Informed Consent Form

WINSHIP5085-20:
Enhancing Cervical Cancer Screening and Treatment in Women Living With HIV in Kenya, the ENHANCE LINKAge Trial

NCT Number: NCT04890236

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EMORY | WINSHIP CANCER INSTITUTE
National Cancer Institute-Designated Comprehensive Cancer Center

You Are Being Asked to Be in a Research Study
Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of the 20 people who are being studied, at Emory University..

Why is this study being done?
This study is being done to answer the question: If approximately two weeks (8 to 15 days)of taking Duvelisib, an oral phosphoinositide 3-kinase (PI3K) inhibitor, will favorably change a patient's T cells to make them more efficient and have a longer duration for manufacturing of CAR-T cells. You are being asked to be in this research study because you have a diagnosis of relapsed or refractory Diffuse Large B Cell Lymphoma or follicular lymphoma and are eligible to participate in this trial.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition at Emory. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate for four clinic/study visits. The researcher team will ask you to do the following: draw blood and undergo a physical exam by a physician once a week for two weeks. All of these procedures will be paid for by the study and should be of minimal harm to you.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. This will allow doctors to make better CAR-T cells for patients that also have relapsed/refractory Diffuse Large B Cell Lymphoma or follicular lymphoma.

What are the risks or discomforts I should know about before making a decision?
Your participation in the study will only take two weeks. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include side effects from Duvelisib, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is to not participate and receive standard of care treatment, which is undergoing manufacturing of CAR-T cells without any pre-treatment.

Costs
You WILL NOT have to specifically pay for the studies procedures or medication. Costs will be covered by the study sponsor, cell manufacturer, or your insurance company.

There is more information in the cost section below.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to consider this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Duvelisib Exposure to Enhance Immune Profiles of T Cells in Patients with Diffuse Large B Cell Lymphoma (DEEP T CELLS)

Principal Investigator: Edmund K. Waller, MD, PhD

Investigator-Sponsor: Edmund K. Waller, MD, PhD

Study-Supporter: Secura Bio

Cell Manufacturer: Novartis

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask all your questions and get all your answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?

The purpose of this study is to determine if a short, approximately two week course of Duvelisib will favorably change a patient's T cells for manufacturing of CAR-T cells and shorten manufacturing time of CAR-T cells. The actual duration of the Duvelisib treatment can be between 8 and 15 days, depending upon the schedule for apheresis chosen by your doctor and nurse coordinator.

All CAR-T related procedures, including immune cell apheresis, manufacturing, pre-CAR-T conditioning, CAR-T infusion, and post CAR-T clinical management, labs, and follow-up appointments will follow standard of care protocols.

What will I be asked to do?

You will be asked to take the oral medication, Duvelisib, for 8 to 15 days prior to manufacturing of your CAR-T cells for treatment of your lymphoma. This medication is taken twice a day. You will need to be seen in our clinic three times after you start taking the Duvelisib (the first day, the 8th day and the last day you are taking the Duvelisib). We will draw blood from you on each of those clinic visits and test/examine it for any side effects that you may be having from the medication. We will also test your blood on the first and last day that you take the Duvelisib to determine how your T cells have changed from taking the Duvelisib.

How will my medicine be provided?

The medicine that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the medicine to you. If you have questions about the medicine, you should ask Dr. Waller. You may also call the pharmacy at [redacted] you have questions about the medicine. The number for the pharmacy is included on your medicine package.

Who owns my study information and samples?

If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study. Study patients who request destruction of samples will be notified of compliance with such request and all supporting details will be maintained for tracking.

What are the possible risks and discomforts?

There may be side effects from Duvelisib that are not known at this time.

The most common (>25%) risks and discomforts expected in this study are: Diarrhea, Nausea, Fatigue, Fever, Cough and/or shortness of breath (due to inflammation of the lungs), low blood count, and skin rash. A recent analysis of patients with chronic lymphocytic leukemia who had been taking Duvelisib continuously for up to five years showed an increased rate of serious side effects, dose modifications, and deaths resulting from these side effects were also higher among patients who received Duvelisib compared to a comparable group of patients treated with an anti-B cell monoclonal antibody. The serious side effects included infections, diarrhea, inflammation of the intestine and lungs, skin reactions, and elevated liver enzyme levels in the blood. Many of these side effects are typically seen, on average, two months after starting Duvelisib and not expected to be seen among lymphoma patients taking Duvelisib for only one to two weeks (8 to 15 days). You will be monitored for side effects during the one to two weeksthat you will be taking Duvelisib. If these or other serious side effects are noted while you are taking Duvelisib as part of this study the doctors will tell you to stop taking the medication.

The less common risks and discomforts (~10%) that may occur in this study are: Abdominal pain and vomiting, joint and muscle aches, headache, swelling of the legs (edema), headache, or kidney injury
Rare but possible risks leading to drug discontinuation include: Pneumonia, Colitis (severe gut inflammation), pneumonitis (severe lung inflammation), and liver injury (transaminitis).

If you are a woman: to protect against possible side effects of the study drug, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo,

or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. Options for contraception include hormonal or barrier method of birth control or total abstinence. Contraception will last for at least 12 months from enrollment into this study until at least 12 months after CAR-T infusion, and longer if CAR-T cells are still present after 12-months. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study. We will ask that you submit a pregnancy test prior to starting Duvelisib.

If you are a man: the effect of the study drug on sperm is not known. To protect against possible side effects, if you are a man you should not get a sexual partner pregnant while taking the Duvelisib.

Men enrolled on this study agree to use highly effective contraception. Contraception will last for at least 12 months, starting from enrollment into this study until at least 12 months after CAR-T infusion, and longer if CAR-T cells are still present after 12-months. You and the study doctor should agree on a method of birth control to use throughout the study. Contraception options include sterilization (at least 6 months prior to screening), total abstinence, or regular condom use with sexual activity. A condom is also required of all sexually active male patients to prevent delivery of study treatment via seminal fluid to their partner.

All patients also agree not to donate blood, sperm/ova or any other organs while taking protocol therapy and for at least 12 months after stopping treatment.

If you will be taking the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study may not benefit you directly. This study is designed to learn more about changing the make-up of T cells for CAR-T cell manufacturing. There is a possibility that your T cells will be favorably changed for better CAR-T cell manufacturing, but this is not a guarantee. Your participation in the study will give us valuable information about if Duvelisib and how it effects patients' T cells.

Will I be compensated for my time and effort?

You will not be offered compensation for being in this study. However, we will provide parking validation and meal vouchers during your clinic visits.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. You can proceed with CAR-T cell collection without any pre-treatment. The study doctor will discuss these with you. You do not have to be in this study to be treated for your lymphoma at Emory.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have

concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

Your data from this study will not be shared with anyone outside this study, even if we take out all the information that can identify you.

Storage Specimen and Specimen Data for Future Research

All stored samples will be maintained in the laboratory to which it was sent initially for analysis. The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: research blood collection.

We will use your sample and data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

As they become available, do you want us to contact you and ask whether you want to receive your results? If so, let the study team know, and they will contact you as the results become available.

Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory Healthcare medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: research blood collection. To help further science,

Investigators may provide de-identified data and/or specimens to other researchers. Any information that could identify patients will not be included. If data or specimens are labeled with study ID, we will not allow other investigators to link that ID to identifiable information.

Samples and data collected under this protocol may be used to study lymphoma. Access to stored samples will be limited to IRB-approved investigators. Samples and data will be stored using codes assigned by the investigators or their designees. Data will be kept in password-protected computers. Only investigators will have access to the samples and data.

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Dr. Edmund Waller at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. “Negligence” is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

If you get ill or injured from being in the study, Emory will help you get medical treatment. Emory has not set aside any money to pay you if you are injured as a result of being in this study. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence. “Negligence” is the failure to follow a standard duty of care.

The sponsor will not pay for co-payments or co-insurance that Medicare, Medicaid or your private insurer says you must pay. Also, the sponsor will not pay for illness or injury:

(a) from medical conditions you had before you started the study;

(b) from the natural progression of your disease or condition;

(c) from your failure to follow the study plan; or

(d) that is directly caused by the negligence of an Emory employee.

You will have to pay for any treatment costs that are not paid for by the sponsor or by any insurance you may have. Novartis (cell manufacturer) will not pay any money to you or your medical bills.

Costs

There are no costs, research or standard of care related, associated with the study.

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done, specifically:

- Blood work (CBC, CMP)

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:

- Severe Side Effects from Duvelisib
- Failure to comply with study schedule
- Rapid progression of disease requiring urgent treatment

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We

will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form. If you do not sign this form, you may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator/Investigator-Sponsor and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- The Principal Investigator/Investigator-Sponsor and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Secura Bio is the Supporter of the study. The Supporter may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Supporter may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- Novartis is the Cell Manufacturer. Novartis and its authorized agents may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research.
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:

    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

- Government agencies that regulate the research including: Food and Drug Administration

- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Edmund K. Waller, MD, PhD
Winship Cancer Institute, Emory University
1365-C Clifton Road NE
Atlanta, GA 30322

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

<u>Contact Information</u>
Contact Dr. Edmund Waller at [redacted]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or

- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted] or [redacted] or [redacted]:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study, and any optional studies you initialed above. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____ ____:____ **am / pm**

Signature of Subject (18 or older and able to consent) Date Time (please circle)

_____ _____ ____:____ **am / pm**

Signature of Legally Authorized Representative Date Time (please circle)

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Authority of Legally Authorized Representative or Relationship to Subject

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TO BE FILLED OUT BY STUDY TEAM ONLY

_____ _____ ____:____ **am / pm**

Name of Person Conducting Informed Consent Discussion **Date Time (please circle) (when IC discussion took place)**

_____ _____ ____:____ **am / pm**

Signature of Person Conducting Informed Consent Discussion **Date Time (please circle) (when IC was signed)**