HALIFAX HEALTH

Prescreening Patient Information and Consent Form

I3Y-MC-JPBK
JUNIPER: A Randomized Phase 3 Study of Abemaciclib plus Best Supportive Care versus Erlotinib plus Best Supportive Care in Patients with Stage IV NSCLC with a Detectable KRAS Mutation Who Have Progressed after Platinum-Based Chemotherapy

Participant Information and Consent Form

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Introduction

As a possible participant in Study I3Y-MC-JPBK, you are being invited to take part voluntarily in a prescreening activity for research on advanced lung cancer patients who have a specific type of lung cancer with a KRAS mutation.

Purpose

The purpose of this prescreening activity is to collect and store a piece of your tumor sample that was removed during a previous biopsy of your tumor. The tumor sample will undergo a test which may help your doctor to determine if you might be a candidate for a clinical study (Study JPBK) with an experimental drug called abemaciclib (also known as LY2835219). Abemaciclib is being tested in patients who have advanced lung cancer and a positive KRAS test result.

The test will identify changes in the KRAS gene. It is investigational which means that it is not approved by regulatory authorities except for use in clinical studies. How well this test works is not known. If the test result is not correct, your doctor may receive incorrect information about your cancer. This may affect your ability to participate in Study JPBK and may expose you to drug that may provide no benefit or keep you out of the trial for a drug that may benefit you. In addition to the investigational test, your sample may also be tested by 1 or 2 other methods.

Prescreening Study Procedures

If you choose to participate in this research, your doctor will ask your consent to collect and test a piece of a tumor sample that was taken from your tumor previously.

Your tumor sample will be sent to a central laboratory for testing.

Your tumor sample will be stored for up to 15 years after the clinical Study JPBK is done (last patient left the study). Any samples left at that time will be destroyed. Unused tumor tissue could also be returned to the site.

Risks

There is no risk to you, because the piece of a tumor sample to be tested was taken from your tumor previously.

Participation in the Study

Your agreement to take part in the prescreening activity is entirely voluntary. You may refuse to take part in the prescreening activity or you may stop your participation in the prescreening activity at any time, without penalty or loss of benefits to which you are otherwise entitled. If you decide later not to consent to Study JPBK, data generated from your prescreening tumor sample will continue to be used and analyzed by the sponsor. Testing of your tumor sample is required for entry into Study JPBK; participation in that study is also entirely voluntary.

Possible Benefits

The tumor sample collected from you for this research will not be used to monitor your care. You will receive no direct medical benefit from allowing the testing of your tumor sample. If the result of the KRAS test is positive, your doctor may propose that you participate in Study JPBK. In this case, your doctor or the study staff will provide you with all the related information and you will be given a specific consent form.

The analysis of your sample may contribute to the creation of new diagnostic tests, new medicines, or other items that may be commercially valuable to the sponsor.

You will not receive, either now or in the future, any compensation, royalty, or any other financial benefit which might result from any product, procedure, or other item that may be developed from studying your sample or information, or data that is derived from such research.

You will not be paid for participating in this study.

Privacy

Your personal health information will be handled by the study doctor and staff in a confidential manner. Your health information will be used and disclosed in accordance with the Data Privacy Statement attached to this consent document (Attachment 1).

Your tumor sample will be identified by your patient number, and not by your name. The sample and any data generated from the sample can only be linked back to you by the site staff, if needed.

Signatures

By signing and dating this Consent Form, you authorize the collection, storage, and analysis of your tissue sample for research (see Attachment 2).

Attachment 1
Data Privacy Statement

The study doctor and staff will handle your personal health information in a confidential manner. Your health information will be used and disclosed in accordance with the following U.S. Data Privacy Statement.

U.S. Data Privacy Statement

A federal government rule has been issued to protect the privacy rights of subjects/patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality of your personal health information. Your personal health information is information about you that could be used to find out who you are. For this research study, this includes information in your existing medical records needed for this study and new information created or collected during the study.

This Data Privacy Statement explains how your personal health information will be used and whom it will be given to ("disclosed") for this research study. It also describes your privacy rights, including your right to see your personal health information.

By signing the consent document for this study, you will give permission ("authorization") for the uses and disclosures of your personal health information that are described in this Data Privacy Statement. If you do not want to allow these uses, you should not participate in this study.

How do I authorize the use or disclose of my protected health information that identifies me for this research study?

The privacy of your health information is important to us. We call your health information or medical records that identify 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 (HIPAA).

This authorization describes how we may use or disclose your PHI for the main research study. This authorization also describes how we may use or disclose your PHI for the any optional studies in which you may choose to participate in as part of this study.

If you choose to participate in this study, the study doctor and Halifax Health will obtain/ use and/ or disclose (share) personal health information (PHI) about you. The PHI that we want to use for the research study may include the following:

- The history and diagnosis of your disease,
- Specific information about the treatments you have received, including previous treatments(s) you may have had;
- Information about other medical conditions that may affect your treatment;
- Medical data, including laboratory test results, CT scans, MRI's, x-rays, and pathology results;
- Response to the study drug and information on side effects (adverse events) you may experience, and how these were treated;
- Other tests, questions regarding your health, study visits, phone calls made as part of this research, and
- Long-term information about your general health status and the status of your disease.
- It also includes information related to the medication you take and information related to your health including any hospitalizations, records from your primary care or other doctors, if different from the study doctor.
- Data that may be related to tissue and/or blood samples that may be collected from you;
- Numbers or codes that will identify you, such as your social security number, medical record number, initials, and date of birth.

You are allowing the researchers at Halifax Health to use your personal information about your health for the conduct and oversight of this research. You are also allowing Halifax Health to disclose your personal information to outside organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis. A study number rather than your name will be used on study records whenever possible.

Who Will Disclose, Receive, and/or Use Your Information?

Your records are confidential and they will be kept in a secure environment and protected to the full extent of the law.

To do this research, different people, groups and/or organization(s) will be allowed to disclose, use, and receive your information. They will do so only in connection with the research study. They may only use and disclose the information to the other parties on this list, to you or as permitted by law:

- Every member of Halifax Health workforce who provides services in connection with this study, and medical staff,
- Any person who provides services or oversight responsibilities in connection with this study. Including Halifax Health Research Oversight Committee a group of individuals who provides research oversight at Halifax Health,

- Liberty IRB (Institutional Review Board) a committee that has reviewed this research study for Halifax Health to help ensure that your rights and welfare as a research participant are protected and the research study is carried out in an ethical manner,

- The person who is responsible for the study nationwide or worldwide (study chairperson),

- Any laboratories, individuals, and organizations that use your health information in connection with this study,

- The sponsor, Eli Lilly and Company and its representatives,

- Any federal, state or local government agency that regulates the study (such as the U. S. Food and Drug administration (FDA) and Florida Department of Health (FDH). The U.S. Department of Health & Human Services (DHHS), Office for Human Research Protections (OHRP),

- Study data may be sent to other countries as well as other government agencies in this or other countries,

- The designated Protocol review and monitoring committees, Institutional review boards such as Liberty IRB, privacy boards, data safety monitoring board and their related staff that have oversight responsibilities for this study.

- Monitors and Auditors

- Your health care payer, your study doctor or the sponsor may share medical records with their insurance carrier to resolve your insurance claim, and the study doctor may also request medical records from your other health providers to learn more about your condition.

The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze and conduct the study. They may see your name, other personal information such as date of birth and gender and your medical information, but will not give your name to anyone else unless required by law or a regulatory authority.

Halifax Health cannot guarantee the privacy of your information, or block further use of distribution, after the information has left Halifax Health. Others listed above may further disclose your information, and it may no longer be covered by federal privacy regulations. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes. You may have the right to see and copy your health records; the remaining information will no longer be subject to this authorization and may be used or shared for other purposes. You might have the right to see and copy our health records related to this research. You might not be able to see a copy of your records until after all participants finish the study. If it is necessary for your care, your records will be provided to you or your regular doctor.

What Information Will Be Used Or Disclosed?

By signing this form, you authorize the use and disclosure of your entire study record and any medical or other records held by Halifax Health, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you during the informed consent and research authorization process and to ensure that the information relating to that study is available to all parties who may need it for research purposes.

Your authorization to use your health information will not expire. You may, however, revoke (take back) your authorization later. This would be done by writing to the study doctor listed on the first page of this form.

At that point, the researchers would not collect any more of your PHI. But they may use or pass along the information you already gave them so they can follow the law, protect your safety or make sure the research was done properly. If you have any questions about this, please ask.

You will receive a copy of this signed and dated form.

If you refuse to give permission, you will not be able to participate in this research study. Your refusal will not affect your ability to receive treatment, or eligibility for health care benefits.

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.

Authorization To Use And Disclose Protected Health Information For Research

I agree to permit **Halifax Health Medical Center,** my doctors and my other health care providers (together "Providers") to use and disclose (release) health information about me as described below.

1. The health information that may be used and disclosed includes:

- All information collected during the study described in the Informed Consent Form for the study; and
- Health information in my original medical records that is relevant to the study.

2. The Providers may
   - Use and share my health information among themselves and with the sponsor of the study, Eli Lilly and Company, and its representatives and contractors (together "Sponsor"); and
   - Disclose my health information to representatives of government agencies, review boards, and other persons who watch over the safety, effectiveness and conduct of research.
3. The Sponsor may use and share my health information as permitted by the Informed Consent Form and with its business partners in drug development
4. The sponsor will use the study data for research purposes to support the scientific objectives of the study described in the consent document, to assess the safety or efficacy of any drug or treatment included in the study, to better understand the disease(s) included in the study, or to improve the design of future studies.
5. Study data that does not directly identify you may be published in medical journals or shared with others as part of scientific discussions.
6. You have the right to see and copy your personal health information related to the research study for as long as this information is held by the study doctor or research institution. However, to ensure the scientific integrity of the study, you will not be able to review some of the study information until after the study has been completed.

If you cancel your authorization, the study doctor and staff will no longer use or disclose your personal health information in connection with this study, unless the study doctor or staff needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. The sponsor will still use study data that was collected before you cancelled your authorization. If you cancel your authorization, you will no longer be able to participate in the study.

7. Once my health information has been disclosed, federal privacy laws may no longer protect it from further disclosure.

8. Please note that you do not have to sign this Authorization, but if you do not, you may not participate in the study. You may change your mind and revoke (take back) this Authorization at any time and for any reason. To revoke this Authorization, you must contact the person below. He/she will make sure your written request to withdraw your permission is processed correctly.

   Clinical Trials Coordinator

   Halifax Health Center for Oncology

303 N. Clyde Morris Blvd.

Daytona Beach, FL 32114

Phone (386) 254-4213

FAX (386) 257-0321

However, if you revoke this Authorization, you will not be allowed to continue taking part in the study. Also, even if you revoke this Authorization, your Providers and the Sponsor may continue to use and disclose the information they have already collected to protect the integrity of the study or as permitted by the Informed Consent Form.

9. This Authorization does not have an expiration (ending) date.

10. You will be given a copy of this Authorization after you have signed it.

Signatures:

I agree that my personal health information may be used for the research purposes described in this form.

Signature of Patient:_____ Date: _____

Printed Name of Patient: _____

Signature of Person Obtaining Permission: _____ Date:_____

Printed Name of Person Obtaining Permission:_____

Prescreening Patient Information and Consent Form Attachment 2 Signature Page

YOUR CONSENT TO TAKE PART IN THIS STUDY

I have been given a copy of 12 pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study. By signing this document, you are confirming that:

(1) I have carefully read and understand the information presented in this consent document.

(2) I voluntarily agree to be a part of this study and will follow all study procedures and provide all required information.

(3) The purpose and procedures related to this research study have been fully explained to me and I have had the opportunity to ask questions and all of my questions were answered to my satisfaction.

(4) I have received my own signed, dated, and timed copy of this document

(5) I understand that this study is voluntary and that I am free to withdraw this authorization and to discontinue my participation in this program any time. The consequences and risks, if any, of withdrawing from the program while it is ongoing have been explained to me.

(6) You authorize that your health information can be used and shared as described in this form.

(7) You do not give up any of your legal rights by signing this form.

(8) I understand that such withdrawal will not affect my ability to receive medical care to which I might otherwise be entitled.

_____

Participant's Printed Name

_____ _____ _____

Participant's Signature Date Time

_____

Printed Name of Impartial Witness (if applicable)

_____

Signature of Impartial Witness Date Time

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions and voluntarily agreed to be in this study.

_____ _____

Printed Name of Person Conducting Informed Consent Discussion

_____ _____ _____

Signature of Person Date Time

Conducting Informed Consent Discussion

Statement of Investigator:

I certify that I have taken part in the consent process before the participant's signature and discussed the details of the study, anticipated benefits, potential risks and discomforts, and treatment alternatives. I have answered any and all questions the participant and/or family have asked.

I certify that I am signing this form after the participant's signature has been obtained and before randomization and/or treatment.

_____

Physician's Printed Name

_____ _____ _____

Physician's Signature Date Time

Each person who signs the consent must personally enter the date for his/her signature

This section is to be completed by an employee of Halifax Health Medical Center, "the study center" if they are taking part in this research.

You are an employee of Halifax Health Medical Center "the study center" where this research study is taking place. The purpose of this information is to make sure that you have not been influenced or pressured to agree to be in this study because you are an employee of the study center.

Your taking part in this research study is voluntary. You do not have to be in this study because you are an employee of this study center. You may choose not to take part or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled. Your decision to be in the study or to leave early will not have any effect on your job or employment benefits.

I understand I am free to stop my study participation at any time without giving a reason and without effect on my medical care.

Please mark your choice below. I freely accept to participate in this study. (Please initial beside choice.)

____Yes	**____No**

*Participant Printed Name:*_____

Participant Signature:_____

Date:_____ Time:_____