

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co. Inc. MK-1439-007, Amendment 7, 10/17/12
Multicenter, Double-Blind, Randomized, 2-Part, Dose Ranging Study to Compare the Safety, and
Antiretroviral Activity of MK-1439 Plus TRUVADA® Versus Efavirenz Plus TRUVADA® in Antiretroviral
Treatment-Naïve, HIV-1 Infected Patients

FUTURE BIOMEDICAL RESEARCH CONSENT FORM

Your contacts for this study at the Hospital of the University of Pennsylvania [HUP] are:

Site address: 502 Johnson Pavilion, Philadelphia, PA 19104

Principal Investigator:	Pablo Tebas, MD	(215) 349-8092
Manager:	Joseph Quinn, RN, BSN	(215) 349-8092
Study Nurses:	Jenna Lewis, RN, BSN	(215) 349-8092

24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call

INTRODUCTION

You have already agreed to take part in the main research study, "Multicenter, Double-Blind, Randomized, 2-Part, Dose Ranging Study to Compare the Safety, and Antiretroviral Activity of MK-1439 Plus TRUVADA® Versus Efavirenz Plus TRUVADA® in Antiretroviral Treatment-Naïve, HIV-1 Infected Patients" which we will call 'the main study' in this document. You are also being invited to take part in a separate study we will call "the sub-study". This consent form has information to help you decide if you want to take part in the sub-study. Take your time, and read this form carefully. This consent form may contain words that you do not understand. Please ask the study doctor or study staff to explain any words that you do not know or any information that is unclear or confusing. You should not sign this form until you understand all of the information presented in the following pages and until all of your questions about the research have been answered to your satisfaction.

The study doctor will be paid by the Sponsor, Merck & Co., Inc., for conducting this study.

What is this SUB-STUDY about?

The purpose of this sub-study is to find out more about what causes disease and the differences in the way that people respond to drugs and therapies. We will look at components of your samples and how they relate to the way that drugs and therapies work and relate to human disease and health. Many differences in the way people respond to drugs can be learned by studying differences in:

- 1) genes, which are found in your DNA and
- 2) molecules made by genes like proteins and breakdown products called metabolites. These are found in parts of your blood called plasma or serum.

For example, with some drugs we know that there are differences in genes that can change how long the drug stays in the body. Scientists are also learning more about differences in genes that may predict whether a subject will be at risk for disease. The more we learn about these differences, the more it will help to improve our understanding and treatment of patients. These tests are exploratory research. They are different from testing done to diagnose you with a genetic disease or find out your risk of having a genetic disease.

We may also use your samples to look for "biomarkers". A biomarker is something found in the blood, other body fluids, or tissues that can be used to measure the progress of disease or the effects of treatment. An example of a biomarker is looking at the fat levels of your blood to predict your risk of heart disease.

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What Do I Have to Do If I Am In this Sub-study?

You are being asked to provide:

- a) blood samples for DNA. This blood sample will be obtained during one of your main study visits. Less than 2 teaspoons (10 mL) of blood will be taken.
- b) blood samples for plasma for exploratory analyses. 90mL of blood will be collected over 6 study visits. Approximately 6 tablespoons of blood will be taken.

Your agreement to give these samples *is entirely up to you*. Whether or not you decide to participate in the sub-study, you may still participate in the main study.

All samples will be used by the Sponsor or designees.

What bad effects can happen to me by giving these biological samples?

The main study may already involve blood or other sample collection. Additional blood will be taken for this sub-study. The blood sample will be drawn at the same time a routine blood test is done and so there will not be an added risk for you. No extra needle stick will be needed. The amount of blood taken for the study will not be harmful to you. The risks in providing blood samples for this research study are the same as when blood for the main study is taken or for purposes of your standard medical care. You may have pain, bruising, lightheadedness, and rarely, infection.

- There is a risk that if people other than the researchers get your medical and genetic information they could misuse it. The Sponsor has strict privacy and confidentiality protection procedures to prevent this from occurring so the chance of this happening to you is extremely small. To help prevent others from finding out anything about you, your name and other information that directly identifies you will not be included with your sample or your medical and genetic information.

If I have an adverse (bad) effect, who will pay the doctor and hospital bills?

If you become sick or injured directly from a properly performed sample collection procedure, the sponsor will pay for the reasonable costs of medical treatment. The study sponsor will not provide any other form of compensation.

What benefit can I expect from the giving these samples?

There is no direct benefit to you for taking part in this sub-study. However, there may be a benefit to people in the future because this sub-study is focused on developing better treatments and understanding human disease and health. The Sponsor does not intend to provide you with ownership or financial benefits that may result from this sub-study.

How will information that identifies me be protected?

Information about you will be collected and shared as described in the main study consent form. This information will then be used in the sub-study consistent with the main study consent, this sub-study consent and any related consent that you have signed giving permission to use your personal health information.

All identifying information collected in this sub-study will be kept strictly confidential, except as may be required by law or regulatory authority request. If any publication results from this research, you will not be identified by name.

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In addition, you will be asked to provide information about your ethnicity based upon your family history. This information will help us learn how drugs impact different groups of people. You do not have to provide this information if you do not want to, and you may still participate in this sub-study.

To protect your privacy, we will only use a subject number, instead of your name or other identifiers, on your sample(s). Your name and other information that directly identifies you will not be disclosed outside of the research clinic and will not be known by the Sponsor. A unique code will be applied to your samples at the site. The study investigator will keep the key linking your personal information to this code at the study site. We have set up study records to keep your participation and all your test results separate and confidential.

Your sample will be sent to a facility designated by the Sponsor. Your sample will be processed, and a different unique number will be applied to your sample. The "key" that will link the sample at the Sponsor-designated facility with the number used on your sample taken at the clinic will be maintained in a secure system under strict supervision and security by authorized personnel and will not be released to clinicians or researchers.

Results from this sub-study will be maintained separately from the clinical trial results. An entrusted keyholder, someone who is not involved in the clinical study or the biomarker research, will hold the key files. Only the entrusted keyholder will have access to information that links clinical trial results to sub-study results. All reports from the entrusted keyholder will be de-identified for release to researchers. No test results from this sub-study will be kept in your medical record.

Although all identifying information will be removed from your sample before it is analyzed and stored, it is possible that members of a Health Authority or other persons required by law may have to see your study information. For example, a significant safety finding in the main study may require connecting your study information with these sub-study samples.

Will I be provided with the results of these analyses?

No. You will not be provided the results of this sub-study. The sub-study is exploratory research and is not designed to provide any information that is useful to you or your doctor. Exploratory research tests are performed under conditions which are different from the types of laboratory testing that your doctor may do. Therefore, it would not be appropriate to provide you or your doctor these results. The Sponsor also will not provide the analyses to your family, your insurance company or your employer. Research information from this sub-study will not become part of your medical records.

If there are critical safety findings discovered from the sub-study while you are still actively enrolled in the main study the Sponsor will contact all study doctors and offer to pay for clinical diagnostic testing. If important research findings are discovered after you have stopped taking part in the main study, the Sponsor will publish results, present results in national meetings, and make results accessible on a public website in order to rapidly report this information to doctors and subjects.

What will happen to my sample(s)?

Your sample(s) will be shipped to a central laboratory, Quest Diagnostic Clinical Trials, Valencia, California, and then sent to the Sponsor's designated storage facility. Your samples will be stored under strict supervision in a limited access facility which operates to assure the security and integrity of the samples.

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Your sample(s) s will be securely stored for up to 20 years. At this time, your specimen will be physically destroyed. The Sponsor reserves the right to destroy your sample(s) for any reason, during the storage period. We will only analyze the blood or tissue cells you provide to us. Your blood cells will not be made to grow in the laboratory.

Your sample(s) may be stored for longer than these specified periods if the sponsor is required to answer questions from a regulatory or governmental agency. In this special circumstance, samples will be stored until these questions have been adequately addressed.

During the 20 year period that your samples are stored, no additional permission will be obtained from you and you will not be notified when testing is performed on your sample.

The research will be monitored and reviewed by a committee of the Sponsor's scientists and clinicians.

Can I request that my sample(s) be destroyed?

At any time, you may request that the Sponsor destroy your sample by contacting your study site. As long as it is possible to identify your samples (i.e., your samples are still labeled with information that can still be linked back to you), then the Sponsor will destroy the sample. However, data obtained from your samples prior to receiving your request for destruction will not be deleted. If you request destruction of your sample(s), you will not lose any benefits, medical treatment or legal rights to which you are otherwise entitled.

Withdrawing from the main study does not mean that your sample(s) used for this sub- study will automatically be destroyed. If you want your samples to be destroyed after you withdraw from the study, you will have to make a request for them to be destroyed.

SOURCE FOR ADDITIONAL INFORMATION

For questions about this study or a research-related injury, contact:

- Pablo Tebas, MD (215-349-8092)
- Clinical Trials Unit (215 349-8092)

You will receive a signed copy of this consent form.

I have read this consent form. All my questions have been answered. I consent to provide samples under the conditions described in this consent form.

Signature of Volunteer

Date

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Signature of Person Conducting Review of Consent

Date