Official Title	A pilot single arm trial with Sacituzumab Govitecan as neoadjuvant therapy in pts with non-urothelial muscle invasive bladder cancer
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Fred Hutchinson Cancer Center

Consent to take part in a research study:

Title of Study: A pilot single arm trial of Sacituzumab govitecan as neoadjuvant therapy in patients with non-urothelial carcinoma histologic variant

Short Title: SG NeoAdj IIT

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Emergency Number (24 hours): 206-598-6190, Request Oncology Fellow On-Call

IMPORTANT THINGS TO KNOW ABOUT THIS STUDY

You are invited to participate in a research study. The purpose of this research is to answer scientific questions about non-urothelial bladder cancer that may inform standard routine practice in the future.

Research is not the same as standard treatment or routine medical care. The purpose of a research study is to answer scientific questions that may inform standard routinepractice in the future. You do not have to join the study. You are free to say "yes" or"no" or drop out after joining. If you say "no," you would have no penalty or loss ofbenefits. Whatever you decide, your regular medical care would not change.

The purpose of this research is to see whether the medication Sacituzumab govitecan given before the surgical removal of the bladder and pelvic lymph nodes (known as radical cystectomy (RC) and pelvic lymph node dissection (PLND) is effective in treating people who have non-urothelial bladder cancer. We want to find out if using Sacituzumab works better or worse than the standard treatment for your type of cancer. This medication could cause side effects such as hair loss, tiredness, vomiting, andnausea, as described below in this form.

People who agree to join the study will be asked to attend 9 visits over approximately 9 weeks. If you choose to be in this study, you will receive 1 dose of Sacituzumab govitecan on the 1st and 8th day of each 21-day study cycle for a total of 3 cycles. Within 10 weeks of your final dose of Sacituzumab govitecan (week 9), you will undergo surgery to remove your bladder. The removal of your bladder is standard for patients with bladder cancer that has grown into the muscle layer of the bladder wall.

You do not have to join this study. You can choose to receive standard methods to treat your cancer instead of participating in this study. We will give you details about the purposes, procedures, risks, and possible benefits related to this study. We will explain other choices that you have. We will also give you any other information that you need to make a well-informed

decision about joining this study.

The following is a more complete description of this study. Please read this description carefully. You can ask any questions to help you decide whether to join the study. You should not join this research study until all your questions are answered. Please take as much time as you need to make an informed decision. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your doctor for more information. If you join this study,we will give you a signed copy of this form to keep for future reference.

WE INVITE YOU TO JOIN THIS RESEARCH STUDY

We invite you to join this research study because you have non-urothelial bladder cancer. You are also being asked to take part in this research study because you are planning to undergo a surgical procedure called radical cystectomy to remove your bladder and a pelvic lymph node dissection. We hope to treat up to 17 people in this study.

PURPOSE OF THE STUDY

This research study uses a drug called Sacituzumab govitecan. The U.S. FDA has approved Sacituzumab govitecan for sale in the U.S. It is approved for adults with breast cancer that has spread or cannot be removed by surgery. It has also recently been approved for advanced bladder cancer and cancers of the urinary tract (renal pelvis, ureter, or urethra) that have been treated before and have spread or cannot be removed by surgery. The brand name for Sacituzumab govitecan is TRODELVY™.

Sacituzumab govitecan is still being studied in research studies like this one to find out what its side effects are and if it works in other types or stages of cancer. We do not yet know if Sacituzumab govitecan is better or worse than other treatments for your stage of cancer.

Sacituzumab govitecan is a type of drug called an antibody drug conjugate or ADC. ADCs usually have 2 parts, an antibody, and a drug.

- **Antibody:** Antibodies are part of your immune system. Usually, they help protect you from getting sick. Sacituzumab govitecan contains an antibody designed to find and stick to the cancer cells in your body. It may also stick to some non-cancer cells in your body.
- **Drug:** The drug is the part of the ADC that kills cells. The cell-killing part of Sacituzumab govitecan is a chemotherapy drug called a topoisomerase inhibitor.

We are studying Sacituzumab govitecan to find out if it works for your type of cancer given prior to surgery. We want to find out if using Sacituzumab govitecan works better or worse than the standard treatment for your type of cancer. We also want to learn more about the side effects. A side effect is anything the drug does to your body besides treating your disease.

More than 1013 people with cancer have already been given Sacituzumab govitecan in research studies. These studies tested different doses of Sacituzumab govitecan to see if it is safe in people with cancer. They also tested Sacituzumab govitecan to see if it worked to treat cancer, and if it did, they tested how well it worked.

STUDY PROCEDURES

There are 3 phases to this study: Screening, Treatment, and Post-treatment. If you join this study, we will do these tests and procedures described below:

SCREENING PROCEDURES

You will have the following tests and procedures to make sure you are eligible to be treated on this study; most of these tests are standard-of-care (routine) and are done regardless of whether or not you decide to be in this study. You will have these procedures within four weeks of starting therapy in this study:

- Transurethral Resection of Bladder Tumor (TURBT) within 12 weeks of starting study treatment. TURBT is a standard surgical procedure that is used to diagnose bladder cancer (and see how deep it goes into the bladder wall) and remove cancer from the bladder. You may have already had this procedure.
- Obtain your medical and surgical history.
- Review all medications you are taking including over-the-counter medicines, vitamins, dietary and herbal supplements.
- Detailed physical exam.
- Obtain vital signs (temperature, pulse, and blood pressure), including your height and weight.
- Evaluate how physically active you are.
- Draw blood samples for screening tests. We will take about 1 tablespoon of blood. We will use your blood sample to test for the following:
    - complete blood count and chemistries
    - to check your thyroid function. The thyroid is a gland located beneath your voice box that helps regulate growth and metabolism.
    - to check your adrenal gland function. Your adrenal glands are located on top of each kidney and help regulate your metabolism, sugar levels and blood pressure. The adrenal glands also help regulate how you respond to stress.
    - blood (serum) pregnancy test for females of childbearing potential. The test must be negative before you can be entered in this study.
- Collect a urine sample for analysis.
- Chest, abdomen, and pelvic CT (Computed Tomography- type of x-ray using computers) scan with intravenous (IV) contrast, if possible, or MRI (Magnetic Resonance Imaging- takes pictures using magnetic rather than x-ray energy) to determine the extent of your disease.
- Perform an EKG (electrocardiogram), which is a test that assesses the electrical function of the heart
- Other routine radiology studies may be needed to assess your cancer if recommended by your doctor.
- We will collect a sample of your tumor tissue during a standard/routine TURBT. If this was performed previously, we will request this tissue. This sample is required for you to take part in this study. A doctor well-trained in diagnosing cancer under the microscope will review the sample before you are registered to the study to make sure there is enough

tumor in the sample. The tumor tissue sample will also be sent to a central lab. Some of the sample will be used to check how your immune system is reacting and the rest will be stored for future research; this will not impact your treatment.

TREATMENT PROCEDURES

If you are eligible to be in this trial, you will start the study treatment. During the treatment period, you will be asked to come to the clinic to receive the study drug (Sacituzumab govitecan). Before receiving each treatment, you will be seen and asked about any new problems that may have occurred since your last visit.

Sacituzumab govitecan is an infusion that will be given over approximately 1-2 hours on the 1st and 8th day of each 21-day study cycle for a total of 3 cycles. Within 2-6 weeks after your last treatment (week 9), you will undergo surgery to remove your bladder and surrounding lymph nodes, which is usual standard of care for patients with bladder cancer that grows into the muscle layer of the bladder wall. Your surgeon will go over your surgical procedure in more detail closer to the date of surgery.

During each of these treatment visits, the following tests, procedures, and assessments will be done:

- A detailed physical exam.
- Vital signs (temperature, pulse, and blood pressure), including weight. These will also be done before and through your infusion.
- Evaluation ofphysical activity.Blood draw (approximately 1 tablespoon). We will use your blood sample to test for the following:
    - complete blood count and chemistries
- On the 1st day of the first and third cycle of treatment, we will collect a research blood sample: 10 mL (approximately 2 teaspoons) of blood will be drawn and stored for future research related to this trial.
- On the 1st day of the first and third cycle of treatment, we will collect urine and stool samples for future research related to this trial.

<u>Prior to Radical Cystectomy with Pelvic Lymph Node Dissection</u>

- Physical exam.
- Vital signs (temperature, respirations, pulse, and blood pressure) including weight.
- Evaluation of physical activity.
- Blood draw (approximately 1 tablespoon). We will use your blood sample to test for the following:
    - complete blood count and chemistries
    - to check your thyroid function.
- Chest, abdomen, and pelvic CT scan (with IV contrast if possible), or MRI to evaluate your disease. This is a standard practice routine test.
- Perform an EKG (electrocardiogram), which is a test that assesses the electrical function of the heart
- Collect blood samples for research: 40 mL (approximately 2¾ tablespoons) of blood will

be drawn. Some of the sample will be used to check how your immune system is reacting and the rest will be stored for future research.
- Collect urine samples for research: 30 mL (approximately 2 tablespoons) of urine will be collected and stored for future research related to this trial.
- Review all medications you are taking including over-the-counter medicines, vitamins, dietary and herbal supplements
- We will monitor for any side effects – you should tell your study doctor immediately if you have new problems or changes at any time if they occur.

End of Treatment (approximately 30 days after radical cystectomy)
- Physical exam.
- Vital signs (temperature, respirations, pulse, and blood pressure) including weight.
- Evaluation of physical activity.
- Blood draw (approximately 1 tablespoon). We will use your blood sample to test for the following:
    - complete blood count and chemistries
    - to check your thyroid function.
- Research samples will be collected for the following:
    - Blood draw: 40 mL (approximately 2¾ tablespoons) of blood will be drawn. Some of the sample will be used to check how your immune system is reacting and the rest will be stored for future research related to this trial.
    - Urine samples: 30 mL (approximately 2 tablespoons) of urine will be collected and stored for future research related to this trial.
- Review all medications you are taking including over-the-counter medicines, vitamins, dietary and herbal supplements.
- We will monitor for any side effects – you should tell your study doctor if you have new problems or changes immediately, at any time if they occur.

Radical Cystectomy with Pelvic Lymph Node Dissection (within 2-6 weeks after last dose of study treatment)
This surgery is standard of care, regardless of the study. Tumor tissue for research will be obtained at the time of your radical cystectomy procedure. The tumor tissue sample will be sent to a central lab. A doctor well-trained in diagnosing cancer under the microscope will review the tumor tissue and some of this tumor tissue will be used for research. If there is no tumor identified in this tissue, we will perform research testing on the normal portion of the tissue. Some of the sample will be used to check how your immune system is reacting and the rest will be stored for future research.

Post-Treatment Procedures (Follow-Up)
Once you are no longer receiving study medication, or if you withdraw from the study at any time, we will follow-up to see how you are doing and ask about any other anti-cancer therapies you may have taken or are taking (either during a routine clinic visit or in a phone call). This will occur approximately every 3-6 months for at least 2 years after your cystectomy or until the study closes (around 3 years).

Afterwards, you will continue to be monitored at regular intervals to make sure that the cancer

does not come back.

Additionally, if your cancer comes back, we would like to obtain:

- Blood samples for research: 40 mL (approximately 2¾ tablespoons) of blood will be drawn. Some of the sample will be used to check how your immune system is reacting and the rest will be stored for future research.
- Urine samples for research: 30 mL (approximately 2 tablespoons) of urine will be collected and stored for future research.
- Stool samples for research that will be stored for future research
- Tumor tissue for research: Tumor tissue obtained after your treatment (by biopsy, fine needle aspirates (FNA), etc.) as part of your normal medical care under the guidance of your doctor. Some of the sample will be used to check how your immune system is reacting and the rest will be stored for future research.

DURATION OF PARTICIPATION

If you join this study, you will receive Sacituzumab govitecan for approximately 9 weeks followed by surgery within 2-6 weeks of your last treatment date. After that, you would have a return visit about one month after your surgery to mark the end of treatment. You will then have follow-up exams or phone calls every 3-6 months (either a routine clinic visits or phone call) for at least 2 years after your cystectomy or until the study closes (approximately 3 years) to check on your health and about any other anti-cancer therapies you may have taken or are taking.

Doctors could take you out of this study at any time. This would happen if:

- They think it is in your best interest not to continue in the study.
- You are not able or willing to follow study procedures.
- The whole study is stopped.

RISKS, STRESS, OR DISCOMFORT

In this part of the consent form, we describe the side effects we expect from the tests and treatments in this study. Sacituzumab govitecan could cause side effects that we do not know about yet. We carefully watch everyone in the study for side effects.

You may experience all, some, or none of the side effects described below. Side effects may be mild or very serious. Medicines could be given to help lessen side effects. Some side effects may not show up until several weeks after treatment is given. Many side effects may go away soon after you stop taking the medications. In some cases, side effects can last a long time or never go away. There is also a risk of death.

There are risks involved with taking Sacituzumab govitecan. You should inform your doctors and other medical staff that you have taken part in this study in your future visits to them.

Seek urgent medical attention if you notice any of the following serious side effects while being given or after you are given Sacituzumab govitecan. Please talk with your Doctor about these adverse reactions.

Very Common Adverse Reaction((≥ 1 in 10 patients experience from clinical studies):

Blood and Lymphatic System Reactions:

- Neutropenia (very common)
    - A condition where you have too few neutrophils, a type of white blood cell, in your blood, resulting in increased risk of infections. These infections can be severe, life-threatening, or deadly. Possible signs and symptoms of neutropenia or infections include:
        - Fever
        - Chills or sweating
        - Sore throat, sores in the mouth, or a toothache
        - Stomach pain
        - Pain near the anus
        - Pain or burning when urinating or urinating often
        - Diarrhea or sores around the anus
        - A cough or shortness of breath
- Anemia (very common)
- Leukopenia (very common)
- Lymphopenia (very common)

Gastrointestinal disorders:

- Diarrhea (very common)
- Nausea and Vomiting (very common)
- Constipation (very common)
- Vomiting (very common)
- Abdominal Pain (very common)

Immune System Reactions:

- Hypersensitivity (very common)

Infections and Infestations:

- Urinary tract infection (very common)

Metabolism and Nutrition Reactions:

- Decreased appetite (very common)
- Hypokalaemia (very common)
- Hypomagnesaemia (very common)
- Hypokalaemia (very common)
- Hypophosphatemia (very common)
- Dehydration (very common)

Respiratory, Thoracic and Mediastinal Reactions:

- Dyspnoea (very common)
- Cough (very common)

Skin and Subcutaneous Tissue Reactions:

- Alopecia (very common)
- Rash (very common)
- Pruritus (very common)

Other Reactions:

- Weight decreased (very common)
- Arthralgia (very common)

- Headache (very common)
- Dizziness (very common)

Common (≥ 1 in 100 patients to < 1 in 10 patients experience from clinical studies):

Blood and Lymphatic System Reactions:

- Thrombocytopenia (common)
- Febrile neutropenia (common)

Gastrointestinal Reactions:

- Stomatitis (common)
- Abdominal Pain Upper (common)
- Dyspepsia (common)
- Abdominal distension (common)
- Gastroesophageal reflux disease (common)
- Colitis (common)
- Neutropenic colitis (common)
    - Neutropenic colitis (inflammation of a part of the large intestine, uncommon) may be associated with infection.

Infections and Infestations:

- Upper respiratory tract infection (common)
- Pneumonia (common)
- Sepsis (common)

Metabolism and Nutrition Reactions:

- Hyponatraemia (common)
- Hyperglycaemia (common)
- Hyponatraemia (common)
- Hypocalcaemia (common)

Respiratory, Thoracic and Mediastinal Reactions:

- Epistaxis (common)
- Rhinorrhoea (common)
- Nasal congestion (common)

Skin and Subcutaneous Tissue Reactions:

- Dry skin (common)
- Rash maculo-papular (common)
- Skin hyperpigmentation (common)
- Dermatitis acneiform (common)

Other Reactions:

- Infusion related reactions (common)
- Blood alkaline phosphatase increased (common)
- Blood lactate dehydrogenase increased (common)
- Activated partial thromboplastin time prolonged (common)
- Insomnia (common)
- Dysgeusia (common)
- Proteinuria (common)
- Hypotension (common)

Uncommon (≥ 1 in 1,000 patients to < 1 in 100 patients experience from clinical studies):

Gastrointestinal Reactions:

- Enteritis (uncommon)

Immune System Reactions:

- Anaphylactic reaction (uncommon)
    - Allergic reactions may cause an itchy rash, throat or tongue swelling, shortness of breath, vomiting, lightheadedness, low blood pressure or death if not promptly treated. Possible signs and symptoms of allergic reactions include:
        - 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

General Reactions and Administration Site Conditions:

- Fatigue (very common)
- Chills (common)
- Pain (common)
    -

Drug Interactions

Sacituzumab govitecan taken in combination with other medicines may be associated with other risks that are unknown at this time. If any physician other than your study doctor prescribes medication for any other condition or you are taking over-the counter medications, vitamins, dietary or herbal supplements, you must inform the study staff.

You may not take certain medications or receive certain medical treatments without the permission of the study staff during the study therapy with Sacituzumab govitecan. This includes other anti-cancer treatments, other medications that can suppress your immune system (such as prednisone) and live vaccines. Ask your medical team about any new medication or supplements.

Other Risks and Discomforts

The risks of having blood drawn and/or inserting the needle in your vein include fainting, bleeding, bruising at the place on your arm where the blood was drawn or needle inserted, pain, swelling, and rarely can cause infection or nerve damage. However, blood work is standard during therapy regardless of the study.

Radiation Risks

Some of the tests that you will have in this research study will expose you to radiation; however, these tests would occur anyway as standard of care regardless of the study.

Everyone receives a small amount of radiation every day called “background radiation.” This radiation is natural and comes from space, air, water, soil, and the food you eat.

Each year you are exposed to about 3 millisieverts (mSv) of this background radiation. A

millisievert is a unit of radiation dose.

There is minimal risk to your health from the amount of radiation you will receive in this study (these tests would occur anyway as standard of care regardless of the study). The usual lifetime risk of getting cancer is 42%. For every 10 mSv you receive, your risk may increase 0.1%. If you have more procedures that expose you to radiation, your risk will go up. For comparison, the estimated radiation dose from each of these tests is listed below:

- CT chest: 7 mSv
- CT abdomen: 8 mSv
- CT pelvis: 6 mSv

Reproductive Risks
Taking the study drugs (Sacituzumab govitecan) during pregnancy may involve unknown risks to an embryo fetus (unborn baby) or nursing infant. Therefore, you could not join this study if you are pregnant, if you are planning to become pregnant during treatment and within 6 months after the last dose of study treatment, or if you are breast feeding.

If you join this study, you will have to use an effective method of birth control from the time this form is signed until at least 6 months after the last dose of Sacituzumab govitecan. If you are already using a method of birth control, you would have to check with the study doctor or a member of the study staff to make sure it is acceptable.

If you became pregnant after joining this study, you would have to notify the study doctor immediately. Participation in this study would end, and you would receive counseling and follow up throughout the pregnancy and for some time after the child is born.

The effects of the study drugs (Sacituzumab govitecan) on fathering a child are also unknown. Men who join this study must also agree to use one or more forms of effective and acceptable birth control from the time this form is signed until at least 6 months after last dose of the medication.

Tumor Biopsy
TURBT is standard routine care and may be repeated as clinically indicated, for example, to ensure that there is adequate information for the diagnosis, to assess the extent/depth of the cancer, and to ensure there is adequate tumor content in the sample.

ALTERNATIVES TO TAKING PART IN THIS STUDY

You do not have to join this study. You are free to say “yes” or “no”. Your regular medical care would not change if you decide to say “no”.

You have other choices for treatment. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about these choices.

Other choices include:

- Standard therapy which may include other FDA-approved available therapies for your

cancer, such as cisplatin-based chemotherapy with aMVAC or gemcitabine and cisplatin followed by radical cystectomy (surgery to remove your bladder)
- Radical cystectomy without systemic therapy
- TURBT, chemotherapy with radiation.
- Taking part in another research study.
- Surveillance with TURBTs or close observation with no therapy, also called "watch and wait" approach if you don't want treatment at this time after talking it over with your doctor.
- No therapy with care to help you feel more comfortable if you don't want any treatment at all despite discussion with your doctor.

Enrollment in this study may exclude you from most other research studies.

BENEFITS OF THE STUDY

We are studying Sacituzumab govitecan to find out if it works for your type of cancer given prior to surgery. We want to find out if using Sacituzumab works better or worse than the standard treatment for your type of cancer (non-urothelial bladder cancer). We also want to learn more about the side effects. You might get better if you receive Sacituzumab govitecan, but your condition could stay the same or even get worse. We hope the information from this study will help other people with non-urothelial bladder cancer in the future.

SOURCE OF FUNDING

Gilead Sciences., Inc and their agents will be funding this study.

CONFIDENTIALITY OF RESEARCH INFORMATION

If you join this study, some people or organizations might need to look at your medical records and research records for quality assurance or data analysis. They include:
- Gilead., Inc. (the funder of the study) and their agents.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Center and University of Washington research staff.
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, Food and Drug Administration, and other regulatory agencies as required.

We will do our best to keep personal information strictly confidential, but we cannot guarantee total confidentiality. Personal information may be given out if required by law. For example, workplace safety rules may require health workers to contact you about lab tests. Or a court may order study information to be disclosed. Such cases are very rare.

We will not use personal information in any reports about this study, such as journal articles or presentations at scientific meetings.
If you join this study, information about your participation would be made part of your

permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

USE OF INFORMATION AND SPECIMENS

Your information and samples (such as blood, urine, stool, and tumor tissue) will be used for the purposes of this study.

If you withdraw from the study for any reason, previously collected information would remain in the study records and would be included in the analysis of results. This information could not be removed from the study records.

Your tumor tissue sample from the standard/routine TURBT (mentioned above) are required for you to take part in this research study. Tumor tissue samples will also be obtained at the time of your standard/routine radical cystectomy.

Additionally, we would like to receive samples of tumor tissue obtained after your treatment (by biopsy, fine needle aspirates [FNA], etc.) if the cancer comes back as part of your normal medical care under the guidance of your doctor.

You must also be willing to provide research blood, urine, and stool samples to participate in this research study.

RETURNING RESULTS TO YOU

Your samples might help researchers develop new products or learn more about this cancer. This research will be done by scientists in our institutions but part of it could potentially be done by for-profit companies. There is no plan to share with you any revenue generated from products developed using your samples. During this study, if the researchers learn new information that may be important to your general health or your disease or condition, they are not obliged to share that information with you.

USING YOUR DATA IN FUTURE RESEARCH

After we do tests on tissue in this study, some tissue may be left over. We invite you to donate this leftover tissue for future research studies related to this trial. This may include genetic research. We also would like to use your information for future research studies related to this trial.

If you join this study, you will not have to donate tissue or information for future research. You would be free to say “yes” or “no.” Regular medical care would not change if you say “no.” If you say “no,” your tissue and information (even if made anonymous) will not be used in any future research.

If you donate tissue and information, it would be stored in a secure location. If we want to use

your tissue for other research studies related to this trial or share it with other scientists for research related to this trial, an ethics review committee (IRB) would review the request. The IRB would decide if we need to ask you for permission to do the research.

Your donated tissue and information would be used only for research related to this trial. This research could be done by for-profit companies. Researchers would not report their results to you or your doctors. The research results would not be included in medical records. The results would not affect your medical care.

Research with tissue and information might help develop new products. If these products make money, there is no plan to share the money with the participants who donate the tissue.

If you donate tissue and information for research, you could withdraw the donation at any time by calling Dr. Grivas at 206-606-7416. You would have no penalty for withdrawing the donation, and regular medical care would not change. We could not return donated tissue to you or your doctor, but we might be able to destroy the donated tissue. We could not destroy tissue if it is stored or shared without any label saying who donated it. In this case, it could still be used for research.

Would you like to donate your tissue for future research? *(Initial One:)* **Yes:_____ No:_____**

GENETIC SEQUENCING

Your samples contain DNA and RNA. DNA and RNA make up the genes that serve as the "instruction book" for the cells in our bodies. By studying genes, researchers can learn more about diseases, such as cancer. There are many different types of genetic tests. The testing on your samples might include genetic testing called whole genome sequencing. Whole genome sequencing looks at all the genetic information in your cells. This type of testing can provide very useful information to researchers. It can also present rare risks if the test results became known to others, for example you could have implications with family members or insurance companies, but this could be extremely rare. There is also a risk that these test results could be combined with other genetic information to identify you, but this could be extremely rare.

GENOMIC DATA SHARING

A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect genetic information about people who join research studies.

GINA restricts access to genetic information so that it cannot be used for health insurance coverage decisions. GINA prevent health insurance companies or group health plans from

- Asking for genetic information obtained in research studies, or
- Using genetic information when making decisions regarding your eligibility or premiums

GINA *does not* help or protect against genetic discrimination by companies that sell life, disability, or long-term care insurance. However, there is no plan to have genetic information derived from study research procedure as part of your medical record.

COMPENSATION FOR PARTICIPATION

There is no payment for being in this study.

WOULD YOU HAVE EXTRA COSTS IF YOU JOIN THIS STUDY?

If you join this study, you will potentially have some extra costs. Your insurance company usually pay these costs, but some insurance policies do not cover these costs. We could help find out whether your insurance company would cover these costs.

The extra costs are:

- Cost of tests that are given more often than usual.
- Cost of standard doctor visits and lab tests.
- Cost of any other medical care needed because of this study.

If you join this study, you or your insurance company would have to pay for the costs of standard/routine treatment in this study.

You would **not** be billed for:

- Study drug, Sacituzumab govitecan
- Submission and storage of tumor samples obtained from TURBT or surgery
- Submission and storage of tumor samples obtained at time of your radical cystectomy and at any time during your follow-up
- Collection and storage of research blood samples
- Collection and storage of research urine samples
- Collection and storage of research stool samples

RESEARCH-RELATED INJURY

For a life-threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact Dr. Petros Grivas at 206.606.7416. They will treat you or refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You will not lose any legal right to seek payment for treatment if you sign this form.

YOUR RIGHTS

- You do not have to join this study. You are free to say "yes" or "no".
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. For example, some information may affect your health or well-being. Other information might make you change your mind about being in this study. If we learn these kinds of information, we will tell you.
- If you join this study, you will not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.
- If you decide to drop out, we will want you to tell the study doctor. The doctor could tell you about the effects of Sacituzumab govitecan. You and the doctor could talk about the follow-up care and testing that would help the most.
- Before you leave the study, the doctor might ask you to continue in on the same imaging schedule used while on treatment to monitor disease status until the start of a new anticancer treatment, disease progression, pregnancy, death, withdrawal of consent, or the end of the study, whichever occurs first.

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.

YOUR RESPONSIBILITIES

If you join this study, you will have some responsibilities.

- Follow the schedule of all study visits and procedures.
- Prevent pregnancy and breastfeeding.
- Tell us about side effects, new problems, medications, and changes.
- Attend scheduled study visits.

FOR MORE INFORMATION

If you have questions or concerns about this study, you could talk to your doctor anytime. Other people you could talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	206-606-7416 (Dr. Petros Grivas)

If you get sick or hurt in this study	206-606-7416 (Dr. Petros Grivas)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center) 206-543-0098 (Human Subjects Division, University of Washington)
Your bills and health insurance coverage	206-598-8260 (UWMC Patient Financial Services) 206-606-1091 (SCCA Patient Financial Services)

Emergency Number (24 hours): (206) 598 - 6190

SIGNATURES

Please sign below if you:

- have read this form (or had it read to you).
- had the opportunity to ask any questions you have.
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant (age 18+):

_____	_____	_____
Printed Name	Signature	Date

If you served as an interpreter or witness during the consent process, sign below to indicate you attest to the accuracy of the presentation to the participant and the apparent understanding of the research by the participant.

Witness or Interpreter:

_____	_____	_____
Printed Name	Signature	Date

Researcher's Statement
I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

_____	_____	_____
Printed Name	Signature	Date

Protocol version: 1.05
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Copies to: