

GlaxoSmithKline Group of Companies, EPZ108859, Version Dated 05-Jan-2007

Safety and Efficacy of an Initial Regimen of Atazanavir + Ritonavir + the Abacavir/Lamivudine Fixed-Dose Combination Tablet for 36 weeks followed by Simplification to Atazanavir with the Abacavir/Lamivudine Fixed-Dose Combination Tablet or Maintenance of the Initial Regimen for an Additional 48 weeks in Antiretroviral-Naïve HIV-1 Infected HLA-B*5701 Negative Subjects

CONSENT FORM FOR PHARMACOGENETIC RESEARCH

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IRB APPROVAL DATE: 05/10/07EXPIRATION DATE: 04/24/08

24-hour emergency Number: (215) 662-6059 (ask for Infectious Diseases Fellow on call)

This form is in addition to the consent form and authorization you signed for the clinical study for Epzicom, Reyataz, and Norvir. All of the information in the main study's consent form still applies.

Purpose and Description of the Research

The purpose of this consent form is to explain what pharmacogenetic research is and to ask you to give a blood sample that may be used in this research. The sponsor of the research is the GlaxoSmithKline group of companies [referred to as GSK in this consent]. The study doctor is paid by GSK to conduct this research. This study may have about 500 subjects at about 75 sites.

What is pharmacogenetic research?

Genes, which we inherit from our parents, may control the way we react to or handle a medicine. Pharmacogenetics is the study of differences in how our bodies respond to or handle medicines. This pharmacogenetic research is looking at genetic differences to better understand why people react differently when they get the same medicine. If it appears that there is a difference in the way people respond to or handle Epzicom, Reyataz, and/or Norvir, GSK may study these differences using your genes or genetic material taken from your blood sample.

What exactly will participation in the research involve?

If you choose to take part in this research, a qualified medical worker will take about 10 ml (or 2 teaspoons) of your blood. In the unlikely case that there is a problem processing your sample, then we may ask you to give a second sample.

What are the risks involved with blood sampling?

The physical risks of giving a blood sample are the same as those for any blood sample taken from a vein. You may feel faint, experience mild pain, bruising, irritation or redness at the site of puncture. In rare cases an infection could develop.

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What are the benefits of participating in this research study?

There will be no direct benefit to you by taking part in this pharmacogenetic research. You may help scientists understand why people react to or handle Epzicom, Reyataz, and/or Norvir differently. This may help identify who is more likely to respond to Epzicom, Reyataz, and/or Norvir and who may experience side effects.

Will there be compensation for participation in the research?

You will not receive any payment for taking part in this pharmacogenetic research.

What other options are there?

You have the choice not to take part in this research.

How are privacy, data protection and confidentiality protected?

As part of the study, medical information about you will be collected and analyzed along with your sample. This medical information can include demographic information (for example, your date of birth, your race or your sex).

To protect your privacy, your sample and medical information will be labeled (or "coded") with a study subject number, not your name. Only your study doctor and his or her staff will keep the link between your subject number and your name.

Your study doctor has been told to keep your pharmacogenetic information including your consent in a separate, secure file, which is not part of your medical records. GSK will control access to its files that hold your coded information and results. Your name will not appear in any publications or reports about this research.

GSK or those working with GSK (for example, other researchers) will only work with your sample for the use stated in this consent. Samples will be stored securely. GSK will require anyone who works with your sample to agree to hold the research information and any individual results in confidence.

Medical information about you may be produced as part of the research or study procedures. If at the time of the study, this information is known to be relevant to your medical care, it will be given to the study doctor who will be encouraged to share it with you or your doctor. You will be told if any of this medical information requires confirmation using a clinical test. This is important because some research results are for research purposes and may have only limited relevance for clinical diagnosis or treatment.

Individual research results that are not known to be relevant to your medical care at the time of the study will not be released to anyone, unless required by a governmental agency or other legal authority. "Anyone" includes you, your family, your doctor, your insurance company, and your employer.

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GSK has taken appropriate measures to ensure the confidentiality of the research-related information. However, if you pass on your individual results (if obtained by you), there is a possibility that this could have an effect on your insurance or employment. This risk is similar as if you were to disclose any type of personal medical information to a third party.

Medical information, samples and research results from you and other research participants may be studied by GSK to make medicines or tests to determine the body's response to or handling of medicine. Your information and any results will be put in a computer and stored in electronic databases. International regulations for information on computers and relevant laws on processing personal information will be strictly adhered to. Your information, sample, and results could be sent to other researchers working with GSK and to other GSK sites.

By agreeing to take part in this research, you will allow your medical information, sample, and pharmacogenetic results to be reviewed as part of collecting and analyzing study results. The people who may check this research include GSK, people working with GSK on this research, ethics committees (institutional review boards), and regulatory authorities such as the FDA. These persons are required to maintain the confidentiality of the information.

Compensation for Study-Related Injury

If you have a medical emergency during the study you may contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

In the event of any physical injury resulting from research procedures, medical treatment will be provided without cost to you, but financial compensation is not otherwise available from the University of Pennsylvania. If you have an illness or injury during this research trial that is not directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

Is participation in this study voluntary?

Participation in this pharmacogenetic research is voluntary. You may decline to take part now or you may decide to take part and then change your mind. GSK may store your sample for up to 15 years after the last subject completes the study or GSK may destroy your sample at an earlier time. If you decide not to participate or to withdraw your consent after starting the study, you do not have to give a reason and there will be no change to your medical treatment or to your participation in the Epzicom, Reyataz, and Norvir study. If you withdraw from this research, your

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sample will be destroyed and GSK will only keep and study information collected/generated up to that point.

If you withdraw from the main study, you will be given the following options:

- Your sample is retained for pharmacogenetic research, or
- Your pharmacogenetic sample is destroyed.

In special cases, your sample may not be used. This might happen if there are not enough subjects, if the study is stopped for other reasons, or if no questions are raised about how people respond to or handle Epzicom, Reyataz, and/or Norvir.

Disclosure of Protected Health Information

Please refer to the HIPAA Authorization form for the main study.

Commercial Issues

GSK and/or others intend to claim sole ownership of any research results consistent with this consent. The results of this research may have commercial or intellectual property value. By signing this consent, you agree that GSK can apply for patents and you understand that you will not receive any financial benefit that might come from the research.

Who can you call for more information about this research study?

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

- Pablo Tebas, MD (215-615-4321)
- Clinical Trials Unit (215 349-8092)

For questions about your rights as a research subject, contact:

- Director of Regulatory Affairs at the University of Pennsylvania by phoning (215) 898-2614

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SUBJECT'S STATEMENT OF CONSENT

*Safety and Efficacy of an Initial Regimen of Atazanavir + Ritonavir + the Abacavir/Lamivudine Fixed-Dose Combination Tablet for 36 weeks followed by Simplification to Atazanavir with the Abacavir/Lamivudine Fixed-Dose Combination Tablet or Maintenance of the Initial Regimen for an Additional 48 weeks in Antiretroviral-Naïve HIV-1 Infected HLA-B*5701 Negative Subjects*

A copy of this Consent Form (signed and dated) must be given to the subject or legal representative.

My signature below indicates that:

1. I have read this form and the research has been explained to me.
2. I have been able to discuss the research and ask questions. I am satisfied with the answers, so far.
3. I have been given the time to consider whether or not to take part in this research.
4. I have freely decided to take part in the research study described in this form.
5. I will be given a signed and dated copy of this consent form.

Subject's Name (Please Print): _____

Subject's Signature: _____ Date: _____
(Day/Month/Year)

Name and Signature of Individual Obtaining the Subject's Consent:

Name (Please Print): _____

Signature: _____ Date: _____
(Day/Month/Year)