THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Phase I Study of LVGN3616 plus LVGN6051 and/or LVGN7409 in Combination with Nab-Paclitaxel, or Sacituzumab Govitecan, or Bevacizumab and Cyclophosphamide in Metastatic Solid Tumors

2021-0176

Subtitle:
Regimen F: LVGN7409 + LVGN6051 + Sacituzumab Govitecan + LVGN3616

Study Chair: Siqing Fu

_____ _____
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

The overall goal of this clinical research study is to learn more about the safety and possible effects of different doses of the study drugs, LVGN3616 and LVGN6051 and/or LVGN7409 that can be given in combination with other drugs to patients with cancers that are advanced, relapsed (have come back), refractory (have not responded to treatment), or metastatic (have spread).

In this part of the study, you will receive the combination of **LVGN3616, LVGN6051, LVGN7409, and sacituzumab govitecan.**

This is an investigational study. LVGN3616 and LVGN7409 are not FDA approved or commercially available. They are currently being used for research purposes only. Sacituzumab govitecan is FDA approved and commercially available for the treatment of metastatic HER2-negative breast cancer. It is considered investigational to give the study drugs together to treat cancer. The study doctor can describe how the drug is designed to work.

The study drug(s) may help to control the disease. Future patients may benefit from what is learned. There may be no benefits for you in this study.

The study drug(s) may help to control the disease. Future patients 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. You may not want to take part in this study due to the potential for side effects, costs, or hospitalization.

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

You may receive the study drug(s) for up to about 2 years, including at least 6 months of follow up, as long as the study doctor thinks it is in your best interest. You will no longer be able to receive the study drugs if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

LVGN3616, **LVGN6051** and LVGN7409 will be provided at no cost to you while you are on study. You and your insurance provider will be responsible for the cost of sacituzumab govitecan. If you stay in the hospital, you and/or your insurance provider will be responsible for the costs of hospitalization.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive other therapies suitable for the type of cancer you have (for example: chemotherapy, radiation treatment, as well as other immunotherapies). 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. You should discuss all possibilities with your primary doctor and the study doctor before deciding to participate.

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:

- You will have a physical exam.
- You will have an EKG and either an echocardiogram (ECHO) or MUGA scan to check your heart function.
- Blood (about 3 teaspoons) will be drawn for pharmacodynamic (PD) testing, routine testing, including tests to check your thyroid function, and tests to check for viruses like hepatitis and HIV (the AIDS virus). PD testing measures how the level of study drug in your body may affect the disease. Depending on the type of cancer you have, this sample may also be used for tumor marker testing. Tumor markers may be related to the status of the disease.

- You will have imaging scans (such as CT scans, PET scans, or MRIs) to check the status of the disease.
- If you can become pregnant, blood (about 1 teaspoon) will be collected for a pregnancy test. To take part in this study, you must not be pregnant.

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 dose level of sequential sacituzumab govitecan plus LVGN7409, and LVGN3616 plus/minus LVGN6051. Up to 6 participants will be enrolled at each dose level. The first group of participants will receive the lowest dose level. Each new group will receive a higher dose than the group before it, if no intolerable side effects were seen. This will continue until the highest tolerable dose of the study drugs is found.

Up to 248 total participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration:
Each study cycle is 21 days (about 3 weeks).

You will receive LVGN7409, and sacituzumab govitecan by vein on Day 1 and sacituzumab govitecan and LVGN3616 plus/minus LVGN6051 by vein on Day 8 of each cycle. You will stay in the clinic for at least 6 hours initially and then at the discretion of your treating physician after you finish receiving the infusions, so the study team can watch you for side effects.

You will be given standard drugs to help decrease the risk of side effects, such as infusion reactions. You may ask the study staff for information about how the drugs are given and their risks.

Study Visits
You will come to the clinic at the following time points. However, if needed for your safety, the study doctor may ask you to come to the clinic more often to have some of these tests/procedures repeated to check on your health. This will be discussed with you.

On **Day 1 of all cycles:**
- You will have a physical exam.
- Blood (about 6 teaspoons) will be drawn for routine tests. During Cycle 1 (depending on the type of cancer you have), this sample will also be used for tumor marker testing.

On **Days 8 and 15 of Cycle 1,** blood (about 6 teaspoons) will be drawn for routine tests.

On **Day 1 of odd-numbered cycles (Cycles 1, 3, 5, and so on):**

- Urine will be collected for routine tests. Depending on the results, you may be asked to collect your urine over about 24 hours. If this happens, the study staff will give you a container and instructions on how to collect the urine.
- Blood (about 1 teaspoon) will be drawn for routine tests, including tests to check how well your blood clots (coagulation tests) and how well your thyroid is working.
- If you can become pregnant, part of the above blood sample will be used for a pregnancy test.

Every 3 cycles, you will have imaging scans to check the status of the disease. Blood collected at this visit will be used for tumor marker testing.

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.

The study doctor will discuss this option with you. If you agree to continue taking the study drug, you will be asked to sign this consent form again. 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.

Follow-Up

Within 30 days after your last dose of study drug:

- You will have a physical exam.
- Blood (about 6 teaspoons) and urine will be collected for routine tests. Depending on the type of cancer you have, this blood sample will also be used for tumor marker testing. If you can become pregnant, one of these samples will be used for a pregnancy test.
- You will have imaging scans to check the status of the disease

Every month until about 90 days after your last dose of study drug, you will be called to ask how you are doing. This call should last about 5-10 minutes.

If you can become pregnant, blood (about ½ teaspoon) will be drawn for a pregnancy test every month for up to 6 months after your last dose of study drug. This may be done at MD Anderson or a local doctor's office.

Other Instructions

- Tell your study doctor if you have any allergies, including drug allergies. If you are unsure, ask your primary doctor.
- Attend all scheduled visits and take the study drug as directed.
- Follow the study doctor's instructions about whether you may continue to take your regular prescribed medications or over-the-counter medicines during the study period.
- Tell the study doctor of any changes to your current medications, illnesses or injuries, side effects, or problems that occur during the study.
- Tell the study doctor if you plan to have an elective surgery or any other medical treatment or procedure.
- You should not perform activities requiring mental alertness, judgment, or physical coordination such as driving or operating machinery, or doing anything that requires you to be alert, unless you feel secure and safe to do so.
- You should continue to make regular visits to your primary doctor or any other special doctors you were seeing before starting the study, since being in the study does not replace regular medical care.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. 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 the study drug(s) are 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 the study drug(s). Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs/procedures.

LVGN7409 Side Effects

This is an early study of LVGN7409 in humans, so the side effects are not well known.

LVGN7409 may cause infusion/allergic reactions. Infusion reactions can occur during and after the infusion of the drug. This can be shown by an increase or decrease in blood pressure, wheezing, less oxygen in the blood, difficulty breathing, chest pain, rigors (extreme chills), headache, swelling around the mouth, throat, or eyes, fast pulse, rash (reddening/blistering of the skin), and sweating. If an infusion reaction occurs, the infusion will be stopped and you will receive appropriate medical care. If the reaction is not severe, and the symptoms get better, the infusion may be started again, often at a slower rate.

The drug could leak outside of the vein into the skin. This may cause a local inflammatory reaction, with aching, burning, tightness, pain, and inflammation at the injection site, local burning or tingling at the infusion site, mild redness, and swelling.

LVGN7409 may cause cytokine release syndrome. This involves a release of a large amount of proteins into the blood stream. This may cause changes in blood pressure and heartbeat, flu-like symptoms (nausea, fever, and chills), and/or affect your lung/liver/kidney function. It may also cause certain brain-related symptoms, such as dizziness, weakness, confusion, difficulty speaking, hallucinations, seizure, tremor, or headache, and/or decreased brain function (possible paralysis and/or coma).

Based on similar drugs, LVGN7409 may also cause liver damage or low blood cell counts (white or red blood cells):

- 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.

LVGN7409 works by boosting the immune system. This may result in side effects that have not been seen yet, such as inflammation and inflammation-related side effects in any organ or tissue.

Sacituzumab Govitecan Side Effects

Common (occurring in more than 20% of patients)

• dizziness • fatigue • headache • nerve damage (loss of motor or sensory function) • hair loss (partial or total) • skin rash • high blood sugar (possible diabetes)	• 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) • abdominal pain • constipation • loss of appetite	• diarrhea (may be severe) • nausea • vomiting • abnormal blood test • abnormal liver test (possible liver damage) • abnormal kidney test (possible kidney damage) • allergic reaction • back pain • cough • difficulty breathing

Sacituzumab govitecan may commonly cause low blood cell counts (red blood cells, and 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 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 or deadly. Fever with neutropenia (a condition where you have too few neutrophils, a type of white blood cell) may require antibiotics or other medicines. Neutropenic colitis (inflammation of a part of the large intestine) may be associated with infection. Symptoms of infection may include fever, chills or sweating, sore throat, pain, redness, diarrhea, and difficulty breathing.

Occasional (occurring in 3-20% of patients)

• low blood pressure (possible dizziness/fainting) • swelling • chills • blood clot in a vein (possible pain, swelling, and/or redness) • difficulty sleeping • itching • dry skin	• fever • mouth blisters/sores (possible difficulty swallowing) • weight loss • heart burn • indigestion • intestinal blockage • dehydration • abnormal taste • blood in the urine	• joint/limb pain • runny nose • stuffy nose • nosebleed • bacteria in the blood • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)

Sacituzumab govitecan may occasionally cause a low platelet count. 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.

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

• inflammation of the intestines	• darkening of the skin	• build-up of fluid around the lungs

Your body may develop its own antibodies against the sacituzumab govitecan that is given in this study. It is possible that your own antibodies may interfere with some laboratory tests. In addition, you may not be eligible to take part in other trials that use antibodies. For these reasons, you should inform doctors and other medical staff that you have taken part in this study in your future visit to them.

Participants with known reduced UGT1A1 activity have an increased risk of severe side effects from sacituzumab, especially neutropenia, febrile neutropenia, and a low red blood cell count (anemia).

Anaphylactic reaction (a serious type of allergic reaction)
Sometimes people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Some signs that you may be having an allergic reaction are:

- Rash or hives
- Having a hard time breathing
- Wheezing when you breathe

- Sudden change in blood pressure (making you feel dizzy and lightheaded)
- Swelling around the mouth, throat and eyes
- Fast pulse
- Sweating

Frequency Unknown

• weakness	• swelling (around the eyes)	• throat inflammation

LVGN3616 Side Effects

This is an early study of LVGN3616 in humans, so the side effects are not known. Based on animal studies and early human studies (when the study drug was given alone or with other drugs), LVGN3616 may cause:

• fatigue • fever • decreased blood circulation • 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) • skin rash and/or itching • abdominal pain • loss of appetite • constipation • diarrhea	• nausea • abnormal liver test (possible liver damage) • pain • abnormal kidney test (possible kidney damage) • cough • difficulty breathing

LVGN3616 may 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.

LVGN3616 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.

LVGN6051 Side Effects

This is an early study of LVGN6051 in humans, so the side effects are not well known. Based on studies in animals and early human studies (when LVGN6051 was given alone or with another drug called pembrolizumab), LVGN6051 may cause the following side effects.

• flushing • changes in blood pressure and heart rate • chest pain • fatigue • confusion • difficulty forming or speaking words	• headache • fever/chills • skin rash • itching • nausea/vomiting • abdominal pain • abnormal liver tests (possible liver damage)	• pain • difficulty breathing • abnormal digestive blood test (possible inflammation and/or damage of the pancreas)

LVGN6051 may cause cytokine release syndrome. This involves a release of a large amount of proteins into the blood stream. This may cause changes in blood pressure and heartbeat, flu-like symptoms (nausea, fever, and chills), and/or affect your lung/liver/kidney function. It may also cause certain brain-related symptoms, such as dizziness, weakness, confusion, difficulty speaking, and/or decreased brain function (possible paralysis and/or coma).

LVGN6051 may cause body-wide inflammation, which could result in shock, very low blood pressure (possible dizziness and/or fainting), high fever, blood leaking from vessels into tissue, blood clots, and/or organ failure.

LVGN6051 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.

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.

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

MUGA scans may cause allergic reactions to the radioactive tracer, injection site soreness, and/or swelling. They may cause damage to cells or tissue from being

exposed to the radiation used in the scan. These side effects may occur in less than 10% of patients.

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.

A **PET scan** may cause you to 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 technicians will give comfort or the scanning will be stopped.

The PET scan exposes your body to radiation. The radioactive solution does not remain in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

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.

If you can become pregnant or father a child, you must use 2 methods of birth control during the study if you are sexually active. Talk to the study doctor about acceptable methods of birth control for you and your partner.

You must use birth control while on nab-paclitaxel, bevacizumab, cyclophosphamide and sacituzumab govitecan for the following lengths of time depending on whether you are male or female:

- Nab-paclitaxel:
  - Females – for at least 6 months after last dose
  - Males – for at least 3 months after last dose
- Bevacizumab:
  - Females – for 6 months after the last dose
  - Males – for 6 months after the last dose
- Cyclophosphamide:
  - Females – for 12 months after the last dose
  - Males – for 12 months after the last dose
- Sacituzumab govitecan:
  - Females – for 6 months after the last dose
  - Males – for 3 months after the last dose

Effective methods include diaphragm, copper intrauterine device (IUD), sponge, spermicide (male and female), or condom (male). Hormonal methods include birth control pills and injections that contain an estrogen and/or progesterone.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy. If your partner/spouse becomes pregnant while you are on this study, the sponsor would like to collect information about the pregnancy. The study sponsor's contact information will be made available so that, if you and your partner wish to, you can share information about the outcome of the pregnancy with the sponsor. If you and/or your partner choose not to share this information, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

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.

Getting pregnant will result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

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 #1: If you agree, you will complete a questionnaire about your overall health and any symptoms you are having at screening and at the end of each cycle. The questionnaire should take about 30 minutes to complete.

Optional Procedure Risks

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

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 complete a questionnaire at screening and at the end of each cycle?

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 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.

If you require medical treatment for an illness or injury that is a direct result of taking the study drug, Lyvgen Biopharma will pay for reasonable and routine costs of such treatments if the following conditions are met:

- The illness or injury was a result of taking part in the study as agreed by Lyvgen and the treating doctor.
- The illness or injury was not a result of a failure to follow study instruction or from the mistake, negligence, or misconduct of the study personnel.
- The cost of treatment or any part of the costs is not already covered by any other health insurance, government health program, or other institutions providing coverage for health care.

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. Siqing Fu, at 713-563-1930) 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, Lyvgen Biopharma Holdings Limited, 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, or if you are unable to follow study directions.

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 not 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 sponsored and/or supported by: Lyvgen Biopharma Holdings Limited.

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 Lyvgen Biopharma Holdings Limited 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. Lyvgen Biopharma Holdings Limited will not store leftover samples.

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 do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

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

Genetic Research
Exploratory 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
   - Lyvgen Biopharma Holdings Limited, 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 study sponsor (Lyvgen Biopharma Holdings Limited) is in a collaboration with Merck and may share data and results of the analysis of tumor tissue with Merck. To keep your identity private, all data that is sent or provided outside of the study center will show only a coded identification number instead of your name.

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

MD Anderson IRB Approved 06/18/2025