THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Phase I/II Dose Escalation and Cohort Expansion of Safety and Tolerability Study of Intratumoral CD40 Agonistic Monoclonal Antibody APX005M in Combination with Systemic Pembrolizumab in Patients with Metastatic Melanoma
2015-0654

Subtitle: APX005M plus Pembro

Study Chair: Adi Diab

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

You are being asked to take part in this study because you have metastatic (cancer that has spread) melanoma.

The goal of Part 1 of this clinical research study is to find the highest tolerable dose of APX005M (sotigalimab) that can be given with pembrolizumab that can be given to patients with metastatic melanoma.

The goal of Part 2 of this study is to learn if the combination can help to control metastatic melanoma.

The safety of this drug combination will also be studied.

This is an investigational study. Sotigalimab is not FDA approved or commercially available. It is currently being used for research purposes only. Pembrolizumab is FDA approved and commercially available for the treatment of metastatic melanoma. The combination of these drugs to treat metastatic melanoma is investigational.

The study doctor can explain how the study drug is designed to work.

Receiving the study drugs may help to control the disease. Future participants may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. If you take part in this study, you may experience costs associated with travel and a prolonged stay out of town. You may choose not to take part in this study because it is a first in human treatment or you may choose to take part in other standard options.

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

You will be on study for up to 2 years.

Sotigalimab will be provided at no cost to you during the study. You and/or your insurance provider will be responsible for the cost of pembrolizumab.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive immune therapies, targeted therapy, and/or chemotherapy. You may choose to receive pembrolizumab alone outside of this study. You may choose to receive other investigational therapy, if available. The study doctor will discuss the possible risks and benefits of these treatments. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. You will have the following screening tests to help the doctor decide if you are eligible:

- You will have a physical exam.
- Blood (about 4 teaspoons) will be drawn for routine tests, including tests to check your thyroid function and to check for HIV. This routine blood draw

may include a pregnancy test if you can become pregnant. To take part in this study, you cannot be pregnant. Urine may also be collected for this test.
- You will have computed tomography (CT) scans of the chest, abdomen, and pelvis to check the status of the disease.
- You will have a magnetic resonance imaging (MRI) or CT scan of the brain to check the status of the disease.
- You will have an electrocardiogram (EKG) to check your heart function.
- The tumor may be photographed. Your private areas will be covered (as much as possible), and a picture of your face will not be taken unless there are lesions on your face.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other options will be discussed with you.

Study Groups

If you are found to be eligible to take part in this study, you will be assigned to a study group based on when you join this study. Up to 4 groups of 3 participants will be enrolled in Part 1, and up to 20 participants will be enrolled in Part 2.

If you are enrolled in Part 1, the dose of sotigalimab you receive will depend on when you join this study. The first group of participants will receive the lowest dose level of sotigalimab. Each new group will receive a higher dose of sotigalimab than the group before it, if no intolerable side effects were seen. This will continue until the highest tolerable dose of sotigalimab is found.

If you are enrolled in Part 2, you will receive sotigalimab at the highest dose that was tolerated in Phase 1

All participants will receive the same dose level of pembrolizumab.

Up to 41 participants will be treated in this study. All will take part at MD Anderson.

Study Drug Administration

Sotigalimab will be injected directly into 1 tumor every 3 weeks (Weeks 0, 3, 6, and 9) for up to 4 doses.

The injections may be done with or without the help of an ultrasound, CT, and MRI.

If the doctor thinks it is needed, you may need to stay in the hospital overnight or be monitored by a caregiver for 24 hours after you receive sotigalimab.

You will receive pembrolizumab by vein on Day 2 of Cycles 1-4. The first dose of pembrolizumab will be given 1-2 days before or after your first dose of sotigalimab. Please note that you will receive sotigalimab first and then the pembrolizumab.

You will be given a diary to write down any injection site reactions you may have.

Study Visits

Within 1 week before your first sotigalimab injection:

- You will have a physical exam.
- You will have a punch biopsy or image-guided biopsy of a tumor to check the status of the disease. To collect a biopsy, the area of skin is numbed with anesthetic and a small cut is made to remove all or part of the affected tissue. To collect a punch biopsy, the area of skin is numbed with anesthetic and a small cut is made to remove all or part of the affected tissue. To perform an image-guided biopsy, a needle is inserted into the affected area using imaging such as CT or ultrasound to collect cells or tissue from an organ, lymph node, or suspected tumor mass. The doctor will use the imaging to guide the needle into the area.
- Blood (about 4½ tablespoons) will be drawn to test your immune system. If you can become pregnant, blood (about 1 teaspoon) may be drawn for a pregnancy test or urine may be collected to test for pregnancy.
- The tumors may be measured and photographed.

On **Day 1 of Cycle 1**:

- You will have a physical exam.
- Blood (about 5½ tablespoons) will be drawn for routine tests and test your immune system.
- The tumor may be measured and photographed.

On **Day 2 of Cycle 1:**

- Your vital signs (blood pressure, heart rate, temperature, and breathing rate) will be measured.
- Blood (about 1 teaspoon) will be drawn for routine tests.
- You will have a biopsy of one of the injected tumor sites within about 24 hours after the 1st injection to check the status of the disease.

On **Day 3 of Cycle 1:**

- Your vital signs will be measured.
- Blood (about 5 tablespoons) will be drawn for routine tests and to test your immune system.

On **Days 8 and 15 of Cycle 1:**

- Your vital signs will be measured.
- Blood (about 1½ teaspoons) will be drawn for routine tests.
- Blood (about 4½ tablespoons) may be drawn to test your immune system (Day 8 only).

On **Day 1 of Cycle 2:**

- You will have a physical exam.

- Blood (about 5½ tablespoons) will be drawn for routine tests and to test your immune system.

On Days 8 and 15 of Cycle 2:

- Your vital signs will be measured.

On **Day 1 of Cycle 3 (± 3 days)**:

- Your vital signs will be measured.
- You will have a physical exam.
- You will have a biopsy of one of the injected tumors and one of the tumors for which you did not have an injection to check the status of the disease.
- The tumors may be measured and photographed.
- Blood (about 2½ teaspoons) will be drawn for routine tests. If you can become pregnant, a pregnancy test may be performed. Urine may be collected for the pregnancy test.
- Blood (about 4½ tablespoons) will be drawn to test your immune system.

On **Day 1 of Cycle 4**:

- Your vital signs will be measured
- You will have a physical exam.
- Blood (about 2½ teaspoons) will be drawn for routine tests
- Blood (about 4½ tablespoons) will be drawn to test your immune system.

On **Day 1 of Cycles 5-8**:

- Your vital signs will be measured.
- You will have a physical exam.
- Blood (about 1½ teaspoons) will be drawn for routine tests.

On **Day 1 of Cycles 5 and 8 ONLY (± 3 days)**:

- Blood (about 1½ teaspoons) will be drawn for routine tests.
- Blood (about 4½ tablespoons) will be drawn to test your immune system.
- You may have a biopsy of one of the injected tumors and one of the tumors for which you did not have an injection to check the status of the disease (Cycle 5 only).
- The tumors may be measured and photographed.
- You will have CT, MRI/CT, and/or an ultrasound to check the status of the disease.

For **Cycles beyond Cycle 8**:

- You will have CT, MRI/CT, and/or an ultrasound to check the status of the disease (every 3 months for up to 2 years).

You will be taken off study if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

If your doctor thinks it is in your benefit, you may continue to receive pembrolizumab as standard of care after you are off this study. Your doctor will describe this in more detail.

Off-Study Visit

If you have to go off study early because the disease got worse or you had intolerable side effects:

- Your vital signs will be measured.
- You will have a physical exam.
- Blood (about 1½ teaspoons) will be drawn for routine tests.
- Blood (about 4½ tablespoons) will be drawn to test your immune system.

Follow-Up

Within 2 weeks after your last study drug dose and every 8-12 weeks after that, you may have scans to check the status of the disease. Your doctor will decide what type of scans you will have.

If you choose to seek care at another hospital, the study staff will call you every 3 months for up to 2 years after your last study drug dose. You will be asked how you are doing. The calls should last about 5 minutes.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any side effects you may have (such as an injection site reaction), even if you do not think they are related to the study drug and procedures.

Pembrolizumab Side Effects

Common (occurring in more than 20% of patients)

• fatigue • fever • skin rash and/or itching • abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure)	• high blood sugar (possible diabetes) • high blood levels of fat (possible heart disease and/or stroke) • loss of appetite • nausea • constipation • diarrhea • abdominal pain	• low blood cell counts (red, white, platelets) • abnormal liver test (possible liver damage) • pain • abnormal kidney test (possible kidney damage) • cough • difficulty breathing

Pembrolizumab may commonly cause low blood cell counts (red, white, and/or platelets):

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
- A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life- threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.
- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.

Occasional (occurring in 3-20% of patients)

• swelling (face/arm/leg) • inflammation of the tissue around the heart (possible chest pain) • irregular heartbeat • headache • confusion • patches of skin color loss • underactive thyroid gland (possible weight gain, heart failure, and/or constipation)	• overactive thyroid gland (possible weight loss, diarrhea, mood swings, difficulty sleeping, heart rate changes, and/or sweating) • low blood sugar • weight loss • fluid in the abdomen • blood in the urine • vomiting • abnormal liver test (possible yellowing of the skin and/or eyes)	• weakness • nerve damage (possible numbness, pain, and/or loss of motor function) • difficulty breathing (possibly due to lung inflammation) • flu-like symptoms • infusion reaction (possible dizziness, low blood pressure, nausea, pain, and/or difficulty breathing)

Frequency Unknown

• heart failure • heart attack	• abnormal connections or passageways	• blockage in the lung (possible pain and/or

• build-up of fluid around the heart (possible heart failure)	between organs or vessels • bleeding in the rectum and/or uterus	shortness of breath) • nosebleed • coughing up blood

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

• low blood pressure (possible dizziness/fainting) • heart inflammation • build-up of fluid in the tissue around the heart • blood vessel inflammation (possible bleeding, skin rash, numbness/weakness, fever, weight loss, fatigue, and/or bruising, depending on where the inflammation occurs) • seizure • immune system damage to the nervous system (causing muscle weakness, numbness and/or paralysis) • spinal cord inflammation (possible pain, weakness, loss of feeling or movement, and/or paralysis) • brain inflammation (possible paralysis and/or coma) • shedding, scaling and/or inflammation of the skin (possible fatal loss of bodily fluids) • large skin blisters • very severe blistering skin disease (loss of large portion of skin and/or with ulcers of the skin and digestive tract)	• hormonal deficiency that affects the body's ability to control blood pressure and react to stress • pituitary gland inflammation (possible headaches) • inflammation of the thyroid gland (possible tenderness in the neck) • diabetes requiring insulin • severe high blood sugar due to uncontrolled diabetes • decreased production of adrenal hormones (possible weakness and/or low blood pressure) • inflammation of the pancreas (possible abdominal pain) • anemia due to destruction of red blood cells • liver damage (hepatitis) • inflammation/scarring of the bile ducts (tubes that carry digestive fluid that is made in the liver), which may cause liver damage, stomach pain, yellowing of the skin/eyes, fatigue, and/or itching	• inflammation inside the eye (possible vision problems) • kidney inflammation (possible kidney damage/failure) • kidney failure • build-up of fluid around the lungs • immune response that causes the body to attack itself (possible organ damage) • multi-organ disease causing lesions, most often in the lungs (sarcoidosis) • immune response (causing muscle weakness) • immune system reaction (possible fever, jaundice, liver/spleen enlargement, irritability, and/or seizures) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • Vogt Koyanagi Harada syndrome -- pigmented tissue (possible eye pain/swelling and changes in vision, hearing loss, and/or white patches on the skin)

If you have a solid tumor type and you have an organ transplant, pembrolizumab may increase your risk for the transplant to be rejected by your body.

Pembrolizumab works by boosting the immune system. This may cause unknown side effects resulting from your immune system attacking your organs. This may cause inflammation and inflammation-related side effects in any organ or tissue. These side effects can affect more than one of your normal organs and tissues at the same time.

Sotigalimab Side Effects

When given directly into a skin tumor, sotigalimab may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the injection. An allergic reaction to the anesthetic may occur. A scar may form at the injection site.

When given directly into the lymph nodes or deep tissues, including tumors in the liver or adrenal glands or other places in the body that can be injected, it may cause bleeding, anemia, and/or infection.

The following is a list of common (occurring in more than 20% of patients) side effects **when sotigalimab is given by vein** alone or in combination with other drugs. Based on how the drug is given in this study (injected directly into the tumor), it is not expected that side effects will be as frequent or severe as when it is given by vein.

Occurring in more than 20% of patients when given by vein

• fatigue • fever • chills	• itchy skin • nausea/vomiting	• abnormal liver test (possible liver damage)

Sotigalimab may cause low blood cell counts (red blood cells, platelets, and/or white blood cells):

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.
- A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty

Occurring in 10-20% of patients

• headache	• skin rash • diarrhea	• infusion-related reaction or cytokine

• lack or energy or strength	• loss of appetite	release syndrome (see below)

Certain side effects with sotigalimab have been observed either during the infusion or within 48 hours after the infusion. Study doctors have reported some of these side effects or combinations of them as infusion-related reactions or cytokine release syndrome.

An infusion-related reaction (IRR) is a type of hypersensitivity (or immune) reaction that can develop during or shortly after administration of a drug. Signs and symptoms may include itching, rash, hives/welts, fever, rigors/chills, backache, severe perspiration, sweating, difficulty in breathing, reduced blood pressure and (if severe) collapse.
Cytokine release syndrome (CRS) is an acute systemic inflammatory syndrome due to release of chemicals within the body that causes fever and other symptoms. It can develop during the infusion or may occur later (usually not later than 24 hours after the infusion). It can be difficult to determine whether a patient is experiencing an IRR or a CRS. Signs and symptoms of CRS may include chills, tiredness, rigors, fever, nausea, diarrhea, headache, cough, joint pain, rash, vomiting, muscle aches, back pain, fast heart rate, shortness of breath and low blood pressure. Some patients who experienced CRS with sotigalimab had serious symptoms and had to be treated with medications or even admitted to the hospital until the symptoms resolved. In its most severe form, CRS may be fatal, however no fatal case of CRS has been observed with sotigalimab.

Your study doctor will give you certain medications prior to the infusion (called premedication, see below) to lower the risk or severity of these possible side effects. You will be carefully monitored for potential side effects by your study team during the infusions and for at least 4 hours after the first two infusions. If you suspect you are experiencing IRR, CRS, or any side effect, inform your study doctor immediately.

Occurring in 1-10% of patients

• low blood pressure (possible dizziness or fainting) • high blood pressure • flushing • fast heartbeat • fatigue/lack of energy • sudden loss of consciousness • dizziness • sleeplessness	• overactive thyroid gland (possible weight loss, heart rate changes, and/or sweating) • abnormal blood test (possible pancreas damage or inflammation) • high blood levels of potassium (possible kidney failure)	• abdominal swelling • dry mouth • joint/muscle/back pain • tremor • muscle spasm • abnormal kidney test (possible kidney damage) • difficulty breathing • cough • flu-like illness

• hives • dry skin • night sweats • underactive thyroid gland (possible weight gain, heart failure, and/or constipation)	• low blood levels of sodium (possible headache, confusion, seizures, and/or coma) • abdominal pain • weight loss • constipation • abnormal taste	• inflammation of the lungs • wheezing • low oxygen level in the blood (possible lightheadedness)

Using the study drugs together may cause side effects that are not seen when each is given alone. The study drug combination may also increase the frequency and/or severity of the side effects listed above.

Other Risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia, which may create a need for blood transfusions.

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

EKGs may cause discomfort while lying on the exam table, and the tape on the EKG pads may cause skin irritation.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the

scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching. Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks
Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications: Acceptable forms of birth control include:

- surgical sterilization by bilateral tubal ligation or vasectomy
- barrier birth control such as condoms or diaphragm
- birth control implants or injections
- intrauterine device (IUD)
- sponge plus spermicide

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

You must continue using birth control 4 months after the last dose of APX005M and Pembrolizumab.

Getting pregnant may result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, you will have a tumor biopsy of one of the injected tumors and one of the tumors that you did not have an injection in to check the status of the disease if the disease gets worse. The type of biopsy will depend on the size and location of the tumor.

Optional Procedure #2: If you agree, your tumor tissue left over from tissue collected while you are on study (such as biopsies or surgeries) that are performed at MD Anderson will be collected, banked, and stored for 15 years for future testing and

research related to cancer. Before your samples can be used for research, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson. The IRB is a committee of doctors, researchers, and community members. The IRB is responsible for protecting study participants and making sure all research is safe and ethical.

Your samples will be given a code number. No identifying information will be directly linked to your samples. Only the researcher in charge of the bank will have access to the code numbers and be able to link the samples to you. This is to allow medical data related to the samples to be updated as needed.

There are no benefits to you for taking part in the optional procedures. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

Optional Procedure Risks:
Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

MD Anderson and others can learn about cancer and other diseases from your **banked blood and/or tissue**. In the future, people who may do research with these samples may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your privacy, but cannot guarantee complete privacy. Sometimes your samples may be used for genetic research about diseases that are passed on in families. If the samples were used for this kind of research, your samples will be coded as mentioned above. MD Anderson will not be able to give you, your family, or your doctor the reports about the research done with these samples, and these reports will not be put in your medical record. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job.

If you withdraw your consent to the storage of leftover blood and/or tissue in the tissue bank, then the leftover materials will no longer be collected for storage. Any of your tissue that remains in the tissue bank will no longer be used for research and will be removed from the tissue bank and destroyed.

However, if any of your de-identified blood and/or tissue was already released for research purposes before you withdrew consent, MD Anderson will not be able to destroy it

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Optional Procedure #1: Do you agree to have an extra tumor biopsy to check the status of the disease?

Optional Procedure #2: Do you agree to allow leftover blood, tumor tissue, T-cells, and/or genetic material to be stored in a research bank at MD Anderson for use in future research related to cancer?

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or Pyxis Oncology for this injury.
You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Adi Diab, at 713-792-2921) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, Pyxis Oncology, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

9. This study is sponsored and/or supported by: Pyxis Oncology.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Your personal information and/or samples are being collected as part of this study. These data and/or samples may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

Before being shared for future research, every effort will be made to remove your identifying information from any data and/or samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or samples are used for future research. If this research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board

(IRB) of MD Anderson before your data and/or samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research

Samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson

- Pyxis Oncology, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

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

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

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

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION