

**TITLE: A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-1439A Once-Daily Versus ATRIPLA™ Once-Daily in Treatment-Naïve HIV-1 Infected Subjects**

**PROTOCOL No.: MK-1439A-021**

**Consent Type: Future Biomedical Research**

**Sponsor:** Merck Sharp & Dohme Corp., (a subsidiary of Merck & Co. Inc.)

**Study Doctor:** Pablo Tebas, MD  
(215) 662-6059 (Immunodeficiency Program Doctor On Call) - 24-hour number  
(215) 349-8092 - office number

**CONSENT**

You have already agreed to take part in the main research study *A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-1439A Once-Daily Versus ATRIPLA™ Once-Daily in Treatment-Naïve HIV-1 Infected Subjects* 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 document has information to help you decide if you want to take part in the sub-study. Take your time, and read this document carefully. This consent document 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 document 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.

As noted in the main study, the study doctor [or institution] will be paid by the Sponsor, Merck & Co., Inc., for conducting this sub-study.

**About This Sub-Study**

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 the samples collected from you as part of your participation in the main research study 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
- 2) molecules made by genes like proteins and breakdown products called metabolites.  
These are found in parts of your blood called plasma or serum.

Everyone's genes are a little different. Information about these differences among people can help researchers understand more about diseases and how to best use drugs to treat them.

Differences in genes, proteins or metabolite patterns among people can also help researchers understand how different people respond to drugs.

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 scientists learn about these differences, the more it will help to improve understanding and drug treatment of future patients. This is called exploratory research. Exploratory research is different from testing done to diagnose genetic diseases or to determine one's 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 in blood to predict risks of heart disease.

### **What am I being asked to do?**

You are being asked allow the collection and/or use of:

- a) blood samples for plasma. These will be collected over 3-4 study visits. Less than 4 tablespoons (60 mL) of blood will be taken.
- b) any left over DNA samples collected in the main study, that would routinely be thrown out after the main study is over.

Your agreement to participate in this sub-study is 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 tested at the sponsor's laboratory or laboratory designated by the Sponsor.

### **What bad effects can happen to me by allowing the collection of these biological samples?**

The main study in which you are taking part may already involve blood or other biological sample collection. Additional blood will be collected for the research described in this consent document. The blood sample will be collected at the same time a routine blood test is done in the main study. No extra needle stick will be needed. The risks in collecting blood samples for this sub-study are the same as those when blood is collected for the main study. Possible side effects from blood drawing included faintness, inflammation of the vein, pain, bruising, or bleeding at the site where the needle enters the skin. There is also a slight possibility of 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 are injured as a direct result of the study drug or a procedure required by the study plan, the study sponsor will pay the reasonable (customary treatment) costs of medical treatment.

The sponsor will determine if the injury is caused by the study drug and the reasonableness of the expenses taking into consideration the study doctor's evaluation, other physicians' evaluations of the subject, sponsor's experience with the study drug and other relevant factors.

The study sponsor has no plans to provide any other form of compensation. You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing this consent document.

If you are injured during this study, your study doctor will discuss with you the available medical treatment options.

**What benefit can I expect from my participation in this sub-study?**

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 has no plans to provide you with ownership or financial benefits that may result from this sub-study. You do not give up any legal rights by signing this document.

**Who will be able to see my records and know that I am in the sub-study?**

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.

Information from this sub-study will be given to the sponsor. It will also be given to the health authorities such as the U.S. Food and Drug Administration (FDA). Unless otherwise required by law, medical records which identify you and the consent document signed by you may be looked at and/or copied for research or regulatory purposes by:

- the study doctor and staff;
- the sponsor;
- those working for the sponsor;
- the institutional review board; and
- government agencies in other countries where the study drug may be considered for approval.

All identifying information collected in this sub-study will be kept strictly confidential, except as may be required by law or regulatory authority request. Because of the need to release information, complete confidentiality cannot be promised. The study results may be published in medical journals or presented at medical meetings, but your identity will not be revealed.

To protect your confidentiality, only a subject number, instead of your name or other identifiers will be placed 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 main study 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 the main study 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(s) before it is analyzed and stored, it is possible that members of a Health Authority, such as the FDA, 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 exploratory test results to your family, your insurance company, your employer or others. 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, Valencia, CA, 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.

Your sample(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(s) by contacting your study site. As long as it is possible to identify your sample(s), the Sponsor will destroy the sample. However, information obtained from your sample(s) prior to receipt of 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.

**Who do I call if I have questions about...**

- The study: call the study doctor at the telephone number listed on page 1 of this informed consent document.
- A study-related injury: call the study doctor at the telephone number listed on page 1 of this informed consent document. If you go to the hospital or emergency room, tell the hospital doctor that you are taking part in a research study.
- My rights as a person in the study: If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write Schulman Associates Institutional Review Board, Inc., 4445 Lake Forest Drive, Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST.

You will receive a signed copy of this consent document.

I have read and understand this consent document. All my questions have been answered. I consent to the collection and use of biological samples under the conditions described in this consent document.

\_\_\_\_\_  
Printed Name of Subject

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date (MM/DD/YYYY)

\_\_\_\_\_  
Printed Name of Person Conducting  
Review of Consent

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date (MM/DD/YYYY)

**CONSENT FOR SUBJECTS WHO CANNOT READ**

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

\_\_\_\_\_  
Printed Name of Impartial Witness

\_\_\_\_\_  
Signature of Impartial Witness\*

\_\_\_\_\_  
Date

\*Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent and any other written information supplied to the subject. **Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance**