PROVIDENCE Cancer Institute

EARLE A. CHILES RESEARCH INSTITUTE

INFORMED CONSENT FOR A RESEARCH STUDY

TITLE:	Randomized Double-Blind Placebo Controlled Phase II Study of a Galectin-3 Inhibitor (GB1211) and Pembrolizumab Versus Pembrolizumab and Placebo in Patients with Metastatic Melanoma and Head and Neck Squamous Cell Carcinoma (PSJH IRB STUDY2023000353)
PROTOCOL NO.:	2023000353
SPONSOR:	Earle A. Chiles Research Institute
PRINCIPAL INVESTIGATOR:	Brendan Curti, MD
INSTITUTIONS:	Providence Cancer Institute – Franz Clinic 4805 NE Glisan Street Suite 11N Portland, OR 97213
STUDY-RELATED PHONE NUMBER(S), DAYTIME and AFTER HOURS:	(503) 215-5696

INTRODUCTION AND PURPOSE

You are being asked to take part in this research study because you have either melanoma, or head and neck squamous cell carcinoma that has worsened after treatment. This consent form will explain this study to you, and what you need to do if you take part. Make sure you understand what is written and ask as many questions as needed before you decide whether to take part. After this study has been explained to you, and if you choose to take part, you will be asked to sign this consent form.

A standard treatment for your cancer includes a drug called pembrolizumab. Pembrolizumab, also called Keytruda™, is approved by the U.S. Food and Drug Administration (FDA) for the treatment of metastatic melanoma, non-small cell lung cancer, and head and neck cancer in patients whose cancer has worsened after receiving other treatments. This study includes pembrolizumab and an investigational drug (not approved by the FDA) called GB1211. GB1211 is an inhibitor that can block a protein known as galectin-3. We hope that blocking the protein may improve the chances that your cancer will not grow. Galectin-3 is made by some cancer cells to help the cancer cells grow.

All participants in this study will receive the standard treatment of pembrolizumab. Half of the participants will receive GB1211 in addition to pembrolizumab while the other half will receive a placebo (an inactive substance that does not treat your cancer) in addition to pembrolizumab. Your treatment will be assigned randomly (like the flip of a coin), and neither you nor your doctor will get to choose or know which combination you are assigned to receive.

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The purpose of this study is to see if this combination of drugs is safe and helps to treat your cancer. During this study, blood samples and tumor samples will be collected to see how your immune system responds to the drugs.

Up to 94 people will take part in this study.

STUDY PROCEDURES
If you decide to join this study, you will come in for the screening visit. At the screening visit, the following tests and procedures will be done to see if you meet the study criteria:

- Medical history
- Physical exam
- Vital signs will be measured (heart rate, breathing rate, temperature, and blood pressure)
- Weight will be measured
- Routine blood tests for a blood cell count, chemistries (including blood tests to check your liver and kidney), thyroid function, and how well your blood clots
- Blood test to measure hormones in your blood (including testosterone if you are a male, Follicle stimulation hormone / luteinizing hormone (FSH/LH), and adrenocorticotropic hormone (ACTH), and Cortisol)
- Pregnancy test if you are a female. You cannot participate in this study if you are pregnant.
- A single electrocardiogram (ECG) to check the electrical activity of your heart
- A CT scan of your chest, abdomen, and pelvis
- An MRI of your brain
- An optional (not required) biopsy will be collected if it can be performed safely and you agree to it. The biopsy sample will be used to study your immune system's response to the study treatment. Your study doctor will discuss with you the type and location from where the biopsy will be taken.

If these tests and exams show you can be in this study and you agree to it, you will begin the study treatment.

STUDY TREATMENT
The study treatment is given in 21-day periods (or 3 weeks) called a cycle. Pembrolizumab will be given as an intravenous (IV) infusion (given into a vein) over 30 minutes on Day 1 of each cycle, 30 minutes after GB1211/placebo has been taken. GB1211/placebo is taken orally (capsules that you will swallow). You will take 2 capsules twice daily (e.g., at breakfast and dinner), every day of your treatment cycles. The capsules should be taken with water and a meal.

You may receive up to 17 cycles of GB1211/placebo followed by pembrolizumab infusion over 1 year unless your cancer worsens or your study doctor thinks you no longer benefit from it. If you are still getting benefit after 1 year of therapy, your physician can request an extension of GB-1211/placebo supply from the sponsor. Other treatment options to treat your cancer, including continuation of pembrolizumab alone, will be discussed with you.

If your cancer worsens, the study treatment will be stopped, however, you will be contacted every twelve weeks for follow-up. The study staff will keep track of your health status for the rest of your life either by contacting you or by review of your medical records.

You will have the same tests and procedures done during the Treatment and Follow-Up Periods as were done at your Screening visit. See the study calendar on the next page for when the tests and procedures will be performed.

The table below shows the tests and exams that are done during this study:

Study Days	Screening	Cycle 1		Cycle 2	Cycle 3	Cycle 4		Cycle 5	Subsequent Cycles every 3 weeks
		Day 1	Day 4	Day 1	Day 1	Day 1	Day 4	Day 1	
Medical history	X	X		X	X	X		X	X
Physical exam	X	X		X	X	X		X	X
Review of side effects		X	X	X	X	X	X	X	X
Review of medications	X	X	X	X	X	X	X	X	X
Vital signs, weight	X	X	X	X	X	X		X	X
Routine blood tests[1]	X	X	X	X	X	X		X	X
Blood for immunologic monitoring		X		X	X	X		X	X[2]
Blood for pharmacokinetic monitoring		X[3]		X[3]	X[3]	X[3]		X[3]	
Pregnancy test[4]	X	X			X				X
ECG	X								
CT Scan	X[5]							X[5]	X[5,6]
Brain MRI	X								
Optional tumor biopsy	X					X			

1. Routine blood tests include blood counts, blood chemistry, and hormone levels (not all types of these routine tests are done at each timepoint).
2. Immunologic blood tests are every 12 weeks.
3. One sample will be collected anytime before GB1211 dose.
4. Required for participants able to become pregnant.
5. Other imaging to assess tumor status may be performed at the discretion of your study doctor.
6. After Cycle 5, CT scans will be performed every 12 weeks while on study treatment and in follow up until disease worsens.

Follow Up Period
After you stop receiving study treatment, you will have follow-up visits every 12 weeks for one year. These visits will be in the clinic and will involve routine tests and procedures for your cancer. After one year, you will have check-ups at whatever frequency your doctor decides is appropriate.

If your cancer progresses, your participation in this study will end and your ongoing care will be

determined by your doctor. In addition, the study staff will keep track of your health status for the rest of your life either by contacting you or by review of your medical record.

Blood for Research Tests

Immunologic Monitoring
Blood will be collected to examine your immune systems response to treatment. At each timepoint, 60 mL (4 tablespoons) of blood will be collected.

Pharmacokinetic Blood Sampling
Blood will be collected to study how your body interacts with the study drug. At each timepoint, 6 mL (1 teaspoon) of blood will be collected.

Future Research on Biological Samples (OPTIONAL – NOT REQUIRED)
Blood and other tissue will be used in future research tests. The tests are experimental, and the goals of the tests and types of tests may change over time. The general goal of these tests is to learn more about cancer and improve ways of treating cancer.

Your blood and tissue will be frozen and stored indefinitely in a laboratory at the Earle A. Chiles Research Institute. Your sample(s) may be shared with other researchers outside the Earle A. Chiles Research Institute. If your sample(s) is shared with outside researchers, it will be labeled with a code number before it is shared. No personal identifiers (e.g., your name, social security number) will be included with the sample, so the outside researchers will not know who you are. However, outside researchers will be given clinical information (e.g., your diagnosis and previous treatments) and demographic information (e.g., age, gender, race) about you.

Research staff at the Earle A. Chiles Research Institute may also want to contact you in the future to ask if you are willing to donate other biological samples. At the end of this consent form, you will choose whether you agree to be contacted in the future.

POSSIBLE RISKS
There are risks to you if you take part in this study. The treatment used in this study may cause all, some or none of the side effects listed below. In addition, unknown side effects may occur, including possible interaction with other medication you may be taking. Most side effects go away after the study treatment is stopped; however, some may be serious, permanent, or even cause death. If you have any side effects, report them to your study doctor or the research staff.

GB1211 Risks
This is one of the first studies of GB1211 in cancer patients and the first one to look at the combination of GB1211 and pembrolizumab. Therefore, the potential side effects are unknown.

In a study of healthy participants, the following mild side effects were seen in at least 6 and fewer than 9 people:

- Headache
- Difficulty Swallowing
- Constipation
- Diarrhea
- Abdominal distention
- Upper abdominal pain
- Rash

- Increased frequency of urination
- Pain with urination
- Irregular menstrual cycles

In a study of patients with fatty liver disease (not cancer), the following mild side effects have been seen in patients receiving GB1211 or placebo, but this study is ongoing:

- Reduced number of red blood cells (anemia) that may cause you to feel tired or weak or have abnormal lab values and may or may not require transfusion
- Skin itching

In animal studies, at very high doses, the following risks were seen:

- Decreased number of white blood cells that may increase the risk of infection.
- Decreased number of red blood cells (anemia) that may cause fatigue, weakness, and may require blood transfusion(s).

There is always a risk of an allergic reaction when receiving a new medication such as this study drug. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Hives
- Rash
- Fever
- Wheezing and difficulty breathing
- Low blood pressure that may cause dizziness, lightheadedness, nausea, shallow breathing, and cold, clammy, and pale skin
- Dizziness and fainting
- Swelling around the mouth, throat, or eyes
- Fast pulse
- Sweating

The study drug will be stopped immediately if you are having an allergic reaction and you will be treated by the study doctor or study staff. The study drug may also be permanently stopped and you will no longer receive the study drug. If this happens, you will be asked to stay in the clinic for completion of study-related procedures and tests.

Pembrolizumab

Pembrolizumab works by helping your immune system to fight your cancer. However, pembrolizumab can also cause your immune system to attach normal organs and tissues in your body and can affect the way they work. This can result in side effects. These side effects may be serious (i.e., causing hospitalization or be life-threatening), may result in death and/or may occur after you stop taking pembrolizumab. These side effects can affect more than one of your normal organs and tissues at the same time. Not enough information is known about some side effects to determine whether they may be temporary or permanent.

VERY COMMON (may occur in 20 or more people out of 100):

- Itching of the skin
- Loose or watery stools
- Cough

COMMON (may occur in at least 5 but fewer than 20 people out of 100):

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- Joint pain
- Fever
- Back pain
- Rash
- Pain in your belly
- Loss of skin color
- Not enough thyroid hormone, so you may feel tired, gain weight, feel cold, or have infrequent or hard stools (hypothyroidism)
- Low levels of salt in the blood that may cause you to feel tired, feel confused, have a headache, have muscle cramps, and/or feel sick to your stomach (hyponatremia)

UNCOMMON (may occur in 1 to fewer than 5 people out of 100):

- Inflammation of the lungs, so you may feel short of breath and cough (pneumonitis)
- Too much thyroid hormone, so you may feel anxious, feel angry, have trouble sleeping, feel weak, tremble, sweat, feel tired, have loose and watery stools (hyperthyroidism)
- Infusion reaction, where you may feel dizzy or faint, feel flushed, get a rash, have a fever, feel short of breath, experience a decrease in your blood pressure during your infusion (IV) or just after, or have pain at the site of infusion
- Inflammation of the bowels/gut, which may cause severe pain in your belly with loose or watery stools, and black, tarry, sticky stools or stools with blood or mucus (colitis)
- Inflammation of the skin which may include peeling of the skin, itchiness, and/or skin redness. The skin inflammation (i.e., peeling, itching and redness) could also be widespread throughout your body. More severe skin reactions may involve the inside of your mouth, the surface of your eye and genital areas, and/or may cause the top layer of your skin to peel from all over your body which can cause severe infection. (Severe skin reactions, including Stevens-Johnson syndrome/or toxic epidermal necrolysis. Stevens-Johnson syndrome is a group of symptoms that includes a painful blister-like rash, fever, inflamed eyes (redness and swelling), and painful sores on lips and in mouth. The symptoms may be severe enough to require hospitalization. Toxic epidermal necrolysis is a potentially fatal disease characterized by blistering and peeling of the top layer of skin resembling that of a severe burn.)

RARE (may occur in fewer than 1 person out of 100):

- Inflammation of the nerves that may cause pain, weakness, or tingling in your hands and feet, and may spread to your legs, arms, and upper body leading to severe muscle weakness and possible temporary paralysis (Guillain-Barré syndrome)
- Inflammation of the muscles, so you may feel weak or have pain in your muscles (myositis)
- Inflammation of the pancreas (a gland in your abdomen that controls sugar levels), so you may have severe pain in the top part of your belly that may move to your back, feel sick to your stomach, and have vomiting that gets worse when you eat (pancreatitis)
- Inflammation of the eye, so you may have eye redness, blurred vision, sensitivity to light, eye pain, see floaters, or have headaches (uveitis)
- Inflammation of the liver that may make you feel sick to your stomach and vomit, feel like not eating, feel tired, have a mild fever, pain in the right side of your belly, yellow eyes and skin, and dark urine (hepatitis)
- Inflammation of the pituitary gland (a gland in the brain), which may cause you to feel sick to your stomach or have headaches, changes in your behavior, double vision, few to no menstrual cycles, weakness, vomiting and dizziness, or fainting (hypophysitis)
- Adrenal glands (glands on top of the kidneys) that may not make enough hormone, which could

cause tiredness, weight loss, muscle weakness, feeling faint, having joint, muscle, and bellyaches, nausea, vomiting, loose or watery stools, fever, salt craving, and sometimes darkening of the skin like a suntan (adrenal insufficiency)

- Type 1 diabetes, a condition that can cause too much sugar in your blood, feeling thirstier than usual, frequent urination, and weight loss. You are likely to need regular insulin shots.
- Inflammation of the kidney, so you may pass less urine or have cloudy or bloody urine, swelling, and low back pain (nephritis)
- Inflammation of the middle layer of your heart wall that may cause your heart to have difficulty pumping blood throughout your body, which can cause chest pain, shortness of breath, and swelling of the legs. You may experience a fast or irregular heartbeat that may cause dizziness or fainting. (myocarditis)
- Inflammation of the thyroid gland, an organ that makes and stores thyroid hormones. This condition may lead to change in your heart rate, blood pressure, body temperature, and the rate at which food is converted into energy. (thyroiditis)
- A condition called Myasthenia Syndrome that may make you feel weak and tired and may cause drooping of the eyelids, blurred or double vision, difficulty swallowing, slurred speech, weakness in your arms and legs, or difficulty breathing (myasthenic syndrome/myasthenia gravis including exacerbation)
- The formation of small clusters of immune cells (called granulomas) in parts of your body such as your lymph nodes, eyes, skin, or lungs, called Sarcoidosis (sarcoidosis)
- Inflammation of the brain which may cause confusion, fever, disorientation, memory problems, seizures (fits), changes in personality and behavior, difficulty speaking, weakness or loss of movement in some parts of your body, and loss of consciousness (encephalitis)
- Inflammation of the spinal cord with pain, numbness, tingling, or weakness in the arms or legs, bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating, and constipation (myelitis)
- Inflammation of the blood vessels (vasculitis). Symptoms will depend on the particular blood vessels that are involved in the inflammatory process. For example, if it is your skin, you may get a rash. If your nerves are not getting enough blood, you could have numbness and weakness. You may also experience fever, weight loss, and fatigue.
- Low levels of parathyroid hormone (a hormone made by 4 tiny glands in your neck), which may result in low blood calcium and cause muscle cramps or spasms; fatigue or weakness; numbness, tingling, or burning in your fingertips, toes, or lips (hypoparathyroidism)
- Inflammation of the stomach (gastritis). You may have pain in your belly, feel full, or sick to your stomach. You may also experience nausea, vomiting or loss of appetite.
- Low number of red blood cells (cells that carry oxygen) due to destruction of red blood cells (hemolytic anemia). You may feel weak, tired, lightheaded, short of breath, or have a fast heartbeat. You may also experience difficulty with physical exercise, pale or yellow skin, dark urine, or fever.
- Not enough pancreatic enzymes (proteins that break down food) that leads to poor digestion of food (exocrine pancreatic insufficiency). You may have bloating, gas, discomfort in your belly, diarrhea, abnormal stool that is oily, or weight loss.

Additionally, since pembrolizumab was first FDA-approved for certain cancers in September 2014, the following side effects have been reported by people receiving pembrolizumab. These side effects were voluntarily reported from individual patients. It is not possible to estimate how often each side effect occurred:

- Inflammation of the joints which may include joint pain, stiffness and/or swelling (arthritis)

- Severe responses of the immune system that cause the body to attack its own blood cells, spleen, liver, lymph nodes, skin and brain. Symptoms will vary depending on the body part involved, but may include fever, rash, inflammation of the liver, yellowing of the skin, an enlarged liver and spleen, low blood counts, and enlarged lymph nodes. The nervous system may also be affected and cause confusion, seizures, and even coma. (hemophagocytic lymphohistiocytosis)
- Changes in eyesight, eye pain, whitish patches on the skin and hearing loss (Vogt-Koyanagi-Harada syndrome)
- Inflammation and scarring of the bile ducts (tubes that carry digestive fluid that is made in the liver). This can cause symptoms similar to those seen with inflammation of the liver (hepatitis), such as pain in the right side of your belly, yellow eyes and skin, feeling tired, and itching (sclerosing cholangitis).
- Inflammation or swelling of the nerve fibers of the eye, which send visual information from your eye to your brain. This health condition often has a sudden onset of vision loss, loss of color vision, pain when moving your eyes, and/or loss of peripheral vision. It may affect one or both eyes at the same time (optic neuritis).

Tumor Biopsy

A biopsy is a procedure where a sample of your tumor is removed. In most cases, this is done through a needle; occasionally this is done during a surgical procedure. There may be some temporary pain or discomfort associated with this routine procedure. After the biopsy procedure(s), there may be slight pain, redness, swelling, bleeding, bruising, and/or drainage at the site that usually goes away in a few days. Rarely, abnormal wound healing, fever, infection, or allergic reaction to the numbing medicine may happen. Your doctor will give you a separate consent form for this procedure.

PREGNANCY/NEW FATHER WARNING

If you are pregnant or breastfeeding, you cannot take part in this study. The risks of the study treatment to an unborn baby or nursing child are not known and may cause harm. If you are a woman able to become pregnant, you will be required to have a blood and/or urine pregnancy test to see if you are pregnant before you begin this study treatment.

Because the study drug may be dangerous for unborn children, if you are sexually active, you must take adequate precautions to avoid the possibility of becoming pregnant or fathering a child while in this study and until at least 5 months after the last dose of study treatment. Male participants must also refrain from donating sperm while in this study and until at least 5 months after the last dose of study treatment. You must discuss these precautions with your study doctor before agreeing to take part in this study.

If you become pregnant, or your partner becomes pregnant during this study, you should tell your study doctor immediately. If you become pregnant, you will no longer be given the study treatment. If you or your partner becomes pregnant and agree, your study doctor will collect information about the pregnancy, the outcome of the pregnancy, and the health of your baby for 6 months after birth.

After you complete this study treatment, check with your study doctor to see when it might be safe to breastfeed, become pregnant, or become a new father.

POSSIBLE BENEFITS

There are no guaranteed benefits to you for taking part in this study. This study treatment may even harm you. However, if effective, this study treatment may be active against your cancer, slow the growth of your tumor, or prolong your life.

The information learned from this study will help researchers learn more about GB1211 and pembrolizumab and may help future patients.

OTHER TREATMENTS
You may choose not to take part in this study. Other treatments available to you include:

- Standard treatment(s) with pembrolizumab
- Other research study treatments, if available
- No treatment
- Supportive care to manage your symptoms and help make you comfortable

Your study doctor will review these with you before you decide to take part in this study.

GENERAL INFORMATION
Agreeing to take part in this study is voluntary. Your refusal to take part will not affect the health care benefits you have. If you decide to take part, you are free to stop at any time, including the follow-up portion, without any effect on your medical care, your relationship with your doctor(s) or Providence Health & Services.

While in this study, any important new information that may affect your wish to continue taking part will be given to you.

Your study doctor may remove you from this study at any time if he/she thinks it is medically necessary, you have a serious side effect, or you do not follow the study plan. In addition, the FDA or Providence St. Joseph Health IRB may end this study at any time. If you stop the study, your study doctor or one of the study staff will talk to you about any medical and/or safety concern.

COSTS
You will not be paid to take part in this study.

You or your health insurer will pay for all routine health care you receive during the study. The sponsor of the study will pay for the study drug, GB1211. The sponsor will pay for items and services that are done only for the purpose of research.

If you have any questions, please speak with your study coordinator and/or a financial coordinator or your health insurer.

CONFLICT OF INTEREST
Providence Health & Services may benefit financially if GB1211 were to become approved by the FDA as a cancer treatment. Your study doctor does not believe that this affects how this study is conducted, or the results. If you have concerns, you should discuss this with your study doctor, or you may contact the Providence St. Joseph Health Human Research Protection Program Office at IRBsharedservices@providence.org or 425-525-3003.

You will not benefit financially if this study results in new treatments.

LIABILITY
If you are injured or become ill as a result of taking part in this study, you should contact your study doctor. All of the necessary medical facilities are available for treatment, as is reasonably possible.

In the event you suffer a research related injury, the costs will be your or your insurance's responsibility, but you are not prevented from seeking compensation for injuries related to malpractice, fault, or blame on the part of those involved in the research.

Providence Health & Services has no plans to pay for the treatment of the normal progress of your disease, or any injury or complication due to the medical condition(s) you already have. You or your health insurance company will be charged for those costs, if any.

Providence Health & Services has no plans to provide any other kind of compensation such as compensation for lost wages, disability, or discomfort.

You do not give up any of your legal rights by signing and dating this consent form and taking part in this study.

PRIVACY
The Health Insurance Portability and Accountability Act of 1996 (HIPAA) gives you certain rights to protect the privacy of your medical information and records. Under HIPAA, you must give your permission before anyone uses or shares your medical information. This information is also called protected health information (PHI). Examples of PHI are your name, address, telephone number, date of birth, past medical records, and the results of tests and procedures done during this study.

The sponsor and your study doctor(s) will need to use your PHI for this study. Your study information is protected using a subject identification number, which is a number specific to you. Only a unique subject identification number for the study will link the data or samples to you.

At the end of this form there is an authorization section that requires your signature to allow members of the study team at Providence Health & Services and The Providence St. Joseph Health Human Research Protection Program (HRPP) to have access to your health records.

If you have questions about your privacy rights, please call the Providence St. Joseph Health HIPAA Privacy Officer at 425-525-5429.

QUESTIONS
Any questions you have about this research study or a research-related injury can be answered by:

Study Doctor: _____ at _____

Study Nurse: _____ at _____

If you have any questions about your rights while participating in this study, or if you have any concerns regarding the conduct of this study, you may also contact the Providence St. Joseph Health Human Research Protection Program Office at IRBSharedServices@providence.org or 425-525-3003.

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.

You are free to ask questions about this study at any time.

CONSENT

I have read, or have had read to me, all of the above, asked questions and received satisfactory answers about what I did not understand. I agree to take part in this research study. I will be given a signed copy of this consent form for my records.

Optional (Not Required) Procedures:
Please circle your choice and initial next to each.

1. My specimens and data may be kept for use in future research to learn about, prevent, or treat cancer.

   Yes No Initials _____

2. My specimens and data may be kept for use in future research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

   Yes No Initials _____

3. Someone may contact me in the future to ask permission to use my specimen(s) and data in new research not included in this consent.

   Yes No Initials _____

Participant (*Print name*):	
Signature:	**Date:**

Name of Person Obtaining Consent (*Print name*):	
Signature:	**Date:**

If this consent form is read to the participant because the participant is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement: *I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood, by the participant. The participant freely consented to participate in the research study.*	
Name of Impartial Witness (*Print name*):	
Signature:	**Date:**

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AUTHORIZATION FOR USE AND/OR DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

What is the purpose of this form?
This Authorization gives you information about how your Protected Health Information (PHI) may be used and disclosed to others as part of the research study, and who may disclose and receive your health information. State and federal privacy laws protect the use and release of your health information. Under these laws, Providence St. Joseph Health (PSJH) cannot release your PHI to the research team unless you give your permission. If you decide to give your permission and to participate in the study, you must sign this form as well as the consent form. By signing this document, you agree to the release of certain PHI by PSJH, your study doctor, and research team.

What Protected Health Information will be released?
If you give your permission and sign this form, you are allowing PSJH to release the health information collected during this research study and from your hospital records that may be reasonably related to the conduct and oversight of the study. Your PHI includes health information in your medical records and information that could personally identify you. For example, PHI may include your name, address, phone number, medical record number or social security number.

Possible Disclosures
Researchers can only use and disclose your health information as described in the consent form or as required by law or regulations and will continue to protect your personally identifiable health information as described in the consent form. The information may be subject to re-disclosure and the HIPAA Privacy Rule may not apply in those circumstances. PSJH complies with the requirements of the HIPAA Privacy Rule and its privacy regulations, and with all other applicable laws that protect the confidentiality of your health information.

How will my Protected Health Information be used?
Information that is recorded about you may be sent to the sponsor of the research study and members of the research team by your study doctor. Information recorded about you may also be released to the following agencies and companies for purposes of study oversight such as:

- Federal government regulatory agencies, including the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP)
- The Institutional Review Board (IRB) that reviewed the study
- The PSJH Human Research Protection Program (HRPP), an office responsible for ensuring the protection of the rights and welfare of research participants
- Individuals supporting the conduct of this study at Providence Health & Services
- Representatives of Galecto Biotech AB
- LabCorp, a central laboratory, for analysis of your pharmacokinetic samples

Information recorded about you may be used for the research purposes described in the consent form, including activities of the research sponsor, or other agencies as required by law. If applicable, your information will be disclosed to your insurance carrier for purposes of obtaining authorization for payment and for processing payment of claims related to this research. However, once your health information is released it may not be protected by the privacy laws and might be shared with others. If you have questions, ask your study doctor or a member of the research team.

Does my authorization expire?
This permission to release your PHI expires after 50 years from the date of your signature, or when the research ends, whichever is sooner.

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Can I revoke my authorization?
You can change your mind at any time and revoke your authorization to allow your PHI to be used in the research. Beginning on the date you revoke your authorization, no new PHI will be used for research. However, researchers will continue to use the health information that was provided before you withdrew your permission. Your authorization may be revoked in writing or through a verbal request made to and documented by your study doctor or a member of the research team. Write to your study doctor or inform a member of the research team that you would like to revoke your authorization. If you revoke your authorization, you may no longer be in the research study. Also, if the law requires it, the research sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

If you agree to the use and release of your PHI, please sign below. If you do not agree to the release of your PHI, you cannot participate in the research study, but this will not affect treatment, payment, or eligibility for benefits for which you are normally entitled to. If you have questions, you may contact your study doctor. You will be given a signed copy of this form**.**

Participant (*Print name*):	
Signature:	**Date:**

If this authorization form is read to the participant because the participant is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the reading of authorization and sign the following statement: *I confirm that the information in the authorization form and any other written information was accurately explained to, and apparently understood, by the participant. The participant freely signed the authorization.*	
Name of Impartial Witness (*Print name*):	
Signature:	**Date:**

PSJH IRB
IRB Number: STUDY2023000353
IRB Approval Date: 2/27/2024
IRB Parent Number: STUDY2023000353