the questions in the questionnaire may be upsetting or make you feel uncomfortable. You can skip any of the questions you do not want to answer, and you can stop at any time.

What are the risks related to pregnancy?

If you are able to become pregnant, we will ask you to have a pregnancy test before starting this study. You must use effective birth control methods prior to study entry and try not to become

pregnant while participating in this study *or* during study treatment, and for 6 months after you finish study treatment. If you become pregnant, there may be unknown risks to the fetus or unborn child, or risks that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to a fetus. You must tell the study doctor if your birth control method fails while you are in the study. If you think or know you have become pregnant while participating in this research study, please contact the study team as soon as possible. If you plan to become pregnant in the future, please discuss with the study team how long you need to wait before becoming pregnant after completing the study.

If you are a sexually active person with a partner able to become pregnant, it is important that your partner not become pregnant during your participation in this study *or* during study treatment, and for 6 months after you finish study treatment. There may be unknown risks to a fetus or risks we did not anticipate. You and your partner must agree to use birth control if you want to take part in this study. If you think your partner has become pregnant during your participation in this study, please contact the study team as soon as possible. If you and your partner plan for your partner to become pregnant after your participation in this study, please discuss this with the study team.

Privacy Risks Associated with Genetic Testing

It may be possible that genetic information from you could be used by law enforcement agencies or other entities to identify you or your blood relatives.

Psychological or Social Risks Associated with Return of Incidental or Secondary Findings

As part of the research study, it is possible that you could learn that you have genetic risks for another disease or disability. This may be upsetting and, depending on what you learn, might create a need to make challenging decisions about how to respond.

Although your genomic information is unique to you, you share some genomic similarities with your children, parents, brothers, sisters, and other blood relatives. Therefore, learning your research results could mean something about your family members and might cause you or your family distress. Before joining the study, it may be beneficial to talk with your family members about whether and how they want you to share your results with them.

Protections against misuse of genetic information

This study involves genetic testing on samples. Some genetic information can help predict future health problems of you and your family and this information might be of interest to your employers or insurers. The Genetic Information Nondiscrimination Act (GINA) is a federal law that prohibits plans and health insurers from requesting genetic information or using genetic information. It also prohibits employment discrimination based on your health information. However, GINA does not address discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed condition or disease that has a genetic component.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You might not benefit from being in this study. However, the potential benefit to you given the scientific rationale of this study is that the study drug may reduce inflammation that may be driving

your cancer and leading to other physiologic stress on your body and other organs; may reduce your cancer burden and improve your blood counts; may prevent progression to leukemia – while these are all potential benefits, you may not benefit from the study drug. Participating in this study will also help benefit other patients with your condition, MDS, by contributing more to the current knowledge of effective therapies and will help move progress in the field forward.

Are there any potential benefits to others that might result from the study?

There is a need for new treatments in patients with MDS as standard therapies often do not work. In the future, other people might benefit from this study because of the knowledge gained from the outcome of this trial using BMS-986253.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Before you decide whether or not to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could:

- choose to be treated with drugs already approved by the FDA for your disease, to be prescribed by your home provider,
- choose to take part in a different study clinical trials at NIH or at another institution
- choose not to be treated for cancer at all but instead opt to receive comfort care to relieve symptoms.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

When we are examining your DNA, it is possible that we could identify possible changes in other parts of your DNA that are not related to this research. These are known as "incidental medical findings".

These include:

- Changes in genes that are related to diseases other than cancer
- Changes in genes that are not known to cause any disease. These are known as normal variations.
- Changes in genes that are new and of uncertain clinical importance. This means that we do not know if they could cause or contribute to a disease or if they are normal variations.

Since the analyses that we perform in our laboratory are not nearly as sensitive as the tests that are performed in a laboratory that is certified to perform genetic testing, the genetic changes that we find may or may not be valid. Therefore, we do not plan to inform you of all of the genetic results of testing on your tissue and blood that is performed in our research lab. However, in the unlikely event that we discover a finding believed to be clinically important based on medical standards at

the time we first analyze your results, we will contact you. This could be many years in the future. We will ask you to have an additional sample drawn to verify the findings we have seen in our lab. If the results are verified, you will be re-contacted and offered a referral to a genetic healthcare provider to discuss the results.

EARLY WITHDRAWAL FROM THE STUDY

Your doctor may decide to stop your therapy for the following reasons:

- if he/she believes that it is in your best interest
- if your disease worsens or comes back during treatment
- if you have side effects from the treatment that your doctor thinks are too severe
- if you become pregnant
- if BMS-986253 may become unavailable
- if new information shows that another treatment would be better for you
- if you do not follow the study rules
- if the study is stopped for any reason

In this case, you will be informed of the reason therapy is being stopped.

After therapy is stopped we would like to see you for a safety visit 30 days after your last dose.

You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.

If you decide at any time to withdraw your consent to participate in the trial, we will not collect any additional medical information about you. However, according to FDA guidelines, information collected on you up to that point may still be provided to our collaborators or designated representatives.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

Will your specimens or data be saved by the study team for use in other studies?

As part of this study, we are obtaining specimens and data from you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. The specimens and data will be kept in a way that we will still know that they came from you (i.e., they will be identifiable to us). If we use your identifiable specimens or data for future research, our study will be reviewed and approved by an Institutional Review Board who will make sure that we are protecting your confidentiality. These future might help us to better understand myelodysplastic syndromes, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to the development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my identifiable specimens and data to be stored and used by the study team for future studies as described above.

_____ Yes _____ No

Initial Initial

Will your specimens or data be shared with other researchers for use in other studies?

We may share your specimens and data with other researchers. The other researchers may be doing studies in similar areas to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

If we do share your specimens or data, we will know that the specimens and data came from you. However, the other researchers will not know that they came from you (i.e., they will be de-identified).

I give permission for my identifiable specimens and data to be shared with and used by other researchers for future studies.

_____ Yes _____ No

Initial Initial

In addition to the planned use and sharing described above, we might remove labels from your specimens and data that might identify you (i.e., anonymize them), and use them or share them with other researchers for future studies at the NIH or other places. When we or the other researchers use your anonymized specimens and data for these projects, there will be no way to know that they came from you. We want to make sure that you understand that this is a possibility if you participate in this study. Once we do this, we would not be able to remove your specimens or data from these studies to prevent their use in future research studies because we would not be able to tell which specimens or data belong to you.

Can you change your mind about use and sharing for future research?

If you change your mind and do not want us to store and use your specimens and data for future studies, you should contact the study team. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data is already complete, the information from that research may still be used. Also, if the specimens and data have been shared already, it might not be possible to withdraw them.

Will your genomic data be shared outside of this study?

As part of this study, we will put your genomic information in a large database for broad sharing with the research community. These databases are commonly called data repositories. The information in this database will include but is not limited to, genetic information, race, ethnicity and sex. If your information is placed in one of these repositories, it will be labeled with a code

(not with your name or other information that could be used to easily identify you), and and only qualified researchers will be able to access it. These researchers must receive permission from individuals or committees with the authority to determine whether these researchers can access the data. Before receiving the data, the researchers must promise that they will not attempt to re-identify the subjects whose data they will receive.

Genomic summary information about all of the participants included in this study (including you*)* is being placed in a database and will be available through open access. This information will help the researchers understand if some genetic patterns are more common than others among the subjects who participated in the study. The researchers and non-researchers will be able to access genomic summary information about all the participants included in the study, or summary information combined from multiple studies, without applying for permission. The risk of anyone identifying you based on this information is very low.

How long will your specimens and data be stored by the NIH?

Your specimens and data may be stored by the NIH indefinitely.

Risks of storage and sharing of specimens and data

When we store your specimens and data*,* we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or that no one will gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your specimens and data.

PAYMENT

Will you receive any type of payment for taking part in this study?

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

REIMBURSEMENT

Will you receive reimbursement or direct payment by NIH as part of your participation?

On this study, the NCI will reimburse the cost for some of your expenses such as those for hotel, travel, meals. Some of these costs may be paid directly by the NIH and some may be reimbursed after you have paid. The amount and form of these payments are determined by the NCI Travel and Lodging Reimbursement Policy. You will be given a summary of the policy which provides more information.

If your travel to the NIH Clinical Center (e.g. flight, hotel) is arranged and paid for by the NIH, the agency making the reservations and their representatives will have access to your identifiable information.

COSTS

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

- If some tests and procedures are performed outside the NIH Clinical Center, you may have to pay for these costs.

CONFLICT OF INTEREST (COI)

The NIH reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.

The NIH and the research team for this study are using BMS-986253 developed by Bristol Myers Squibb through a collaboration between your study team and the company. The company also provides financial support for this study.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- The study Sponsor (Center for Cancer Research) or their agent(s)
- Qualified representatives from Bristol Myers Squibb, the pharmaceutical company who produces BMS-986253.

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical information that we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal

Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Steven Pavletic, MD, pavletis@mail.nih.gov, 240-760-6174. Other researchers you may call are: Noa Holtzman, MD, at 240-858-3224. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness should sign below if either:

1. **A short form consent process has been used to enroll a non-English speaking subject or**
2. **An oral presentation of the full consent has been used to enroll a blind or illiterate subject**

Signature of Witness	Print Name of Witness	Date

NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.