SUBJECT INFORMATION AND INFORMED CONSENT FORM 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 Contact(s): (Study Staff)	**Eileen Donaghy, MSN, CRNP** **Yan Jiang, RN, BSN, MSN**
Address:	**Perelman Center for Advanced Medicine** **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 possible risks of being in this study has become available as noted below.

WHAT ARE THE POSSIBLE RISKS OF BEING IN THIS STUDY?

B/F/TAF (Previously referred to as GS-9883/F/TAF)

B/F/TAF (50/200/25 mg) is a fixed dose combination tablet containing three medications: bictegravir (BIC, B, GS-9883), emtricitabine (FTC, F) and tenofovir alafenamide (TAF). The safety information known about this tablet is from studies GS-US-380-1489 and GS-US-380-1490, in which 634 subjects who had never been treated for HIV received B/F/TAF (50/200/25 mg) for 48 weeks. Adverse drug reactions that have been identified are as follows:

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

- Headache
- Diarrhea

—Common (greater than or equal to 1% and less than 10%):

- Nausea
- Vomiting
- Abdominal pain
- Indigestion
- Passing gas
- Fatigue (feeling tired)
- Rash

If you are infected with hepatitis B virus (HBV), there is a possibility of an unexpected worsening of hepatitis B if you stop taking B/F/TAF.

In a study in pregnant rats, a possible effect on the fertility of male and female baby rats born to mothers given BIC 300 mg/kg/day was observed. The decreases in fertility were slight and remained within the range seen in animals not given any drug in other studies. At the next-lowest dose, 10 mg/kg/day, no effects were noted in the baby rats. At this dose, the mother's BIC plasma exposure was approximately 8-times higher than the estimated blood concentrations of BIC in humans when administered as GS-9883/F/TAF (50/200/25 mg).

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)

☐ This addendum consent **does** alter the risks for investigational product or products, alternatives or benefits. The physician or nurse practitioner investigator will discuss the new risks described in this addendum.

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