CONSENT TO TAKE PART IN RESEARCH

Dartmouth-Hitchcock Medical Center

A Microdose Optimization Study of ABY-029 In Primary Sarcoma

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Introduction: You are being asked to take part in a research study. Taking part in research is voluntary.

You are being asked to take part in this study because you have been diagnosed with a sarcoma (cancer) that will be removed by surgery as part of your care.

Taking part in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information to help patients in the future.

Your decision whether or not to take part in this study will not influence your future medical care. Please ask questions if there is anything about this study you do not understand.

Background:

ABY-029 is an experimental drug that has not been tested in humans yet. Our previous animal research showed that ABY-029 can light up portions of many tumors, making them glow a green color. The purpose of this study is to determine if ABY-029 can be detected in human sarcomas.

ABY-029 is given by IV to patients a few hours before surgery. Giving patients ABY-029 before sarcoma surgery has not been approved by the U.S. Food and Drug Administration (FDA). We have received permission from the FDA to use ABY-029 in two limited research studies. In an experiment in animals with tumors, we showed that ABY-029 has the potential to help the surgeon to identify tumor tissue during surgery because the treated tumor cells glow on a display of the imaged tissue. This approach could benefit patients with sarcoma tumors that need to be completely removed through surgery.

What is the purpose of this study?

The purpose of the study is to measure the amount of ABY-029 that reaches your sarcoma with the help of the devices we have made. After the tumor has been

completely removed, we will use imaging systems in a laboratory to record the amount of ABY-029 in your tumor and in the surrounding tissue.

Will you benefit from taking part in this study?

This study is not intended to provide a personal benefit to you. Conventional imaging of your tumor is helpful in guiding the surgeon to remove it, and is part of standard practice for your condition. This information will be available and used during your surgery as it would be, even if you chose not to participate in this study.

This study is the first time that ABY-029 will be used in humans to determine if it can image human tumors in the laboratory. As a result, predicting whether you will benefit from your participation in this study is not possible at this time. We hope to gather information that may help people with sarcoma tumors similar to yours in the future.

What does this study involve?

We will analyze your tumor after it is removed and we may examine your health records during the first 30 days after your surgery to satisfy FDA monitoring and reporting requirements associated with the experimental use of ABY-029. You will have post-operative imaging and clinic follow-up visits as part of the routine care that you would undergo regardless of whether you enroll in this study or not.

Your surgery will be identical to what would happen if you decide not to participate,

What are the options if you do not want to take part in this study?

In order to be considered for this study, your doctor has already recommended that your sarcoma be surgically removed as part of your care, and you will most likely have surgery even if you decide not to participate in this study. Other research studies may be available for patients with your condition, and you can discuss those options with your doctor.

If you take part in this study, what activities will be done only for research purposes?

If you take part in this study, the following activities will be done only for research purposes:

- Being given a very small amount of ABY-029 dissolved in about one teaspoon of saline (salt water) in a syringe approximately 3 hours before surgery. The amount of ABY-029 we will give is called a microdose, a tiny dose weighing about 0.25 mg, which is about 1/10th the weight of a paper clip.
- After the tumor is completely removed, measurements of your tumor will be taken from locations measured with special imaging systems, in addition to the

biopsy specimens used to confirm your clinical diagnosis as part of standard-of-care for your condition.

- Additional lab work that is part of the standard of care:
    - A pregnancy test (urine or blood) will be performed on all women of child-bearing potential prior to your surgery.
- For 30 days after your surgery we will monitor your health.

What are the risks involved with taking part in this study?

We cannot be sure how your body may respond to the ABY-029 used in this study. However, from our previous work with this drug in animals we do not believe there are any safety risks with giving you a very small amount of ABY-029. The research team will discuss possible problems and the chances that they will happen. Unknown problems may happen. Problems may be small, such as a minor side effect, or they may be so serious that they result in death. Or they may be somewhere in between. You should report any problems to your doctor or to the director of this study**: Eric Henderson, MD (603-650-5133).**

Risks/Side Effects of ABY-029

- None known at this time from ABY-029.
- Because this drug is given by IV, there may be some pain or mild bruising from the IV.

Reproductive Risks and Risks to Pregnant Women:

The risks of ABY-029 to a pregnancy are unknown. Pregnant women or women who are breast-feeding may not take part in this research study. All women who could become pregnant will have a pregnancy test before surgery.

All women who could become pregnant need to use a medically approved method of birth control in order to take part in this research study. Please discuss options with the researcher.

If you become pregnant, you should let us know right away. Call Dr. **Eric Henderson, MD at 603-650-5133.**

Other important items you should know:

• **Leaving the study:** You may choose to stop taking part in this study at any time for any reason. If you decide to stop taking part, it will have no effect on the quality of your medical care. If you stop being in the research, already collected data may not be

removed from the study database. You may be asked whether the investigator can collect data from your routine medical care

• A description of this clinical trial will be available on 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.

• This research involves the use of new technology that could lead to a product sold for profit in the future. If the results of this research are used to develop a product sold for a profit, you will not share in the profit. You will not receive money from the profits.

• **New Information:** New information related to this research will be made known to you when it becomes available. This may affect your decision to stay in this study.

• **Funding:** The National Institutes of Health is the sponsor of this research. The ABY-029 is being provided by Dartmouth College through federal funding for this study. The investigators involved in this research are inventors of some of the technology used in this study, and hold intellectual property rights to these ideas jointly with the Trustees of Dartmouth College.

• **Number of people in this study:** It is expected that between 12 and 18 people will be enrolled at this institution.

How will your privacy be protected?

The information collected for this study will be used only for the purposes of research. It includes: optical images and signals collected of your tumor after it is removed and histological analyses of the tissue specimens removed during your surgery. Information on your gender, age, sarcoma diagnosis, etc., will be collected in order to characterize some basic demographics of the subject population enrolled in the study. The data collected for this will be maintained indefinitely.

We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential. Specifically, your identity is coded into a study number and most of the data and analysis occurs with information that is archived only by study number. Information which identifies you as participating in the study is maintained in binders as required by the FDA, and these binders will be kept in the office of research team. The office is kept locked when not in use, and the study team is trained in the importance of maintaining your confidentiality. Research data, if sent electronically to members of the research team, is

de-identified and only secure file transfer methods are used. Pathology information may be sent to a pathologist working outside the institution for evaluation purposes. This data and information is de-identified and is referenced only by the study number of the participant.

Who may use or see your health information?

By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the study director plus others working on this study at Dartmouth-Hitchcock Medical Center and elsewhere. You also permit any health care provider holding health information needed for this study to give copies of your information to the research team.

The information collected for this study may be used by researchers or officials of the following institutions.

- Dartmouth College
- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- National Institutes of Health (NIH)
- Federal Drug Administration (FDA)
- Affibody AB (developer of the study drug)
- LI-COR Biosciences (manufacturer of the glowing dye in ABY-029)
- University of Alabama (research facility where ABY-029 was made)

During this study, information that identifies you may be given to some organizations that may not have a legal duty to protect it. These organizations may also use and disclose your information for other purposes.

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over. You have a right to receive a copy of the information in your medical record at any time.

It is possible for a court or government official to order the release of study data including information about you.

What if you decide not to give permission to use and share your personal health information?

If you do not allow use of your health information for this study, you may not take part in this study.

If you choose to stop taking part in this study, you may cancel permission for the use of your health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

Whom should you call about this study?

If you have questions about this study or need to report a study related injury, you can call your doctor or the research office for this study at 603-650-5133 during normal business hours and they will be able to contact Dr. Henderson for you. If Dr. Henderson is not available, other members of the section of Orthopaedics will be available to answer your questions during normal business hours.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (603) 650-1846 or irb@hitchcock.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

What about the costs of this study?

ABY-029 will be supplied free of charge. All additional tests/visits/procedures as described in the "If you take part in this study, what activities will be done only for research purposes?" section will be paid for by the sponsors of the study. A pregnancy test is usual care and will not be paid for by the sponsors of the study.

Insurance plans will not be billed for research procedures that are not the usual care for your condition. Some of the medical care that you will receive during this study is the usual care a doctor would recommend for your condition. You or your insurance plan are expected to pay for the costs of this usual medical care.

Will you be paid to take part in this study?

You will not be paid for participating in this study.

What happens if you get sick or hurt from taking part in this study?

Sponsor Information: This study is locally funded by a grant from the Prouty Fund at the Norris Cotton Cancer Center and compensation for a research-related injury or illness is limited by federal law. The ABY-029 used here was made for this study with funds from the sponsor. If you develop an illness or have an injury because you are in this research study, the sponsor will not pay for:

- The costs that are covered by your health insurance plan, or
- Treatment of illness or injury that results from the negligence of a health care provider, or
- Treatment of a condition that you had before you were in the study.

The sponsor will not offer any other payments for your study-related illness or injury such as lost wages, expenses other than medical care, or pain and suffering.

If you are injured or become ill as a result of research procedures, you will be provided with medical treatment but the following organizations do not plan to pay for this treatment.

- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- Trustees of Dartmouth College
- The Norris Cotton Cancer Center

If you have any questions or concerns about the legal responsibility of these organizations, please call the Mary Hitchcock Memorial Hospital Office of Risk Management at 603-650-1250 during normal business hours.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

Your responsibilities as a person taking part in this study

(1) Be aware it is important for your safety that the research team knows about your medical history and current condition.
(2) Notify the research team in advance if you plan to undergo any other medical treatment during this study, or are taking or plan to start taking any medications.
(3) Notify the research team immediately if you suffer any injury or unexpected reaction to the study medication or procedures.
(4) Seek treatment with the help of the research team if you suffer any injury or unexpected reaction to the study medication or procedures.

(5) Make reasonable efforts to cooperate with the instructions of the research team.

CONSENT

I have read the above information about **"A Microdose Optimization Study of ABY-029 in Primary Sarcoma"** and have been given time to ask questions. I agree to take part in this study and understand I will be given a copy of this signed consent form.

Participant's Signature	Date	PRINTED NAME
Researcher or Designee Signature	Date	PRINTED NAME