SUBJECT INFORMATION AND INFORMED CONSENT FORM ADDENDUM
NEW INFORMATION ADDENDUM

Sponsor/Study Title:	**Gilead Sciences, Inc. / "A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9883/ Emtricitabine/Tenofovir Alafenamide Versus Dolutegravir + Emtricitabine/Tenofovir Alafenamide in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults"**
Protocol Number:	**GS-US-380-1490**
Principal Investigator: (Study Doctor)	**Pablo Tebas, M.D.**
Telephone:	**215 349-8092** **215 662-6059 (24 hours)**
Additional Contacts: (Study Staff)	**Joseph Quinn, RN, BSN** **Yan Jiang, RN, BSN, MSN**
Address:	**Hospital of the University of Pennsylvania** **3400 Civic Center Blvd** **Philadelphia, PA 19104**

NEW INFORMATION

You are currently taking part in the above-named research study. The purpose of this document is to provide you with more information about the study. It is important that you understand the information in this form. You may ask questions at any time.

Since the time you signed the last consent form for this study, new information related to the study has become available:

RISKS

Emtricitabine/Tenofovir alafenamide (F/TAF)

F/TAF is a fixed-dose combination (FDC) pill containing two medications: emtricitabine (FTC) and tenofovir alafenamide (TAF).

The safety of F/TAF FDC is based on the following adverse reactions identified in two year-long clinical studies (GS-US-292-0104 and GS-US-292-0111) in which 866 treatment-naïve subjects received E/C/F/TAF FDC:

Very common (more than or equal to 10%):

- headache,
- diarrhea, nausea,
- fatigue

Common (≥ 1% and < 10%):

- vomiting,
- abdominal pain,
- dyspepsia (indigestion),
- flatulence (passing gas)
- rash

Across all Phase 2 and Phase 3 studies in which 2,394 subjects received E/C/F/TAF FDC, eye disorders were uncommon, balanced between treatment arms, and most were considered by the investigator as unrelated to the study drugs. None were definitive for posterior uveitis, and none resulted in permanent discontinuation of study drugs. One subject in Study GS-US-292-0106 had an adverse reaction of intermediate uveitis (inflammation in the middle of the eye) that was considered related to study drug by the investigator but resolved while the subject continued on study drug without interruption.

Your continued participation in this research is voluntary. You may withdraw from the research study now or at any time without penalty.

All statements contained in the previous Subject Information and Informed Consent Form (ICF) are still valid, including potential benefits and risks.

If you would like, the information in the previous ICF may be reviewed with you.

Check the 'Yes' or 'No' box and initial next to your choice.

☐ Yes, I would like to review the previous ICF _____ (Initial)

☐ No, I do not want to review the previous ICF _____ (Initial)

AGREEMENT TO BE IN THE STUDY

I have read this Subject Information and Informed Consent Form Addendum and understand the contents. I was able to ask questions and all of my questions were answered to my satisfaction.

All statements of informed consent that were contained in the previous Subject Information and Informed Consent Form that I signed are still valid, including potential benefits and risks.

I agree to continue to take part in this research study. A signed and dated copy of this form will be given to me.

Subject

Subject Printed Name	Signature	Date

Person Obtaining Consent

Printed Name & Title	Signature	Date

Witness (if applicable)

Witness Printed Name	Signature	Date