**UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM**

**ING117172 AMENDMENT 1, 12-AUG-2013: A Phase IIIb, randomized, open-label study of the safety and efficacy of dolutegravir/abacavir/lamivudine once daily compared to atazanavir and ritonavir plus tenofovir/emtricitabine once daily in HIV-1 infected antiretroviral therapy naïve women**

***CONSENT TO RESTART STUDY MEDICATION AFTER LIVER EVENT***

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

| | | |
|---|---|---|
| Principal Investigator: | Pablo Tebas, MD | (215) 349-8092 |
| Coordinator: | Joseph Quinn, RN, BSN | |
| Study Nurse: | Aleshia Thomas, RN, BSN | |

*Site address: 502 Johnson Pavilion Philadelphia PA 19104*
*24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call*

---

**Question 1. What is study drug restart?**

You have already consented to participate in Study ING117172. This is another consent form for study drug restart after a liver related safety event. It is in addition to the consent form you signed at the start of this study. Please review the consent form you signed at the start of the study again now because the content of that consent form will continue to apply if you now decide to consent to the study drug restart.

You have had a liver related safety event (increase in certain liver lab tests with or without symptoms) that the study doctor feels was not caused by your taking the study drug. Treatment with the study drug was stopped due to the liver related safety event. Your liver enzymes (certain liver lab test results) and overall safety are being followed closely.

The study doctor reviewed information about the study drug and your liver related safety event. This review was done in order to decide if taking the study drug again may help your HIV condition. This is called study drug restart.

Study drug will only be restarted if the study doctor feels that you may have been helped by it (stable or improving) before you had the event and the study doctor feels the benefits of restarting the study drug are higher than the risks. Only you, with the help of the study doctor, can decide if you want to take the study drug again.

If you take the study drug again, you may or may not be helped by it - this is the same as when you first took study drug. Serious problems, including serious liver injury or death, may sometimes occur if you take the study drug after such an event.

After you have read this entire form and had the chance to ask the study doctor any questions, if you agree to take the study drug again, sign the page at the end of this form.

If you agree to take the study drug again, you will continue to be followed closely for both good and bad effects.

**UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM**

ARIA: Restart Medications after Liver Event

**Question 2. What procedures are part of restarting study drug?**

As part of restarting study drug, the study doctor will direct you on when and how you should take the study drug again.

Additional drugs and equipment will be available to ensure your safety when you take the study drug again.

You will need to return to the clinic once a week for at least one month to closely follow your safety when first taking the study drug again. You may or may not return to your usual schedule after that time.

If you have serious safety problems, you may be asked to return to the clinic for more tests. This may include more blood tests. The study doctor will explain these tests to you if they are needed. You may also need to stop taking the study drug again after talking with the study doctor.

**Question 3. What are the risks of restarting study drug?**

Serious problems, including severe liver injury or death, may sometimes occur if you start taking study drug again. Certain problems can be dangerous if not treated quickly.

Call the study doctor or your personal doctor right away if you:

- Have fever
- Have difficulty breathing
- Have bad skin rash
- Have swelling of your tongue or hands
- Feel very tired or faint
- Feel pain or sick in your stomach and do not want to eat
- Bruise easily or develop itching
- Have yellow eyes or skin, or dark urine
- Become confused.
- Have symptoms of an abacavir hypersensitivity reaction, in that you have symptoms from at least two of the following groups: i) fever, ii) skin rash; iii) shortness of breath, sore throat or cough, iv) nausea or vomiting or diarrhea or abdominal pain, v) severe tiredness or aches or pains or generally ill feeling.

**Question 4. What are the benefits of restarting study drug?**

The study doctor feels your HIV condition was stable or improving, possibly from taking the study drug.

You should discuss the specific reasons why the study doctor thinks you may be helped by taking study drug again.

Although your study doctor believes you may have been helped from taking the study drug previously, you may not benefit after restarting study drug. Even if you may not benefit directly, your safety information may help others who take this drug.

**UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM**

ARIA: Restart Medications after Liver Event

**Question 5. Is my participation voluntary?**

Yes. You may decide not to restart the study drug. If you decide not to take the study drug again or, if you decide to stop taking part at all in the study, you will not be penalized or lose any benefits for which you qualify.

You may talk to your family, friends and or your family doctor to help make your decision. You can take as much time as you like to decide.

**Question 6. Are there alternatives to restarting drug?**

You can decide either to:

1) take the study drug again or

2) you can decide that you do **not** want to take the study drug again and consider one of the alternatives, which include receiving other HIV medications that are approved in your country, taking part in another clinical study, or getting no treatment at this time.

**Question 7. Whom should I call if I have any questions about restarting study drug?**

You can talk with the study doctor, Dr. Pablo Tebas about any questions or concerns you have about taking the study drug again. Call him at 215 349-8092.

If you have any questions about the rights you have while taking part in the restart of study drug, call the University of Pennsylvania Institutional Review Board at (215) 898-2614.

If you think you have been hurt from taking part in this study, or have any questions about side effects, call the research staff listed on page 1 of this document.

You may also refer to the original consent form for guidance on what compensation may be available.

**CONSENT for study drug restart in Study ING117172**

By signing below, I show that:

1. I have read this form. I reviewed the original consent form.
   Study drug restart has been explained to me in a language I understand.

2. I have discussed study drug restart with the study doctor and asked questions. I am satisfied with the answers.

3. I have reviewed the risks and possible benefits of study drug restart.

4. I have had enough time to make my decision.

5. I freely agree to study drug restart as described in this form.

6. I have been given names of study staff whom I can call with any questions or concerns.

**UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM**

ARIA: Restart Medications after Liver Event

Signature Date

Printed name

Signature of legal representative [if any] Date

Printed name of legal representative

Signature of witness [if any] Date

Printed name of witness

**OR**

I **do NOT** consent to study drug restart:

Signature Date

Printed name

Signature of legal representative [if any] Date

Printed name of legal representative

Signature of witness [if any] Date

Printed name of witness