SCREENING CONSENT TO DETERMINE STUDY ELIGIBILITY AND OPTIONAL RESEARCH AUTHORIZATION TO DONATE ARCHIVED TISSUE SAMPLES FOR MOLECULAR CHARACTERIZATION OF TUMOR YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL 200 FR. 4

Study Title: A Phase 1, Open-Label, Dose-Escalation Study to Evaluate the Safety and Tolerability of SGN-LIV1A in Patients with LIV-1-Positive Metastatic Breast Cancer

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Address: 300 George Street, Suite 120, New Haven CT 06511

Funding Source: Seattle Genetics, Inc.

Invitation to Participate

This consent form is called a "Screening Informed Consent Form," in which you are giving permission to obtain a biopsy of your cancer to perform a molecular test to find out if your cancer has a molecule called LIV1. If your cancer has LIV1 you may be eligible to take part in a clinical trial (Study SGNLVA-001) with an investigational drug called SGN-LIV1 that targets LIV1. You will also be asked if you agree to have already collected cancer tissues from your previous breast cancer surgery tested for LIV1.

Your study doctor or the study staff will explain the research study to you. The research study includes only patients who choose to take part. Please take your time to make your decision about taking part in this study. You may discuss your decision with your family and friends.

You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation. In this consent form, "you" refers to the patient.

Taking part in this study is voluntary. No matter what you decide to do, it will not affect the medical care you would normally receive from your doctor.

Purpose:

The purpose of this Screening Informed Consent Form is to inform you about the risks and benefits of obtaining a biopsy of your metastatic breast cancer to determine eligibility for a clinical trial called "Study SGNLVA-001". You will be asked to sign this consent form if you are interested in participating in this testing. If the test results show that you are eligible to take part in the clinical trial, a separate consent form and more information will be provided to you about the clinical trial and investigational drug. You cannot be considered for participation in the

SGNLVA-001 clinical unless a fresh cancer biopsy is obtained and it shows the presence of the LIV1 molecule.

By signing this consent form, you are agreeing to undergo a biopsy of your cancer to test for the presence of the LIV1A. You will also need to inform us if you agree to obtain pieces from your previous breast cancer surgery to perform LIV1 testing. Results from the old cancer biopsy or surgical tissue will not be used to determine your eligibility for the SGNLVA-001 clinical trial.

Procedures:

If you agree to participate in this study, small pieces of your cancer will be obtained with a needle biopsy. During the biopsy a small amount of tissue is withdrawn through a needle. The biopsy will be performed by an experienced physician who performs these biopsies routinely. Your doctor will select the cancer site that is the easiest and safest to biopsy and the type of needle that will be used. The doctor may use an ultrasound or computed tomography (CT) to guide the needle during the biopsy process.

Four to six core needle biopsies will be collected from the same area of the tumor. Each needle pass removes a piece of cancer tissue (about 1 mm wide by 1 cm long) using a hollow core needle that has a cutting edge. The 4 needle passes are needed so that multiple tests can be performed. All biopsies will be collected during a single biopsy procedure. To perform a core biopsy, your skin will be numbed.

Half of the cancer tissues will be sent for molecular analysis to Seattle Genetics Inc, the sponsor of the clinical trial to test for LIV1. The other half of the tissues labeled only with a code will be stored at Yale University and will be used for future research. This future research may include further testing of the cancer tissue to assess your eligibility to other future clinical trials.

Researchers will study the proteins and genes that are involved in cancer. One of the tests will study the genetic material in the clinical samples to learn about which genes are turned on or off, how these genes are related to your disease, and if certain types of cancer may respond to different treatments.

An optional procedure includes requesting pieces of tumor specimens, called archived tissues, from a previous tumor biopsy or surgery for the breast cancer for LIV1 testing. Results from these tests will determine if you are eligible to take part in the research study.

Risks:

Risks of biopsy:

Biopsies may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsy. An allergic reaction to the anesthetic that is used to numb your skin before the biopsy may occur. There is a small radiation exposure from CT-guided biopsies. The clinical importance of this is unknown. A scar may form at the biopsy site. A biopsy of the lung may cause air leak to the chest cavity that could lead to shortness of breath and may require further treatment including very rarely admission to the hospital. A biopsy of the liver may cause bleeding that may require further treatment and very rarely admission to the hospital. Biopsy-related complications will be treated following standard clinical practice and will be charged to you/your insurance company as standard clinical service.

Archival Tissue -
A sample of your original tumor tissue has already been collected; therefore, there are no additional risks involved in this testing.

Other Potential Risks -
There are also non-physical risks associated with taking part in this study, such as the risks associated with a loss of privacy or confidentiality. For example, if your identity as a participant in this optional research study or your identifiable genetic or health information were disclosed to unauthorized persons, there is the possible risk of discrimination by employers or insurance providers. The Researchers believe that the risks of such improper disclosure are very small because strict privacy and confidentiality procedures for this research have been adopted. (See the "Privacy and Confidentiality" section of this Informed Consent).

Benefits:

No direct benefit can be promised to you as a result of your participation in this research testing. If you are eligible for the clinical trial and you choose to take part, you should know that taking part in the research study may or may not make your health better. There is no proof SGN-LIV1A will make your cancer better. Information from this study will help doctors learn more about SGN-LIV1A as a treatment for breast cancer. This information could help future cancer patients.

Economic Considerations:

You will not be paid for your participation in this optional research study.
There are no costs to you or to your health plan/insurance company to take part in this pre-screening study. The Sponsor, Seattle Genetics, Inc. will cover the cost for the testing.

Privacy and Confidentiality:

If you agree to be screened for the clinical trial, we will keep a record of the result from the screening test. The results will also be sent to Seattle Genetics, Inc. where they will be kept for an indefinite period of time.

Your medical information will be kept as confidential as possible within the limits of the law. Your medical information may be given out if required by law. Seattle Genetics, Inc. may use the medical information collected during this study to describe your tissue samples; however, you will not be identified by name or picture. If information from this study is published in a medical journal or presented at scientific meetings, you will not be identified by name, picture, or any other personally identifying information.

The following people and groups of people may look at and/or copy your medical records to make sure that the study is being done properly and to check the quality of the data:

- Seattle Genetics, Inc. study monitors and representatives
- Seattle Genetics, Inc. collaborators and licensees (people and companies partnering with Seattle Genetics, Inc.)
- The Institutional Review Board (IRB) responsible for protecting the rights and safety of the patients who take part in research studies

- The U.S. Food and Drug Administration (FDA) and other government agencies involved in keeping research safe for people

Review of your medical records by these people or groups of people will not violate your confidentiality.

Although you have the right, subject to policies of Yale School of Medicine and Yale New Haven Hospital to access information in your medical records, including information related to the main clinical trial (once that study is complete), the information that is maintained in databases and created during this screening testing is for research purposes only.

It is possible, however, that members of regulatory authorities, such as the United States Food and Drug Administration and other persons required by law may have access to the research results.

The Researchers may use other laboratories, investigators, commercial or academic third parties as their "agents" to assist in this research. If these agents assist in the research, your sample and some of your health information will be shared with them. The Researchers will require that these agents protect your privacy.

Withdrawal of Consent and Destruction of Samples:

You may withdraw this consent and discontinue your participation in this screening study described above at any time. To withdraw your consent, you must contact the Study Doctor, at the number listed on page 1 of this consent document. You do not need to give a reason for changing your mind.

If you change your mind, and your samples have already been tested, those results will still remain part of the overall research data. If you choose not to participate or if you withdraw it will not harm your relationship with your own doctors or with Yale-New Haven hospital.

Questions:

We have used some technical terms in this form. Please feel free to ask about anything you do not understand and to consider this optional research study and the consent form carefully – as long as you feel is necessary – before you make a decision.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this pre-screening research study, you will receive a signed and dated copy of this consent form for your records.

AUTHORIZATION AND PERMISSION:

I have read (or someone has read to me) this form and have decided to participate in the screening biopsy procedure described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction.

Please also indicate you consent for the optional procedures by checking the appropriate box:

☐ I **agree** to have my previously collected, archived cancer tissue tested for LIV1

☐ I **do not agree** to have my previously collected, archived cancer tissue tested for LIV1

By signing this form, I give permission to the researchers to enroll me in the screening procedure as described in this form. My signature also indicates that I have received a copy of this consent form.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project as described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use and give out information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to participate in this research.

Study Participant (print name)	Signature	Date
Person obtaining consent (print name)	Signature	Date
Interpreter/ Witness (print name) *– only if applicable, otherwise blank*	Signature	Date

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the study doctor, Dr. Lajos Pusztai at 203-737-8309. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at 203-785-4688.