THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Randomized Phase II Study of Platinum-Taxane-Cetrelimab Induction followed by Niraparib plus or minus Cetrelimab Maintenance in Men with Aggressive Variant Prostate Cancers.
2020-0200

Study Chair: Ana M. Aparicio

_____ _____
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 study is funded by the Department of Defense (DoD).

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

STUDY SUMMARY

The goal of this clinical research study is to learn if niraparib with or without cetrelimab, when given after treatment with cabazitaxel, carboplatin, and cetrelimab, can help to control aggressive variant prostate cancer (AVPC). The safety of these drugs will also be studied.

This is an investigational study. Niraparib is FDA approved and commercially available to treat ovarian, fallopian tube, and peritoneal cancers. Cetrelimab is not FDA approved or commercially available. It is currently being used for research purposes only. The use of niraparib to treat Metastatic Castration Resistant Prostate Cancer (mCRPC) is investigational. Cabazitaxel and carboplatin are FDA approved and commercially available for the treatment of certain types of prostate cancer. The study doctor can explain how the study drugs are designed to work.

Receiving the study drug combination may help to control the disease. Future patients may benefit from what is learned. There may be benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. You may not want to take part in this study due to the potential for side effects) and the need for hospitalization.

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

You may receive cabazitaxel, carboplatin, and cetrelimab for up to 6 cycles. You may receive niraparib alone or niraparib in combination with cetrelimab for as long as the doctor thinks it is in your best interest.

Niraparib and cetrelimab will be provided at no cost to you while you are on this study. You and/or your insurance provider will be responsible for the cost of cabazitaxel and carboplatin.

You may choose not to take part in this study. You may choose to receive cabazitaxel and or carboplatin without taking part in this study. You may choose to receive other investigational therapy, if available. The study doctor will discuss with you 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. The following screening tests will help the doctor decide if you are eligible:

Within 28 days before you can receive the study drugs:

- You will have a physical exam.
- Blood (about 2 tablespoons) will be drawn for routine tests including to check your prostate specific antigen (PSA) levels and for tumor marker testing. Tumor markers may be related to the status of the disease.
- Blood (about 2 teaspoons) will be drawn to check for circulating tumor cells (CTCs). This is a test of how many tumor cells are in the blood.
- You will have a bone scan and either an MRI or a CT scan of the chest, abdomen, and pelvis to check the status of the disease.
- You will have an EKG to check your heart function.

Within 7 days before you can receive the study drugs, blood (about 2 teaspoons) will be drawn for routine tests and to check your PSA levels.

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

Study Groups

The study is divided into 2 phases: Induction and Maintenance. The maintenance phase has 2 groups: Group 1 and Group 2.

If you are found to be eligible to take part in this study, you will begin the Induction phase. The Induction phase will last 6 cycles. Each cycle is 21 days.

During the induction phase, you will receive cabazitaxel and carboplatin during Cycle 1, then cabazitaxel, carboplatin, and cetrelimab during cycles 2-6.

After 6 Induction cycles, if you are eligible to take part in the Maintenance phase, you will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups. This is done because no one knows if one study group is better, the same, or worse than the other group.

- If you are in **Group 1**, you will receive niraparib alone.
- If you are in **Group 2**, you will receive niraparib plus cetrelimab.

You and the study staff will know which group you have been assigned to.

Up to 120 participants will be enrolled on this study. All will take part at MD Anderson.

Study Drug Administration

Induction

You will receive cabazitaxel by vein for 1 hour. Then you will receive carboplatin by vein for 1 hour. During Cycles 2-6, cetrelimab will be given by vein for 1 hour before you receive cabazitaxel and carboplatin. You will be closely monitored for side effects during and after the infusions.

Maintenance

During Maintenance you will take 2 capsules of niraparib by mouth once a day starting on Day 1 of Cycle 7. If you are in Group 2, you will also continue to receive cetrelimab by vein for 1 hour on Day 1 of all cycles.

The niraparib capsules should be swallowed whole and not chewed, crushed, dissolved or divided.

If you forget to take a dose of niraparib and it has been more than 6 hours after the time you were supposed to take the dose or if you vomit a dose, do not “make up” the dose. Wait and take your next dose as scheduled. Tell the study doctor if you miss or vomit a dose right away.

You may no longer be able to take the study drugs if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

Your participation on the study will be over after the follow-up visits described below.

Study Visits

Induction

Before Cycle 1, blood (about 3 teaspoons) will be drawn for biomarker testing. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug.

On **Day 1 of Cycles 1-6**:

- You will have a physical exam.
- Blood (up to 5 tablespoons) will be drawn for routine tests, biomarker testing, tumor marker testing, and to measure your PSA level. At the Cycle 4 visit, this sample will also be used for CTC testing. You must fast (not eat or drink anything except water) for up to 12 hours before your blood is drawn at each of these visits.
- At Cycle 4 only, you will have a bone scan and either MRIs or CT scans to check the status of the disease.

In between Cycles 1 and 2 and then between Cycles 3 and 4, you will have a tumor biopsy for biomarker testing. The type of biopsy you have will depend on where the disease has spread and/or what the doctor thinks is in your best interest. The doctor will discuss with you the type of biopsy you will have.

Maintenance

On Day 1 of every cycle:

- You will have a physical exam.
- Blood (up to 3 tablespoons) will be drawn for routine tests, tumor marker testing, and to measure your PSA level. You must fast (not eat or drink anything except water) for up to 12 hours before your blood is drawn at each of these visits. During Cycle 7 and every 3 cycles after that, additional blood (2 tablespoons) will be drawn for biomarker and CTC testing and tests to check your testosterone levels.
- During Cycle 7 and every 3 cycles after that, you will have an EKG, bone scan, and either MRIs or CT scans.

During Cycle 7, blood (about 2-4 teaspoons) will also be drawn for routine tests once a week.

During Cycles 8 and 9, blood (about 2-4 teaspoons) will also be drawn for routine tests every 2 weeks.

In between Cycles 9 and 10, you will have a tumor biopsy for biomarker testing.

If you have severe side effects, you may return to the clinic more often.

End of Study Visits
When you leave the study, the following tests and procedures will be performed:

- You will have a physical exam.
- Blood (about 3 tablespoons) will be drawn for routine tests, CTC tests, and to measure your PSA level and testosterone.

Between 30-90 days after your last dose of the study drugs, the following tests and procedures will be performed:

- You will have a physical exam.
- Blood (about 3 tablespoons) will be drawn for routine tests, tumor marker testing, and to measure your PSA level.

Follow-Up
About every 6 months after the end-of-study visit, the study staff will check on your overall health. This will be done either by a chart review or a phone call. If you are called, this call will last about 5 minutes. If the disease was stable when you left the study, you will have a bone scan and either MRIs or CT scans to check the status of the disease every 9 weeks until the disease gets worse.

Treatment Beyond Progression
If the disease appears to be getting worse or the tumors appear to be getting larger, you may still be able to receive the study drug if you and your doctor decide it is in your best interest. This is because sometimes the disease appears to get worse but the study drug is actually working.

However, there are risks of continuing to receive the study drug. For example, the disease may actually be getting worse and may reach the point that you are no longer able to receive other treatments. You are still at risk for side effects due to the study drug. This could also delay starting other treatments.

If you choose to receive the study drug after the disease appears to get worse, you will continue to have study visits as described above. The study doctor will discuss this option with you.

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.

Side effects will vary from person to person, and some may occur after you have stopped receiving treatment. Tell the study staff about any side effects you may have, even if you do not think they are related to the study drug/procedures.

Niraparib, cetrelimab**,** cabazitaxel and carboplatin, each 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, severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Niraparib Side Effects

Common (occurring in more than 20% of patients)

• fatigue/weakness • difficulty sleeping • headache • low blood levels of potassium (possible weakness and/or muscle cramps)	• skin rash • nausea/vomiting • constipation • loss of appetite • abdominal pain	• low blood cell counts (red, platelets, white) • abnormal liver tests (possible liver damage) • lung inflammation • infection (such as the common cold, UTI)

Occasional (occurring in 3-20% of patients)

• irregular/fast heartbeat • high blood pressure • dizziness • anxiety • swelling (arm/leg) • depression	• diarrhea • mouth blisters/sores (possible difficulty swallowing) • upset stomach • weight loss • painful red eyes	• abnormal taste • dry mouth • back/muscle/joint pain • difficulty breathing • cough • abnormal kidney test (possible kidney damage) • nosebleed

Rare but serious (Frequency Unknown)

• severe increase in blood pressure (possible stroke) • brain injury (possible headache, confusion,	• hallucination (seeing or hearing things that are not there) • cognitive impairment (difficulty concentrating, remembering, learning	• skin sensitivity to sunlight or lamps • allergic reaction • severe life-threatening infection (possible low blood pressure, kidney

seizures, and/or vision loss) • confusion/disorientation • fever due to low white blood cell counts	new things, and/or making decisions)	failure, and/or heart failure)

Niraparib may cause you to develop another type of cancer (such as acute myeloid leukemia [AML]/myelodysplastic syndrome [MDS] or a new primary cancer of another type). If you have had MDS or leukemia before entering this study, you are at an increased risk for developing leukemia again.

Cetrelimab Side Effects

Based on early human studies and similar drugs, cetrelimab may cause the following side effects. It is not well known how often these side effects may happen:

• fast heartbeat • heart inflammation • blood vessel inflammation (possible pain, swelling, and/or redness) • high blood pressure • low blood pressure (possible dizziness/fainting) • headache • brain inflammation (possible paralysis and/or coma) • swelling (arms/legs) • fatigue/feeling tired • fever • anxiety • difficulty sleeping • dizziness • very severe blistering skin disease (loss of large portion of skin and/or ulcers of the skin and digestive tract) • skin rash/redness • dry skin • yellowing of the skin and/or eyes	• inflammation of the thyroid gland (possible tenderness in the neck) • pituitary gland inflammation (possible headaches) • decreased production of adrenal hormones (possible weakness and/or low blood pressure) • abnormal blood test (possible pancreas damage/inflammation) • changes in body salts such as sodium, potassium, and/or magnesium (possible fatigue and/or weakness) • high blood sugar (possible diabetes) • upset stomach • intestinal blockage • inflammation of the stomach and/or intestines • fluid in the abdomen • abnormal taste • nausea/vomiting • loss of appetite	• abnormal liver tests (possible liver damage) • inflammation of nerves (possible pain and/or loss of motor or sensory function) • kidney inflammation (possible kidney damage/failure) • low blood cell count (platelets, white) • pain • weakness (including muscle weakness) • muscle inflammation • eye inflammation (possible pain, redness, dry eyes, vision problems such as blurry vision) • lung inflammation (possible difficulty breathing) • difficulty breathing • build-up of fluid around the lungs • cough (including coughing up blood) • infection • immune response (causing the body to attack itself)

• patches of skin color loss • hair loss (partial or total) • itching • underactive thyroid gland (possible weight gain, heart failure, and/or constipation) • overactive thyroid gland (possible weight loss, heart rate changes, and/or sweating)	• diarrhea • constipation • mouth blisters/sores (possible difficulty swallowing) • difficulty swallowing • weight gain/weight loss • blood in the urine • inflammation of the pancreas (possible abdominal pain) • liver damage	• allergic reaction (possible chills, fever, and/or skin rash)

If you had an organ transplant, cetrelimab may increase your risk for the transplant to be rejected by your body.

If you have a stem cell transplant from a donor before or after you receive cetrelimab, you may have an increased risk of complications, such as severe graft-versus-host disease (when transplanted donor tissue attacks the recipient's organs such as skin, liver, and/or intestines) and/or clotting of blood within the liver. If you decide to receive a stem cell transplant from a donor, please tell your transplant doctor that you received cetrelimab in the past.

Cabazitaxel Side Effects

Common (occurring in more than 20% of patients)

• fatigue • diarrhea	• vomiting • nausea	• low blood cell counts (red, platelets, white)

Occasional (occurring in 3-20% of patients)

• swelling (arm/leg) • irregular heartbeat • low blood pressure (possible dizziness/fainting) • fever • dizziness • headache • abdominal pain • loss of appetite • abnormal taste	• hair loss (partial or total) • dehydration • constipation • upset stomach • abdominal pain • weight loss • mouth sores and/or blisters (possible difficulty swallowing) • difficult and/or painful urination	• blood in the urine • urinary tract infection • nerve damage (possible numbness, pain, and/or loss of motor function) • pain (back/joint) • muscle spasm • weakness • difficulty breathing • cough

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

• changes in body salts such as sodium, potassium, and/or magnesium (possible fatigue and/or weakness) • digestive system bleeding	• paralysis of the intestines • intestinal blockage • hole in the intestines (possibly leaking contents into the abdomen) • abnormal liver test (possible liver damage and/or yellowing of the skin and/or eyes) • kidney failure	• severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • severe allergic reaction (such as skin rash, skin redness, low blood pressure, and/or difficulty breathing due to a narrowing of the airways)

Receiving the study drug by vein may cause temporary irritation and/or bruising at the site of the infusion. It may also cause an allergic reaction.

Carboplatin Side Effects

Common (occurring in more than 20% of patients)

• 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)	• vomiting • low blood counts (red/ white/platelets) • pain	• abnormal liver tests (possible liver damage) • abnormal kidney test (possible kidney damage)

Occasional (occurring in 3-20% of patients)

• nerve damage (possible numbness, pain, and/or loss of motor function) • hair loss (partial or total)	• abdominal pain • nausea • constipation	• diarrhea • weakness • abnormal liver tests (possible yellowing of the skin and/or eyes) • allergic reaction • infection

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

• high blood pressure • low blood pressure (possible dizziness/fainting) • heart failure	• destruction of red blood cells (possible anemia, kidney damage, and/or failure)	• difficulty breathing due to narrowing of the airways

• stroke • dehydration • blood vessel blockage	• reduced blood supply to the arms and legs • blindness • hearing loss	• tissue death at the injection site caused by drug leakage • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

It is not known how often the following side effects may occur:

• decreased bone marrow function

All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening.

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 (low red blood cell count), which may create a need for blood transfusions.

Fasting may cause your blood sugar to drop. You may feel tired, hungry, and/or nauseous. If you have diabetes, it is important to talk to your doctor about managing your blood sugar while fasting.

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. A prostate biopsy may cause you to feel a stinging sensation each time a sample is taken. It may cause infection, soreness, discomfort, bleeding in the urine or rectum, and/or blood-tinged ejaculate (the fluid released by the prostate during sexual intercourse). It may also result in the temporary inability to urinate.

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

A standard **bone scan** exposes you only to the radiation that comes from injecting the standard radioactive imaging solution for bone imaging.

During an **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 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.

If an MRI contrast material is used, your study doctor will tell you about possible side effects or allergic reaction. Contrast agents can cause allergic reactions and kidney damage. Allergic reactions can include mild itching associated with hives but can also result in a serious life-threatening emergency from difficulty breathing. If this occurs, it is treatable. 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.

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 baby, so you must use birth control if you are sexually active.

Birth Control Specifications: If your partner can become pregnant, you and your partner must be willing to use 2 methods of birth control from screening until 120 days after your last dose of study drugs. Check with your study doctor about what kind of birth control methods to use. The 2 methods must consist of:

1. Condom, and

2. The use of another barrier method (such as a diaphragm or cervical/vault caps) with a spermicidal agent, or the use by your female partner of an intrauterine device or system (IUD or IUS) or birth control pills, injections, or implants.

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

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: You may be asked to have a tumor biopsy for biomarker testing if the disease gets worse. The type of biopsy you have will depend on where the disease has spread and/or what the doctor thinks is in your best interest. The doctor will discuss with you the type of biopsy you will have.

Optional Procedure #2: You may be asked to have blood (about 2-4 teaspoons) drawn for biomarker testing if the disease gets worse.

You do not have to agree to the optional procedures in order to take part in this study. There are no benefits to you for taking part in the optional procedures. Future patients may benefit from what is learned. 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. A prostate biopsy may cause you to feel a stinging sensation each time a sample is taken. It may cause infection, soreness, discomfort, bleeding in the urine or rectum, and/or blood-tinged ejaculate (the fluid released by the prostate during sexual intercourse). It may also result in the temporary inability to urinate.

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

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to have an additional tumor biopsy if the disease gets worse?

YES **NO**

Optional Procedure #2: Do you agree to have an additional blood draw if the disease gets worse?

YES NO

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson, the Department of Defense, or Janssen 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. Ana M. Aparicio, at 713-792-2830) 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 who can help you safely stop study treatment. It may be dangerous to suddenly stop study treatment. The study doctor will also decide if you need to have any visits or tests to check on your health. If you

withdraw from this study, you can still choose to be treated at MD Anderson.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the Department of Defense, Janssen, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson. Possible reasons your participation in this study may be stopped include if the disease gets worse, if intolerable side effects occur, if you are unable to follow study directions, or if the study is stopped.

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.

   Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found.

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

9. This study is supported by: Department of Defense (DOD) and Janssen.

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

Future Research

Data

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

Samples

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying

information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If you withdraw your consent to the storage of leftover samples in the tissue bank, then they will no longer be collected for storage. Any of your samples that remain in the tissue bank will no longer be used for research and will be destroyed.

However, if any of your de-identified samples were already released for research purposes before you withdrew consent, MD Anderson will not be able to destroy them.

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

Genetic Research
Research samples collected from you as part of this study will be used for genetic research, which may include 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.

As part of the study, genetic testing may be performed. A federal law, called the Genetic Information Nondiscrimination Act (GINA), provides some protection for 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 collected in 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 collected in this research when making decisions about your employment

However, this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Conflict of Interest

Dr. Ana Aparicio (Study Chair) has received compensation from Janssen Research & Development as a Consultant. The financial interests are within the limits of the conflict of interest policy.

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

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