Pilot Study of [68Ga]Ga-ABY-025 imaging in patients undergoing treatment with HER2-targeted therapy

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PI:	Eben Rosenthal, MD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

General Information
You are invited to take part in this research study to determine the diagnostic utility of [68Ga]Ga-ABY-025 PET imaging for the identification of locally advanced or metastatic breast cancer.

This research study is voluntary, meaning you should not feel obligated to agree to participate. You do not have to participate and it will not affect your usual medical care if you choose to not participate. You may decide to participate now but withdraw your consent at any point in the study without any loss of medical care. If study findings suggest potential risks or benefits, you will be informed so that you may decide on ongoing participation in the study. Risks and benefits are defined later in this document on Page 3 and 4.

Purpose
The purpose of this study is to determine if the radiotracer, [68Ga]Ga-ABY-025, used for PET imaging can help us better identify and visualize lesions or tumors, in patients who are receiving standard of care therapy for advanced breast cancer.

Duration and visits
Your participation in the study will not be more than 13 months. This includes a maximum of 30-day screening period, followed by study agent injection and PET/CT scan with a 21-day follow-up period. A second dose will be given, and PET/CT will be conducted 12 months after enrollment, or at treatment discontinuation, whichever comes first.

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Overview of procedures
If you agree to enroll, you will receive an injection of [68Ga]Ga-ABY-025, followed by a PET/CT scan within 2-3 hours. You will be monitored for any reactions immediately after injection and up to 21 days after your injection. A second dose will be given, and PET/CT will be conducted 12 months after enrollment, or at treatment discontinuation, whichever comes first.

Risks
There are no expected risks with the use of [68Ga]Ga-ABY-025 alone. Risks are detailed further on Page 3 and 4.

Benefits
You may or may not have a direct benefit from being in the study. The study doctors hope to be able to use the information on the safety of the study drug to help treat future cancer patients. The agent is highly specific for the detection of HER2 positive cancers and may help us monitor for treatment response, while minimizing the need for repeated biopsies.

Alternatives
You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, please tell the Protocol Director.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you have been diagnosed with locally advanced or metastatic breast cancer, and plan to undergo standard of care treatment with HER2-targeted therapy. This research study will determine the diagnostic utility of [68Ga]Ga-ABY-025, a HER2 specific radiolabeled drug, for identification and visualization of these lesion/s, and to monitor treatment response.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will

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contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director or study team if you have any questions.

Potential risks of [68Ga]Ga-ABY-025:
There are no expected toxicities of [68Ga]Ga-ABY-025 other than those associated with any injection or infusion. The amount of [68Ga]Ga-ABY-025 that you will receive for this infusion is a smaller amount than you would receive is less than would receive for a therapeutic dose for a standard of care procedure.

Risks associated with injection:
- Risk of local bruising and/or discomfort associated with the needle stick (venipuncture)
- Irritation, pain or swelling at the injection site
- Generalized rash (or urticaria), fainting, or hypotension, although the risk is less than 1%
- Fever, nausea, muscle aches, headache or abdominal pain

Risks associated with venipuncture:
Local bruising and discomfort associated with venipuncture for blood draw or placement of IV lines for the PET studies. A small amount of bleeding may occur when an IV line is inserted or removed. While there is the possibility of infection associated with venipuncture, this is very unlikely.

Radiation risk:
You are agreeing to participate in a research project that involves the use of imaging procedures that expose you to radiation. This section will discuss the risks associated with the imaging procedures that are for research only. Your doctors may order additional imaging procedures as part of your normal patient care that also expose you to radiation. Those normal imaging procedures are not included in the risk discussion below. Please discuss those procedures and radiation risks with your doctors. As part of this research study, you may be asked to have an additional imaging procedure that exposes you to radiation. This procedure is known as a PET/CT scan (Positron Emission Tomography-Computed Tomography). It exposes you to external radiation from the CT portion as well as internal exposure from injection of a radioactive substance. Additionally, to protect your bladder from the effects of the

injected radioactive substance, you should drink plenty of fluids and empty your bladder every two hours for at least the first six hours after you have the PET/CT scan.

Risk in women with childbearing potential:
If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breastfeeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast feeding during this study, you or your child may be exposed to an unknown risk.

Risks that are not known:
Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Good effects that might result from this study:
You may not benefit directly from taking part in this study. However, information obtained from your participation in this study may benefit other people with cancer in the future. We cannot and do not guarantee or promise that you will receive any benefits from this study.

Procedures to be followed:
If you choose to participate in this study, Dr. Eben Rosental and his research team will perform the procedures listed below in addition to your normal pre-operative, surgery and follow up clinic visits and examinations. Please refer to the table below.

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Table 1: Study Calendar for all visit specific procedures.

Procedures	**Screening/ Pre-treatment** (Day -30 to Day -1)	**Day 0**	**Day 2 Follow-up phone call** (+/-1 day)	**SOC follow up with provider** (Day 21+/- 14 days)	**12 months following consent or after HER2-directed therapy discontinuation** (+/-30 days)[1]
Demographics	X				
Informed consent	X				
Medical history	X			SOC	
Vital signs	X	X[2]		SOC	X
Physical examination	X			SOC	
Performance status (ECOG)	X			SOC	
Clinical assessment[3]		X	X	SOC	X
Serum pregnancy test		X[4]			X
Urine pregnancy test[5]	X				
Blood Collection (Hematology)				SOC	
Comprehensive metabolic panel				SOC	
Magnesium				SOC	
ABY-025 loading dose injection		X			X
[68Ga]Ga-ABY-025 injection		X			X
[68Ga]Ga-ABY-025 PET/CT scan imaging acquisition		X			X
SOC imaging[6]	SOC			SOC[6]	
HER2-directed therapy	SOC therapy per treating physician discretion				
Blood draw	X[7]			X[8]	X[7]
Concomitant medications review[9]	X	X		X	X
Adverse events assessment[10]		X	X	X	X

SOC = standard of care, billed to patient/patient's insurance; X = billed to study – if you are billed to this, please reach out to the study coordinator.

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Screening (within 30 days of treatment start)
If you choose to participate in the study and sign this consent form, we will ask you to undergo the following exams and tests to determine if you are eligible to take part in this study**. If you have already had some of these exams and tests recently (within 30 days of the Screening Visit), they may not need to be repeated.** The screening period will not last more than 30 days.

The following procedures will occur during screening:

- Thorough review your medical history, current medications, relative past medications, and any allergies
- Physical examination including height, weight, and vital signs
- Performance status – a measure of how you are feeling
- Pregnancy test, if applicable. If you are currently pregnant or breast feeding, you cannot participate in this study because of the potential unknown risk to your unborn fetus or baby.
- Blood collection

Day 0
If you meet all the requirements to participate, you will come to campus on Day 0 to receive the investigational imaging agents. The following procedures will occur:

Prior to administration of the study agent:

- Pregnancy test, if applicable
- Vital signs
- Assessment for current medications

Administration of study agent: The study agent will be administered as an injection into a vein in your arm. A loading dose that is the same compound without the associated radiotracer will be administered before injecting [68Ga]Ga-ABY-025 (radiolabeled study agent).

Following administration of the study agent:

- Observation for approximately 30 minutes
- Assessment of vital signs after the observation period (blood pressure, heart rate, pulse oximetry, respiratory rate)
- Assessment of adverse events

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Day 1 (up to 3 days after injection of study drug): Phone call with research coordinator to assess to ask about any side effects of the study agent.

Day 15: Clinical assessment in person or via telehealth to collect additional adverse events that are attributable to the study and/or concomitant medications.

Tissue Storage for Future Research
Research using tissues is an important way to try to understand human disease. You have been given this information because the investigators will save your excess tissue samples for future research if they are available from your standard of care. There are several things we would like you to be informed.

Your tissues will be stored in a Tissue Repository at Vanderbilt University Medical Center (VUMC). Samples will be labeled with a study ID code number that does not personally identify you.

The key linking the study ID code with your personal information will not be shared with researchers. Your samples may be sent outside of VUMC for research and analysis.

Identifiers will be removed from identifiable private information and/or identifiable specimens, and after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Saving Images for Future Research
Investigators would like to save the images and data from your imaging for future research projects. Your data will be de identified (removing your name and medical record number), coded for confidentiality, and stored at VUMC in a secure, password protected computer. Your name and other personal identifiers will not be included in any data shared with other researchers. Your images may be sent outside of VUMC for research and analysis.

Payments for your time spent taking part in this study or expenses:
You will be paid to participate in this research study. You may receive up to a total $100 if you complete this study. You will be paid for the visits you completed according to the following schedule:

- $50 for the first Infusion and PET/CT Visit
- $50 for the second Infusion and PET/CT Visit

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If you do not complete the study, for any reason, you will be paid for each study visit you do complete. We will complete a check request for you via Vanderbilt's Finance Department at the end of your participation. The check may take 4-6 weeks to process. We may ask you for your Social Security number and address on a form before you are compensated for taking part in the study. You will also receive travel reimbursement up to $600 total with appropriate receipts and/ or documentation to study team.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Costs to you if you take part in this study:
If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you. Please refer back to Table 1 on Page 8 of this document to see the cost breakdown for the charges that may be charged to you and/or your insurance and those charges that will be charged to the study team.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt or team to pay for the costs of any additional care. There are no plans for Vanderbilt or to give you money for the injury.

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Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact the study coordinator or my Faculty Advisor, Dr. Eben Rosenthal at 615-936-0708. If you cannot reach the research staff, please page the study doctor by calling (615) 322-5000 and ask the operator to page her.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
The Protocol Director may also withdraw you from the study and/or administration of the study agent may be stopped without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and/or study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Other Unanticipated circumstances.

What will happen if you decide to stop being in this study?
If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not change your regular medical care.

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

Confidentiality:

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The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.
Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain information on the safety and effectiveness of [68Ga]Ga-ABY-025. The results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

Your excess tissue samples for future research if they are available from your standard of care will be stored in a Tissue Repository at Vanderbilt University Medical Center (VUMC). Samples will be labeled with a study ID code number that does not personally identify you. Identifiers will be removed from identifiable private information and/or identifiable specimens, and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. Only the investigator(s) and authorized study team members have the access to your data and specimens. These materials will be made available for monitoring or auditing by regulatory agencies.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

At any time, you may ask to have your sample destroyed. You should contact the study coordinator or the Principal Investigator, Dr. Eben Rosenthal, to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your

sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Study Results:
The research results will be shared with you when the study is closed out by request. The shared study results may include peer-reviewed scientific publications, news releases, and clinical trials reports at ClinicalTrials.gov.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers, insurance providers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

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How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Time: _____