PRINCIPAL INVESTIGATOR: Jung-Min Lee, M.D.

STUDY TITLE: Phase II Pilot Study of Sacituzumab Govitecan for Relapsed Ovarian, Endometrial, and Cervical Carcinomas

STUDY SITE: NIH Clinical Center

Cohort: *Affected patient*

Consent Version: *07/07/2025*

WHO DO YOU CONTACT ABOUT THIS STUDY?

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KEY INFORMATION ABOUT THIS RESEARCH

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

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

You are being asked to take part in this study because you have ovarian, endometrial, or cervical carcinoma that has come back after at least two types of chemotherapy or targeted treatment.

The purpose of this study is to learn if giving a drug named sacituzumab govitecan (SG) can shrink your tumor(s).

SG is already approved by the U.S. Food and Drug Administration (FDA) for use in other types of cancers. The use of SG in this study is considered investigational, which means that it has not been approved by the FDA to treat ovarian, endometrial, or cervical carcinomas. However, the FDA has given us permission to use SG in this study.

There may be other drugs that may be used to treat your disease, and these can be prescribed/given by your regular cancer doctor, even if you are not in this study. The way in which the study drug is given in this study and the side effects are not significantly different than if you were to receive standard care therapy.

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

- We will first do some basic tests to make sure you qualify for the trial. These include: standard blood tests and scans to test your health, including your heart and viral infections, and see the status of your disease.

- If you fit the study requirements and decide to take part, you will receive SG by intravenous (IV) (a small catheter is inserted into a vein allowing to give the solution) infusion on Day 1 and Day 8 of every 21-day cycle:
- You can receive the study drug for a maximum 5 years or until, for example, your disease gets worse, you have serious side effects, or you decide to stop receiving the study drug.
- You may experience side effects from taking part in this study. Some can be mild or very serious, temporary, long-lasting, or permanent, and may include death. Examples of some of the side effects include tiredness, nausea, infection, anemia (low red blood cells), fever, rash, diarrhea. You may also have side effects from some of the procedures (such as the biopsy). All of the possible side effects are described in more detail later in the consent form.
- We will see you regularly during the study. You will have clinical, laboratory, and imaging tests to see how you are doing and to see if the study drug is having any effect on your cancer. We will also collect required samples from you including blood and tumor tissue for research purposes.
- Within 2 weeks after your stop taking the study drug, we will see you in the clinic and possibly have more clinical and research tests.
- About 4 weeks after the last dose of the study drug, we may see you in the clinic, or we will contact you by phone for follow-up.
- If your disease worsens or if you start a different cancer treatment, we will then contact you for long term follow-up about every 6 months for up to 10 years after receiving the first dose of SG, to ask about your condition and survival.
- If you are capable of becoming pregnant, you must agree to use birth control during the study and for 6 months after the last dose of study drug. You must also stop nursing while you are taking the study drug and for 1 month after the last dose of the study drug.

We cannot know if you may benefit from taking part in this study. If you do not benefit, this study and the results from our research may help others in the future.

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

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

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you

must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

We are asking you to join this research study because you have been diagnosed with ovarian, endometrial, or cervical carcinoma and your cancer has come back after you have received at least two types of chemotherapy or targeted therapy.

The purpose of this research study is to see if sacituzumab govitecan (SG) can shrink your tumor.

SG is known as an antibody-drug conjugate or, in other words, is like a drug that is made of two parts. Specifically, SG is composed of a chemotherapy drug, called irinotecan, that is attached to an antibody. Antibodies are proteins normally made by the immune system that bind to substances that do not belong in the body to prevent harm. SG works by binding to the cancer cells with the antibody and killing them with the chemotherapy.

SG is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA) to treat ovarian, endometrial, or cervical carcinoma. However, the use of SG is approved to treat triple-negative breast cancer and urothelial cancer.

WHAT WILL HAPPEN DURING THE STUDY?

Below is a description of what we will ask you and what will occur if you decide to take part in this study.

Before you begin the study – Screening

Before beginning the study, you will need to have tests and/or procedures to help your doctor see if you are able to take part. This is called screening. Most of the exams, tests, and procedures you will have are part of the usual approach for your disease. However, there are some extra procedures that you will need to have if you take part in this study. If you have already had some of these tests very recently, your doctor may decide not to repeat them. Briefly, you will need to have:

- Confirmation of diagnosis: we will review your pathology to confirm your diagnosis. If your pathology reports or existing tissue are not available, we will collect tissue (biopsy) from you to confirm your diagnosis and to enter onto the study.
- Medical history: to review any past or current medical conditions.
- Physical examination: including height, weight, vital signs
- Performance status: a review of your symptoms and your ability to perform your normal activities.
- Routine blood tests:
    - to check your blood counts, blood minerals, liver, and kidney
    - to measure how well your blood clots
    - to check for hepatitis B and C
    - to check for HIV: As part of this study, we will test you for infection with human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome (AIDS). If you are infected with HIV, you may still be able to take part

in this study. We will tell you what the results mean, how to find care, how to avoid infecting others, how we report HIV infections, and the importance of informing your partners at possible risk because of your HIV infection.

- Review of your medications (prescription, supplement, and over the counter) and contraception.
- Pregnancy test: if you can bear children, a urine or serum pregnancy test will be done. The results of the pregnancy test must be negative for you be allowed in the study.
- Heart tests:
    - Electrocardiogram (EKG): a record of your heartbeat rhythm. This is done by placing electrodes on your body that are hooked up to a machine. Once the electrodes are placed, the test will begin, is completely painless, and generally takes less than a minute to perform. After the test, the electrodes are removed.
- Imaging tests:
    - Computer tomography (CT) scan to image your chest, abdomen, and pelvis. A CT scan produces a series of x ray images taken of parts of your body. If you cannot get CT scans or if your doctor feels better to assess your disease, magnetic resonance imaging (MRI) will be done.
    - MRI or CT scan of the brain if you have previously treated sites of disease in the brain or there is a suspicion that your cancer has spread to the brain (metastasis).

If the tests show that you are not able to take part in the study, you will not be able to continue. Your study doctor will discuss other care options with you.

During the study – Study drug

Once it is decided that you are eligible to take part in this study, you will begin taking the study drug, SG.

During your participation, you will receive SG on Day 1 and Day 8 of each 21-day cycle. You can receive the study drug for up to 5 years, or until your disease gets worse, you have serious side effects, or you decide to stop taking the study drug.

You will receive SG by IV infusion over a period of about 1-3 hours in the outpatient setting.

We will give you standard medications to try and prevent certain side effects before receiving SG (such as antihistamine and acetaminophen). These are required prior to the first two infusions and then only as needed.

Before you start taking any new medicines, including vitamins and herbal supplements that you can buy “over the counter”, please talk to the study doctor to make sure they are allowed on this study.

While you are taking study medication, we will perform some tests and examinations for safety and to test the effect of the study drug. We will also collect samples from you for purposes of research only. We will see you in clinic at the NIH Clinical Center once every time you receive the study drug.

The assessments and tests to be done include:

- Physical exams and measures of your vital signs and weight, and any current symptoms of your condition. On days of SG administration, we will take vital signs at multiple timepoints before, during and after the infusion.
- Review of your medications (prescription, supplement, and over the counter).
- Performance status to see how you function in your daily activities
- Standard blood tests to measure your organ function, such as liver and kidney, white and red blood cells, platelets, tumor markers, and others and to measure how well your blood clots
- Standard urine test
- Urine or blood pregnancy test in persons who can have children (performed at day 1 of each cycle)
- Imaging tests to show all sites of disease to see if the study drug is helping your cancer. :
    - CT of chest, abdomen, and pelvis (about every 9 weeks (3 cycles) for the first year and then every 12 weeks (4 cycles) thereafter).
    - MRI or CT scan of the brain if you have symptoms or prior history of brain metastases (only before you start taking the study drugs)

Additional research testing

In addition to the tests that we will conduct to determine whether you are having side effects or if you are responding to the study drug, we will also collect samples from you for purposes of research only. Research testing will be done on your blood, urine, and tumor tissue to help us determine the effects of the study drug on your body and how your immune system is responding to the study drug.

We will collect the following samples and tests for research purposes only:

- Blood will be drawn before starting and during the study.
- We will collect tumor samples before you start taking the study drug– We will ask for a sample from your previous surgery and we will also collect a fresh sample, but only if it is safe to obtain. We may collect one more biopsy (optional) when you finish taking the study drug. Biopsies are collected using a small needle under CT guidance by an interventional radiologist. Imaging helps the specialized radiologist know that the needle has been placed into the tumor mass. We will ask you to sign a separate procedure consent form prior to each biopsy. You may receive local anesthesia before undergoing a biopsy, if needed. Local anesthesia is given to minimize discomfort. We will monitor you throughout the procedure. You may receive general anesthesia only if the study doctor thinks you need it.

All of your samples collected for research purposes on this study (such as the tumor tissue) may be used to look for specific changes in the DNA and RNA in tumors that could be used to develop new ways of diagnosing and treating cancer. DNA (also called deoxyribonucleic acid) in the cells carries genetic information and passes it from one generation of cells to the next – like an

instruction manual. Normal tissue contains the DNA (instructions) that you were born with, DNA in tumor cells has changed – or mutated – and we think that change in the DNA is what causes tumors to form and to grow. RNA (also called ribonucleic acid) carries the instructions from the DNA to the parts of your cells that make proteins.

To look at your DNA and RNA which carried genetic information, we may do special tests in the lab to look at the entire sequence, or order, of how your DNA and RNA are put together. This is what makes you unique.

To find which parts of the DNA or RNA have mutated, we will analyze the DNA or RNA of your tumor cells. We will then analyze the results from similar tumors to see if there are any changes in the DNA or RNA that are common to a particular type of tumor.

When you are finished taking the drug

End of Treatment Visit

If you need to stop taking the study drug for any reason, then we will ask you to return to the clinic about within 2 weeks after you have had last dose of study drug or before you begin a new anti-cancer treatment for an end of treatment visit.

The visit will include the following clinical tests:

- Physical exam, seeing how you function in your daily activities, any current symptoms of your condition and a review of all medications that you take.
- Routine blood tests
- Imaging tests (if not done in the last 4 weeks)
    - CT scan of your chest, abdomen, and pelvis
- Blood and optional tumor samples for research studies

Safety Visit

We will ask you to come to the clinic for a safety check-up, about 30 days after the last dose of study drug or before you begin a new anti-cancer treatment to see how you are doing.

The visit will include the following clinical tests:

- Physical exam, seeing how you function in your daily activities, any current symptoms of your condition and a review of all medications that you take.
- Review of contraception

If you are unable to travel to the NIH Clinical Center, we will contact you by phone.

Long term Follow-up

After you stop taking the study drug, we will contact you by phone about every 6 months for up to 10 years after your first dose of study drug to check on your disease status.

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study, your involvement is expected to last for up to 10 years or until your cancer worsens, you have unacceptable side effects, you decide to no longer take part in the study, or your study doctor decides it is no longer suitable for you to continue. We will see

you several times during the study. The outpatient visits usually take about 3 hours but should not take longer than 8 hours.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

Up to 75 people will receive SG at the NIH.

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

If you choose to take part in this study, you are at risk for side effects. The study doctors do not know who will or will not have side effects. Some side effects may go away soon, some may last a long time, and some may never go away. It is also possible that you may experience more than one side effect at the same time. Some side effects may be mild. Other side effects may be very serious and even result in death. You will be watched carefully for any side effects. You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and Possible Side Effects of SG

The side effects described in this section are known to be associated with SG.

You should get immediate medical help and contact the study doctor or staff if you have any of these or any other side effects during the study.

Very Common, may be serious **In 100 people receiving sacituzumab govitecan, 10 or more may have:**
• Nausea, vomiting, constipation, abdominal pain and diarrhea • Low count of different types of white blood cells (including neutrophils and leukocytes) which may cause infection and require antibiotics or other medicines • Bacterial and viral infections including pneumonia and urinary tract infection which may be serious • Fatigue (tiredness) • Hair Loss • Lack of enough red blood cells which may cause tiredness, or may require blood transfusion • Decreased appetite • Cough • Decreased levels of calcium in the blood that can cause muscle twitching and/or contractions, abnormal heart beats or seizures • Decreased levels of sodium in the blood which can cause confusion, seizures, fatigue and low levels of consciousness • Decreased levels of phosphate in the blood which may cause muscle weakness, bone pain, confusion, and muscle breakdown • Decreased levels of magnesium in the blood which could cause weakness and muscle cramping and/or irregular heartbeat • Decreased levels of potassium in the blood which can cause an abnormal heart rate • Increased sugar levels in the blood • Decreased protein levels (albumin) in the blood • Changes in kidney function test

- Increased levels of enzyme called alkaline phosphatase in the blood that can cause liver damage
- Changes in your laboratory results related to issues with levels of liver enzymes (indicating damage to the liver)
- High level of lactate dehydrogenase which is an enzyme in your body which indicates tissue damage to certain organs
- Changes in your laboratory results including issues with clotting
- Dehydration (when your body does not have as much water and fluid as it should)
- Joint stiffness or pain
- Headache
- Dizziness
- Shortness of breath
- Rash
- Itching
- Antibody Risks: 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 office visits.
- Urinary tract infection which may cause frequent and painful urination
- Weight loss

Common, may be serious

In 100 people receiving sacituzumab govitecan, from 1 to 9 may have:

- Painful swelling and sores inside the mouth (stomatitis)
- Gastroesophageal reflux disease (when your stomach contents come back up into your esophagus)
- Abdominal distention (when substances, such as air (gas) or fluid, accumulate in the abdomen causing its expansion)
- Pain in belly (upper part)
- Inflammation of the inner lining of the colon (colitis).
- Chills
- Pain
- Nosebleed
- Runny nose or nasal congestion
- Low blood pressure
- Infection of the upper airways
- High level of protein in the urine
- Rash with both flat and raised parts
- Dry skin
- Skin hyperpigmentation
- Acne-like rash

- Infection, especially when white blood cell count such as neutrophils or lymphocytes is low. Having a high temperature or fever while your white blood cell count is low is a life-threatening medical emergency and you must proceed to the nearest emergency room as soon as possible.
- Sepsis - infection of the blood
- Decreased number of a type of blood component that helps to stop bleeding (platelet), causing bruising and/or bleeding
- Inflammation of the inner lining of the colon (colitis) caused by low white blood cells (including neutrophils)
- Pneumonia-Infection in the lungs
- Altered sense of taste
- Insomnia (trouble falling asleep or staying asleep)
- 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 or lightheaded)
  - Swelling around the mouth, throat, or eyes
  - Fast pulse
  - Sweating

Uncommon, may be serious

In 1000 people receiving sacituzumab govitecan, from 1 to 9 people may have:

- Anaphylaxis reaction (a life-threatening allergic reaction to the compound)
- Inflammation of the small intestine
- Abnormal weakness or lack of energy
- Low number of platelets, which may cause bleeding and bruising.

If you have any questions about drugs or supplements to avoid, you may speak with your study doctor.

Risks of study research procedures

Blood draws

Side effects of blood draw include pain and bruising in the area where the needle was placed, lightheadedness, and rarely, fainting and infection. When large amounts of blood are collected, a low red blood cell count (anemia) can develop. We will not collect more than about 5 ½ tablespoon of blood any day of the study or 14 ½ tablespoons within 8 weeks.

Urine collection

There are no risks associated with urine collection.

Electrocardiogram (EKG)

To perform the test, we will place adhesive patches (electrodes) on your skin to record your heart's activity. If results from one test are abnormal, the test may be repeated. You may feel some discomfort when the technician removes the adhesive patches after the procedure, similar to pulling off an adhesive bandage. The adhesive patches can also cause skin irritation or rash in some patients.

Tumor biopsy

If a sample from a previous biopsy is not already available, your study doctor may ask you to have a biopsy of your tumor if it can be safely done. The risks or side effects involved with a tumor biopsy may include bruising, discomfort, and bleeding after the procedure. There are potentially life-threatening risks associated with this procedure, depending on the location of your tumor. Please talk with your study doctor if you have any questions about this tumor biopsy.

Imaging

MRI and CT scans may involve the administration of a contrast dye either orally or by injection in your veins. The contrast dye that is injected into your body may cause you to get a metallic taste in your mouth and to feel warm. Rarely, it causes nausea and vomiting. The dye can also cause damage to the kidneys, which may lead to kidney failure. This is a concern if you have poor kidney function. Some people can have allergic reactions to this material. The allergic reactions can cause itching or rash. More serious allergic reactions can cause difficulty breathing, dangerously low blood pressure, or kidney damage.

MRI

MRI uses a strong magnetic field and radio waves to take pictures of the body. We will obtain pictures of your chest, abdomen, and pelvis for this study. The MRI scanner is a metal cylinder surrounded by a strong magnetic field. People are at risk for injury from the MRI magnet if they have some kinds of metal in their body. It may be unsafe for you to have an MRI scan if you have pacemakers or other implanted electrical devices, brain stimulators, some types of dental implants, aneurysm clips (metal clips on the wall of a large artery), metal prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, tattoos, an implanted delivery pump, or shrapnel fragments. Welders and metal workers may have small metal fragments in the eye. We will screen you for these conditions before having any MRI scan. If you have a question about metal in your body, you should inform the staff. We will ask you to complete an MRI screening form before each MRI scan you have.

In addition, we will ask you to remove all magnetic objects (like watches, coins, jewelry, and credit cards) before entering the MRI scan room.

People with fear of confined spaces may become anxious during an MRI. Those with back problems may have back pain or discomfort from lying in the scanner. The noise from the scanner is loud enough to damage hearing, especially in people who already have hearing loss. Everyone having a research MRI scan will be fitted with hearing protection. If the hearing protection comes loose during the scan, you should let us know right away.

There are no known long-term risks of MRI scans.

Risks from gadolinium

During part of the MRI you may receive gadolinium, a contrast agent, through an intravenous (IV) catheter (small tube). It will be done for both research and medical purposes.

It is not known if MRI with contrast is completely safe for a developing fetus. Therefore, all participants able to bear children will have a pregnancy test performed no more than 24 hours before each MRI scan with contrast. The scan will not be done if the pregnancy test is positive.

The risks of an IV catheter include bleeding, infection, or inflammation of the skin and vein with pain and swelling.

Mild symptoms from gadolinium infusion occur in fewer than 1% of those who receive it and usually go away quickly. Mild symptoms may include coldness in the arm during the injection, a metallic taste, headache, and nausea. In an extremely small number, fewer than one in 300,000 people, more severe symptoms have been reported including shortness of breath, wheezing, hives, and lowering of blood pressure. You should not receive gadolinium if you previously had an allergic reaction to it. We will ask you about such allergic reactions before gadolinium is given.

People with kidney disease are at risk for a serious reaction to gadolinium contrast called "nephrogenic systemic fibrosis (NSF)". This condition always involves the skin and can also involve the muscles, joints, and internal organs. NSF has resulted in a very small number of deaths. A blood test of your kidney function may be done within the month before an MRI scan with gadolinium contrast. You will not receive gadolinium for a research MRI scan if your kidney function is below the safe level.

Most of the gadolinium contrast leaves the body in the urine. However, the FDA has issued a safety alert that indicates small amounts of gadolinium may remain in the body for months to years. The effects of the retained gadolinium are not clear. At this time, retained gadolinium has not been linked to health risks in people whose kidneys work well. Some types of gadolinium contrast drugs are less likely to remain in the body than others. In this study, we will use the gadolinium contrast drugs that are less likely to remain in the body.

Local anesthesia

Biopsies may be done under local anesthesia. Potential side effects of local anesthesia include drowsiness, headaches, blurred vision, twitching muscles or shivering, continuing numbness, weakness or pins and needles sensation.

General anesthesia

Temporary confusion and memory loss, dizziness, difficulty passing urine, bruising or soreness from the IV drip, nausea, and vomiting, shivering, and feeling cold, sore throat due to the breathing tube.

What are the risks related to pregnancy?

The effects of the study drug on a developing pregnancy or breastfeeding infant are unknown. To reduce the risk of any harmful effects, people who are pregnant, planning a pregnancy, or breastfeeding are not allowed to participate in studies using the study drug.

Participants who can become pregnant

If you are a person who could possibly become pregnant (you have not completed menopause, had a hysterectomy and/or both tubes and/or both ovaries removed), a blood or urine pregnancy test will be performed, and it must be negative to take part in this study.

You will also have additional blood or urine pregnancy tests at some study visits, as described above, and they also must be negative for you to continue in the study.

You and your partner must agree to use a highly effective method of contraception before you start taking the study drug and for 6 months after the last dose of study drug. The methods of highly effective birth control methods include:

- intrauterine device (IUD)
- hormonal (birth control pills, injections, or implants)
- tubal ligation

If you have been abstinent for at least 6 months before this study (you have not had vaginal heterosexual intercourse) and you agree to be abstinent for the duration noted above, this is also an acceptable method.

If you do become pregnant during the study, your study doctor will stop the study drug.

If you and your partner are not currently using one of the above methods your study doctor will discuss options with you. Because no birth control method (other than abstinence) is 100% effective, you should notify your study doctor immediately if you think there is any chance you could be pregnant.

If you become pregnant, we will ask to follow you for the duration of the pregnancy to better understand the potential effects of the study drug on pregnancy outcomes.

What are the risks of radiation from being in the study?

During your participation in this research study, you may be exposed to radiation from up to 3 CT guided biopsies and up to 7 CT scans per year. The amount of radiation exposure from these procedures is equal to approximately 12.5 rem. A rem is a unit of absorbed radiation.

Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. The average person in the United States receives a radiation exposure of 0.3 rem per year from these sources. This type of radiation is called "background radiation." No one knows for sure whether exposure to these low amounts of radiation is harmful to your body.

The CT and PET/CT scans that you get in this study will expose you to roughly the same amount of radiation as 41.7 years' worth of background radiation. Being exposed to too much radiation can cause harmful side effects such as an increase in the risk of cancer. The risk depends on how much radiation you are exposed to. Please be aware that about 40 out of 100 people (40%) will get cancer during their lifetime, and 20 out of 100 (20%) will die from cancer. The risk of getting cancer from the radiation exposure in this study is 1.3 out of 100 (1.3%) and of getting a fatal cancer is 0.6 out of 100 (0.6%).

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You might not benefit from being in this study. However, the potential benefit to you might be shrinking of your tumor or lessening of your symptoms, such as pain, that are caused by the cancer.

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

In the future, other people might benefit from this study because the knowledge gained from this study may help others in the future who have cancer.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

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

- choose to be treated with surgery, radiation or with drugs already approved by the FDA for your disease
- choose to take part in a different study, if one is available
- choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

DISCUSSION OF FINDINGS

New information about the study

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

Return of research results

You will get the results from regular tests done in certified labs during the study as part of your medical record.

However, we will not share the results of research tests. This includes the test results from the genetic research we will do in this study. The tests we do in our lab are only for research, so they are not as accurate as tests done in a certified lab for regular health care. Also, our tests only look at your tumor tissue so they may not show all the details about your genes that could impact your future health. For these reasons, we won't share the results of the research tests we did on your samples with you.

Protections against misuse of genetic information

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

EARLY WITHDRAWAL FROM THE STUDY

Your doctor may decide to stop taking the study drug for the following reasons:

- if he/she believes that it is in your best interest
- if your disease worsens or comes back during treatment
- if you have side effects from the treatment that your doctor thinks are too severe
- if you become pregnant
- if you need a treatment that's not allowed on this study
- if you have an illness that prevents you from getting the SG
- if you do not follow the rules of the study
- if the SG may become unavailable
- if new information shows that another treatment would be better for you
- if the study is stopped for any reason

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

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

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

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

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

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

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

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

_____ Yes _____ No

Initial Initial

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

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

One way that we may share your data is by putting it into a large database called a repository, which is a way to make it widely available to the research community. If we do place your data in a repository, it will be labeled with a code, (not with your name or other information that could be used to easily identify you). Even though it will only be labeled with a code, some types of data, in particular data about your genes (called genetic or genomic data), can be used to figure out who you are, although this is difficult to do, and we think it is unlikely to happen.

The data in the repository will only be available to qualified researchers. These researchers must receive permission before they are allowed to access the data. Before receiving the data, the researchers must promise that they will not try to figure out the identity of the research participants.

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

I give permission for my **de-identified** specimens and data to be shared with and used by other researchers for future studies.

_____ Yes _____ No

Initial Initial

In some cases, it may help other researchers to know that the specimens or data were collected from you (i.e., they will have your identifiers). If we share your identity with other researchers, their study will be reviewed and approved by an Institutional Review Board who will make sure that the study team is protecting your confidentiality.

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

_____ Yes _____ No

Initial Initial

Information about all the people (including you) in this study may be combined to create what is called summary information. The summary information may be placed in a database and shared in scientific publications. This information will help the researchers understand if some patterns are more common than others among everyone who was a part of this study. The summary

information will be available to anyone without the need for any permission. The risk of anyone identifying you based on this information is very low.

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

Risks of storage and sharing of specimens and data

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

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

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

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

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

PAYMENT

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

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

REIMBURSEMENT

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

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

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

COSTS

Will taking part in this research study cost you anything?

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

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

CONFLICT OF INTEREST (COI)

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

The NIH and the research team for this study are using SG developed by Gilead Life Sciences through a collaboration between your study team and the company. The company also provides financial support for this study.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We do our best to keep your medical information private. However, we cannot promise this. Certain groups may look at and copy your medical records. This may be for research, quality and data review including:

- The NIH and other government groups. (For example, the Food and Drug Administration (FDA) to help keep research safe.)
- NIH Institutional Review Board
- The study Sponsor, Center for Cancer Research
- Qualified people from Gilead Life Sciences, and the drug company who makes SG.

NIH and researchers doing this study follow special laws and policies to keep your information as private as possible. However, your identity and information about being in this study may accidentally be seen by others.

In most cases, NIH will not share any identifiable information about you unless you say it is okay in writing. More information about sharing your information is below.

Information gathered for this study is protected under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, NIH has a Certificate of Confidentiality (Certificate). With this Certificate, researchers may not release or use information about you except in certain cases.

NIH researchers must not share information that may identify you in any legal proceedings, such as if a court requests it with a subpoena.

The Certificate does not protect your information when it:

1. is shared with people connected with the research. For example, information may be used for internal reviews by NIH; or
2. is required by law to be disclosed. For example, information may be shared with the FDA or with public health agencies.
3. is for other research if allowed by other regulations;
4. is shared with your consent.

Researchers may provide your information when you say it is okay. The Certificate does not keep you from sharing your own information.

The Certificate will not prevent telling authorities about harm to yourself or others. Examples are child abuse and neglect.

Privacy Act

The Privacy Act helps keep your NIH medical information confidential. In some cases, it is different from the Certificate. Sometimes the Privacy Act allows sharing your information without your permission. An example is if Congress requests it.

Information may also be shared for some research. It can be given to some federal and state agencies. It can be used for HIV partner notification, or for infectious disease, abuse, or neglect reports. It may be shared with tumor registries, for quality and medical reviews. It may also be shared if NIH is involved in a lawsuit. However, NIH will only release medical record information if allowed by both the Certificate and the Privacy Act.

RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Jung-Min Lee, M.D. at leej6@mail.nih.gov (240-760-6128). You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713 if you have a research-related complaint or concern.

CONSENT DOCUMENT

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

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

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness should sign below if either:

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

Signature of Witness	Print Name of Witness	Date

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

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

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