NCI Protocol #: 10220

Local Protocol #: NCI10220

Protocol Version Date: January 3, 2025

Protocol Title: A Phase II Basket Trial of Glutaminase Inhibitor (BeGIN) Telaglenastat (CB-839) HCl in Patients with NF1 Aberrations, NF1 Mutant Malignant Peripheral Nerve Sheath Tumors (MPNST), KEAP1/NRF2 and LKB1 Aberrant Tumors

Informed Consent Version Date: January 3, 2025

SUMMARY OF CHANGES—Informed Consent

#	Section	Changes
1	How will information about me be kept private?	Per the recent Executive Order regarding Defending Women (https://www.whitehouse.gov/presidential-actions/2025/01/defending-women-from-gender-ideology-extremism-and-restoring-biological-truth-to-the-federal-government/), DCTD/CTEP is making investigators aware of several changes that are being introduced to comply with this Order. CTEP is requiring that the term 'gender' in the protocol be amended so that 'gender' is replaced with the word 'sex'. **PI Response:** The consent has been amended so that 'gender' is replaced with the word 'sex'.

Research Study Informed Consent Document

Study Title for Participants: Testing Whether Cancers with Specific Mutations Respond Better to Glutaminase Inhibitor, Telaglenastat (CB-839) HCl, Anti-Cancer Treatment

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: NCI Protocol# 10220, A Phase II Basket Trial of Glutaminase Inhibitor (BeGIN) Telaglenastat (CB-839) HCl in Patients with NF1 Aberrations, NF 1 Mutant Malignant Peripheral Nerve Sheath Tumors (MPNST), KEAP1/NRF2 and LKB1 Aberrant Tumors (NCT TBD)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you have advanced cancer that has spread and your cancer has a change in the gene called the NF1 (Neurofibromatosis type 1) gene (ex. NF1 mutant malignant peripheral nerve sheath tumor [MPNST] or other tumors), KEAP1 (Kelch-like ECH-associated protein 1)/NRF2 (nuclear factor [erythroid-derived 2]-like 2) gene or STK11/LKB1 (Serine/Threonine Kinase 11/Liver Kinase B1) gene.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This study is being done to answer the following question:

Can we lower the chance of your cancer growing or spreading with the treatment of Telaglenastat (CB-839) HCl (telaglenastat)?

We are doing this study because we want to find out if this approach is better or worse than the usual approach for your cancer with NF1, KEAP1/NRF2 or STK11/LKB1 mutation. The usual approach is defined as care most people get for advanced-stage cancer with NF1, KEAP1/NRF2 or STK11/LKB1 mutation.

What is the usual approach to my advanced-stage cancer?

The usual approach for patients who are not in a study is treatment with surgery, radiation or drugs (including chemotherapy, hormonal drugs and U.S Food and Drug Administration [FDA]-approved drugs). Sometimes, combinations of these treatments are used. Your doctor can explain which treatment may be best for you. These treatments can reduce symptoms and may stop the tumor from growing for a few months or longer.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated for cancer.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will get Telaglenastat (CB-839) HCl (telaglenastat) for as long as your disease does not worsen and you do not experience unacceptable side effects. This could be for a period of weeks or months.

After you finish the study treatment, your doctor will continue to watch you for side effects and follow your condition every 3 months (±) 14 days after your last dose of study drug.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

If you choose to take part in this study, there is a risk that the study drug Telaglenastat (CB-839) HCl may not be as good as the usual approach for your cancer at shrinking or stabilizing your cancer.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The Telaglenastat (CB-839) HCl (telaglenastat) used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drug(s)/study approach.

Here are important things to know about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may make it hard for you to have children.
- Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

There may be some risks that the study doctors do not yet know about.

Benefits

Telaglenastat (CB-839) HCl (telaglenastat) has shrunk/stabilized cancer in animal models and a limited number of people with cancer. While doctors hope Telaglenastat (CB-839) HCl (telaglenastat) will be useful against cancer and patients with NF1/KEAP1/NRF2/LKB1 mutations, there is no proof of this yet. We do know that the information from this study will help doctors learn more about Telaglenastat (CB-839) HCl (telaglenastat) as a treatment for patients with cancer who may have NF1/KEAP1/NRF2/LKB1 mutations. It is unlikely that it will work in everyone with your cancer or help you live longer. This study may help us learn things that may help people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- For women: You become pregnant while on the study.
- The study is stopped by the Institutional Review Board (IRB) or Food and Drug Administration (FDA).
- The study drug becomes unavailable.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

The purpose of this study is to test the good and bad effects of the drug called Telaglenastat (CB-839) HCl (telaglenastat). Telaglenastat (CB-839) HCl (telaglenastat) could shrink your cancer, but it could also cause side effects, which are described in the risks section below. The study doctors hope to learn if the study drug will help control the disease in patients with advanced cancer with changes in specific genes.

We don't know if Telaglenastat (CB-839) HCl works to treat cancer in people, but it has shrunk several types of tumors in animals.

There will be about 108 people taking part in this study.

What are the study groups?

In this study, you will get the study drug Telaglenastat (CB-839) HCl.

Treatment schedule: You will get Telaglenastat (CB-839) HCl by mouth twice a day every day, without breaks starting on Day 1 of each cycle. Each cycle lasts 28 days (4 weeks). You will not be able to get additional doses of the drug beyond the daily doses. This drug is not approved by the FDA for treatment of your disease.

What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects.

These exams, tests, and procedures to monitor your safety and health include:

- Physical exams done every other week for the first 2 cycles on the study, then on the first day of each cycle.
- Blood will be collected weekly for the first 2 cycles on the study, then on the first day of each cycle.
- Urinalysis (urine test) as clinically indicated
- Pregnancy test (for women capable of having children)
- ECG (a tracing to record the electrical activity of your heart) as clinically indicated

Some exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are procedures that will be done for research purposes only.

You will need to have a biopsy for the study before you begin the study. The study biopsy takes small pieces of cancer tissue from your body. This is like the biopsy you had that helped diagnose your cancer. The biopsy specimen will be used for exploratory genetic sequencing and biomarker analysis. This information will be important to understand why the treatment you received worked or did not work to stop the growth of your cancer. Researchers hope to find potential "biomarkers" (changes present in tumor tissue or blood that predict if current or future treatments would stop your type of cancer from growing). You and your study doctor will not get any results of this testing.

All patients enrolled in this study will have blood samples collected at the following times:

- Before you begin Telaglenastat (CB-839) HCl treatment (screening)
- Up to 3 tablespoons of blood will be collected on Cycle 1 Days 1 and 15 under fasting conditions before you take Telaglenastat (CB-839) HCl and then 0.5, 1, 2, 4, and 8 hours after you take Telaglenastat (CB-839) HCl HCl with a meal.
- Up to 1 tablespoon of blood will be collected on Week 4 (Cycle 1 Day 22) and Week 8 (Cycle 2 Day 22) after you take Telaglenastat (CB-839) HCl with a meal.
- When you disease gets worse (end of treatment visit)

What risks can I expect from taking part in this study?

General Risks

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The study drug used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for 4 months after you have completed the study.

This study will use a sample of your tissue. Generally, your hospital will keep some of your tissue. This tissue may be used to help treat your cancer in the future. Because this study will need to use some of this tissue, there is a small risk that it could be used up.

Blood Draw Risks

Blood draws for research may require an additional needle stick. You may feel discomfort during some of the tests or procedures during this study or may experience some inconveniences. Some of the risks from drawing blood from your arm may include pain, bruising, lightheadedness, and rarely, infection. Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Genetic Testing Risks

As part of this study, we are also studying a genetic test. The test is designed to find out if your tumor has the genetic changes that are needed for this study. If it does, we will assign you to a study group based on the genetic changes in your tumor.

Because this genetic test is still being studied, there is a risk that the test results may be wrong. If the test results are wrong, you may be included in this study even though it may not offer the best treatment option for you. Or, you may not be included in this study even though it may offer a good treatment option for you.

The genetic test used in this study will test your tumor for genetic changes, NF1. This change also may be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down.

Since this study is only testing tumor tissue, we will not know if a genetic change in your tumor is also in your normal tissue. If you want to find out if the change is in your normal tissue, then you will need to get other tests done outside of this study.

Genetic tests of normal tissue can reveal information about you and also about your relatives. Your study doctor will talk with you about what testing your normal tissue may mean for you and your family. He or she also may suggest that you talk with a genetics counselor to learn more. You or your insurance plan would have to pay for any genetic tests and visits to a genetic counselor done outside of this study.

Biopsy Risks

Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, bruising, and pain at the biopsy site. Pain can be treated with regular pain medications. Rarely, an infection can occur. You may sign a separate consent form for the study biopsy that describes the risks in more detail.

Side Effect Risks

The study drug used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and let you know if changes occur that may affect your health.

There is also a risk that you could have other side effects from the study drug.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. Some side effects may make it hard for you to have children.
4. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

Drug Risks

The tables below show the most common and most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

COMMON, SOME MAY BE SERIOUS In 100 people receiving Telaglenastat (CB-839) HCl, more than 20 and up to 100 may have:
• Tiredness

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Telaglenastat (CB-839) HCl, from 4 to 20 may have:
• Anemia which may require blood transfusion • Discomfort from light • Nausea, vomiting • Bruising, bleeding • Loss of appetite

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Additional Drug Risks

The study drug could interact with other drugs. Telaglenastat (CB-839) HCl interacts with CYP2C9 (an enzyme in your liver), which may stop or slow the breakdown of drugs broken down by this enzyme. Proton Pump Inhibitors (or PPIs, acid suppressing drugs) are also to be avoided. Your study doctor will give you a drug information handout and wallet card that lists these possible interactions. Share this information with your family members, caregivers, other health care providers, and pharmacists.

Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.

- Tell your doctor about:
  - all medications and supplements you are taking
  - any side effects
  - any doctors' visits or hospital stays outside of this study
  - if you have been or are currently in another research study.
- Write down in your medication diary when you take the study drug at home.

For women: Do not get pregnant or breastfeed while taking part in this study. **For men:** Do not father a baby while taking part in this study. **For all:** Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 4 months after your last dose of study drug.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your cancer. This includes:

- the costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.
- your insurance co-pays and deductibles.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

- The biopsy for genetic and biomarker testing at the beginning of the study.
- The blood collection for biomarker testing at the beginning of the study and on week 4.

You or your insurance provider will not have to pay for the Telaglenastat (CB-839) HCl while you take part in this study.

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment

What happens if I am injured because I took part in this study?

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsor and any company supporting the study Telaglenastat (CB-839) HCl now or in the future.
- The National Cancer Institute (NCI) Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The FDA and the groups it works with to review research.
- The NCI and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *[name(s)]* at _____ *[telephone number]*.

For questions about your rights while in this study, call the _____ *[name of center]* Institutional Review Board (a group of people who review the research to protect your rights) at _____ *[telephone number]*.
[Note to Local Investigator: Contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here.]

Optional studies that you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading this optional study hope the results will help other people with cancer in the future.

Taking part in this optional study is your choice. You can still take part in the main study even if you say "no" to this study. There is no penalty for saying "no." You and your insurance company will not be billed for this optional study. If you sign up for, but cannot complete this study for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the following studies.

Optional sample collections for known laboratory studies and/or storage for possible future studies

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Known future studies
If you choose to take part in this optional study, researchers will collect blood and tumor tissue for research on biomarkers (including genetic).

If you choose to take part in this optional study, researchers will collect your tumor tissue and blood for research on evaluating the changes in your DNA and RNA that occur during treatment. Researchers will obtain genetic material (DNA and RNA) from both your tumor cells and your blood. Your DNA and RNA will be used for genomic sequencing, which is sequencing of all or part of your DNA. This is done to compare your tumor and blood cells to look for changes in your genome to understand why you did or did not respond to the treatment you received. Researchers hope to find potential "biomarkers" (changes present in tumor tissue that predict how patients with your type of cancer may respond to current or future treatments). This optional study may improve the ability to select future treatments or treatment combinations for others in the future. This optional study will not affect the cancer treatment or approach that you receive.

Neither you nor your study doctor will be informed when the genetic sequencing research will be done. You and your study doctor will not receive reports of these studies, as they are intended for research purposes only and cannot be used to plan treatment.

Unknown future studies

If you choose to take part in this optional study, a sample of tissue from your biopsy will be collected and stored. Storing samples for future studies is called "biobanking." The biobank is being run by Early Therapeutics Clinical Trials Network (ETCTN) and is supported by the NCI. This is a publicly funded study. Samples from publicly funded studies are required to be shared

as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people's health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now, we don't know what research may be done in the future using your tissue samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumor tissue. These are called somatic changes. Changes may also be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes. If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue.

What is involved in this optional sample collection?

If you agree to take part, here is what will happen next:

1. A sample from the tissue that was collected at the time of your biopsy will be sent to the biobank. Samples of tissue will be collected from optional extra biopsies. A sample of tissue will be collected from optional extra biopsies on week 4 and when your disease worsens. For the biopsy procedure, the study doctor will use a needle to take pieces of your tumor. This process may be repeated several times in the same appointment in order to get enough tissue. If a biopsy is not possible or cannot be done safely before you begin the study drug, then your study doctor, with your consent, will need to use some of the tissue left over from your biopsy when you were diagnosed with cancer or had surgery to remove your tumor.
2. Blood will also be collected from a vein in your arm. Up to 1½ tablespoons of blood will be collected at each time point: before you begin the study, on week 4, on week 8 and when your disease worsens.
3. Your sample will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
4. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.

5. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

- The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.
- Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, bruising, and pain at the biopsy site.
- Generally, hospitals will keep some of your tissue. This tissue may be used to help treat your cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.
- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

How will information about me be kept private?

Your privacy is very important to the study researchers and biobank. They will make every effort to protect it. Here are just a few of the steps they will take:

1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information. Only your study doctor and a few study researchers will have access to the master list linking the code numbers to names. The biobank and the genomic sequencing laboratory will receive your samples with the following information only: your sample code number; your age, race/ethnicity, and sex~~gender~~; your type of cancer; any previous treatments you received for your cancer; and the treatment you will receive for this current study.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are. The researchers must be trained in the handling of private information. Any researcher who wants to study your stored samples and genetic information must apply and be approved to do so.
3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?

You will not benefit from taking part.

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments to this optional sample collection?

There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about this optional sample collection?

If you decide you no longer want your samples to be used, you can call the study doctor, _____ (*name of study doctor for main trial*), at _____ (*telephone number of study doctor for main trial*), who will let the biobank know. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I need my tissue or blood samples to be returned?

Tumor tissue or blood samples that remain in the biobank can be returned if needed for medically necessary events or procedures to assure appropriate medical care, such as for DNA or RNA analysis. Specimens may also be retuned if tissue is needed to determine eligibility for enrollment in a research protocol or clinical trial. Every effort will be made to facilitate medically necessary events or procedures to assure appropriate medical care for a patient with a serious or life-threatening illness.

Tumor tissue or blood samples and genetic material (DNA and RNA) that is no longer in the biobank or that has already been given to or used by researchers cannot be returned. No samples will be returned for matters related to patients needing or wanting genetic testing to determine medically important risks.

What if I have questions about this optional sample collection?

If you have questions about the use of your samples for research, contact the study doctor, _____ (*name of study doctor for main trial*), at _____ (*telephone number of study doctor for main trial*).

Please circle your answer below to show if you would or would not like to take part in each optional study:

Samples for known future studies:

I agree that my samples and related health information may be used for the study described above.

YES NO

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to learn about results from this study.

YES NO

Samples for unknown future studies:

I agree that my samples and related health information may be kept in a biobank for use in future health research.

YES NO

Contact for Future Research

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

YES NO

Contact for Medically Important Genetic Test Results

I agree that my study doctor, or someone on the study team, may contact me and my doctor if the laboratory finds a possible genetic test result that may be important to the health of me and/or my family members.

YES NO

Before you join this study, you may wish to talk with family members to see if they would like to learn of any genetic test results that may be important to their health. You have the right to decide how to handle sharing this information with your family members. However, if you were to become unable to share this information with family members due to illness or injury, or if you were no longer alive, please select and sign one of the options below on releasing genetic information to family members. Only genetic test results that may be medically important to your family members would be released.

Select and sign ONE option from below:

(1) **You have my permission** to release my genetic test results to **any and all** family members involved, in the event that I am unable to or have not survived to grant permission myself.

Participant's signature

_____

Date of signature

_____

Witness's signature

_____

Date of signature

_____

(2) **You have my permission** to release my genetic test results or stored DNA **only** to the family members listed. Please write the name of the family member(s) in the space provided below.

Participant's signature

_____

Date of signature

_____

Witness's signature

_____

Date of signature

_____

(3) **You do NOT have my permission** to release my genetic test results or stored DNA to any family members. I request that this information be kept private.

Participant's signature

_____

Date of signature

_____

Witness's signature

_____

Date of signature

_____

This is the end of the section about optional studies.

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled "yes".

Participant's signature

_____

Date of signature

_____

Signature of person(s) conducting the informed consent discussion

_____

Date of signature

_____

Patient Calendar

	Pre-Study	Cycle 1				Cycle 2				Cycle 3 Onward[5]	When your cancer grows	Follow-up[6]
Days	**Within 28 days of Cycle 1 D1**	**1**	**8**	**15**	**22**	**1**	**8**	**15**	**22**	**1**		**Every 3 Months**
Pre-study procedures including informed consent, demographics, and medical history	X											
Concurrent meds	X	X----------X										
Side effects evaluation		X----------X										
Physical exam and weight	X	X		X		X		X		X	X	
Performance status	X	X		X		X		X		X	X	
Vital signs	X	X		X		X		X		X	X	
Height	X											
Pregnancy Test	X					X				X	X	
Blood draws for complete blood count and general health status	X	X	X	X	X	X	X	X	X	X	X	
Urinalysis	X	As clinically indicated										
Electrocardiogram (EKG)	X	As clinically indicated										
Medical imaging scans for tumor measurements	X									X	X	
Mandatory blood draw for research purposes[1]	X	X		X	X							
Optional blood draw for research purposes[2]	X				X				X		X	
Mandatory tumor biopsy for research purposes[3]	X											
Optional tumor biopsy for research purposes					X						X	

Telaglenastat (CB-839) HCl[4]		X----------X										
Telephone Check												X

Footnote:

1. Blood will be collected on Day 1 and Day 15 before you receive the drug and after you receive the drug at 0.5, 1, 2, 4, and 8 hours. The Week 4 (C1D22) collection will be after you receive the drug. For all "before drug" samples you will need to fast for at least 8 hours (must not eat or drink anything but water). All "after drug" samples should be collected after you receive the drug immediately after a meal.
2. You will need to fast for at least 8 hours (must not eat or drink anything but water) for this optional blood collection.
3. You will have a mandatory biopsy and archival tissue will be collected if available.
4. Telaglenastat (CB-839) HCl: Dose by mouth twice a day, immediately after a meal (unless otherwise instructed to fast) every day of a 28-day cycle.
5. If the study doctor determines you are doing well, the study assessments may be decreased to once every 3 cycles (such as at Cycles 16, 19, 22, etc.) and 3 cycles worth of study medication can be provided at clinic visits.
6. You may be contacted by phone every 3 months to check how you are doing.