Pregnant Partner Release of Information Form

STUDY INFORMATION: (to be completed by investigator/study doctor)

Study/Protocol ID: **AN INTERNATIONAL, MULTICENTER, PROSPECTIVE OBSERVATIONAL STUDY OF THE SAFETY OF MARAVIROC USED WITH OPTIMIZED BACKGROUND THERAPY IN TREATMENT-EXPERIENCED HIV-1 INFECTED PATIENTS**

Subject ID: _____

USE AND DISCLOSURE OF PREGNANCY INFORMATION

In compliance with the requirements of the study noted above, your partner has informed the study doctor that you are pregnant. ViiV Healthcare Limited (ViiV), the study sponsor, continuously improves knowledge of its products and meets the recommendations of regulatory agencies by collecting information about pregnancy in women who are pregnant or become pregnant while they or their partner are participating in a Viiv study. Viiv therefore requests that you participate in an important safety monitoring activity. This will help ViiV and others to understand the effects, if any, that Maraviroc may have on your pregnancy or your unborn child.

ViiV requests this information whether the pregnancy goes to term or not. Although the study doctor will collect information about your pregnancy and outcome, neither ViiV nor the study doctor will be responsible for any expenses related to this pregnancy.

If you sign this document, you are giving permission for the use and disclosure of your and your child's health information for the purposes of the safety monitoring activity described below. You do not have to give this permission. If you do not sign this document it will not affect your or your partner's right to receive healthcare or other benefits you would normally receive within your country.

TYPE OF INFORMATION REQUESTED

Information related to the progress of your pregnancy and its outcome will be collected by the study doctor. This may include information related to your health, the date of conception, the course of your pregnancy, medical treatments that you receive and the health of your child after birth.

CONFIDENTIALITY

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your health information. The Privacy Rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you. The study doctor is required by the Privacy Rule to protect your health information. After your information is shared with others, such as ViiV, it may no longer be protected by the Privacy Rule.

ViiV respects the confidentiality of personal and medical information, and recognizes the importance of protecting the privacy of information collected. The information will be collected by the study doctor

IRB Approval from 11/1/16 to 1/10/17

and his or her research staff and provided to ViiV or its representatives, including Pfizer. The information sent to ViiV or its representatives will not include your name or address, only a code, and may be used by ViiV and its representatives during and after your participation in this safety monitoring activity. The information collected may be sent to government health agencies, the institutional review board that approved the study and others working on ViiV's behalf. The study sponsor and people working with the sponsor will take appropriate steps to maintain confidentiality. Sensitive personal data (e.g., date of birth) will be collected and processed but ViiV or its representatives will use and disclose your information only for safety monitoring activities or for regulatory purposes. Information will be collected until the birth of your child, although additional information may be requested by the study doctor, if needed. You and your child will not be referred to by name or identified on any report or publication.

You have a general right to access your health information and, where it is shown to be incorrect, request its correction. Any request seeking access or changes to any information should be directed to the study doctor.

RIGHT TO WITHDRAW AUTHORIZATION TO RELEASE INFORMATION

Your participation is voluntary and you are free to withdraw your authorization at any time by informing the study doctor in writing at the contact address provided. If you withdraw your authorization the study doctor will not collect any new health information about you or your child. However, ViiV and its representatives may continue to use and disclose any information already collected. Refusal to participate in this safety monitoring activity will not affect your partner's continued participation in this Maraviroc study or future ViiV studies. This authorization does not have an expiration date.

QUESTIONS

If you have any questions about this form or how your information will be used, please contact the study doctor or their representative at the address and/or telephone number provided. The study doctor is collecting only information related to the progress of your pregnancy and its outcome; you should contact your regular health care provider for any health concerns you may have.

Investigator/Study Doctor (or representative) Name: Pablo Tebas, MD

Address: University of Pennsylvania, 502 Johnson Pavilion

Philadelphia PA 19104

Telephone: 215 349-8092

Please complete this release of information form and return it to the study doctor. PLEASE PRINT.

AUTHORIZATION FOR RELEASE OF MEDICAL INFORMATION

- I voluntarily agree to allow the use and disclosure of my health information related to the progress of my pregnancy and its outcome in connection with this safety monitoring activity as described in this Authorization form.
- I understand that I will receive a signed and dated copy of this Authorization form.
- I understand that I may revoke my Authorization at any time.
- I have had a chance to ask questions and I understand the answers I received.

_____	_____	_____
Full Name *(Printed)*	Signature	Date

If individual is a minor or non-legally consenting adult:

Legally Authorized Representative Full Name (Printed): _____

Legally Authorized Representative Signature: _____

Date: _____

Relationship to Minor: _____

(e.g., father, maternal grandfather):

Pregnancy Healthcare Provider's Name: _____

(e.g., physician, midwife)

Address: _____

_____

Telephone: _____

A copy of this signed authorization form may be provided to your pregnancy healthcare provider by the study doctor.

Your information is very important to us. Thank you for taking the time to complete this form.