SUBJECT INFORMATION AND INFORMED CONSENT FORM
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

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.**
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WHAT IS A CLINICAL RESEARCH STUDY?

You have been asked to take part in a clinical research study. This study will test an experimental drug named GS-9883/emtricitabine/tenofovir alafenamide (GS-9883/F/TAF) fixed dose combination (FDC) for the treatment of HIV-1 Infection**.** An experimental drug means that the United States Food and Drug Administration (FDA), Health Canada, and European Medicines Agency (EMA) have not approved it for use by the general public. The GS-9883/F/TAF FDC will be compared to another drug called Dolutegravir (DTG) plus Emtricitabine/Tenofovir Alafenamide (F/TAF). Dolutegravir is approved for use by the FDA however F/TAF is not.

This Subject Information and Informed Consent Form will explain the study to you. Your study doctor or study nurse will go over this form with you. Your study doctor or study nurse will answer all questions you have about the information in this form.

If you agree to take part, you will be asked to sign and date this form. You will be given a signed and dated copy to keep. No one can force you to take part in this study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to evaluate safety and to determine whether GS-9883/F/TAF FDC is effective against HIV-1 in subjects not currently receiving treatment for their chronic HIV-1 infection compared to DTG plus F/TAF.

The safety and how well both of these drugs are tolerated, will be determined by using physical exams, laboratory tests, and any symptoms or problems you might experience during the study.

HOW DOES THIS STUDY WORK?

If you agree to take part in this study, you will be one of approximately 600 subjects in this study. About 5-10 people are expected to participate at the University of Pennsylvania. The study will take place at approximately 150 centers in North America, Europe, Latin America and Asia Pacific**.** Your study doctor has asked you to come to the clinic for a screening visit to see if you are able to take part.

This is a randomized, double-blind study.

Double-blind means you and your study doctor will not know what study drugs you will be taking.

You will also receive placebo-to-match FDC. Placebo-to-match (or placebo) means the pill has no medicine in it but it looks like the active study drug.

Randomized means the study treatment you take will be chosen by chance (like flipping a coin) to receive one of the two study treatments listed below:

Study Treatment Group 1: Approximately 300 subjects will receive GS-9883 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg (GS-9883/F/TAF) + Placebo-to-match dolutegravir 50mg (DTG) and Placebo-to-match fixed-dose combination of emtricitabine 200 mg/tenofovir alafenamide 25 mg (F/TAF) once daily, without regard to food.

Study Treatment Group 2: Approximately 300 subjects will receive dolutegravir 50mg (DTG) and fixed-dosed combination of emtricitabine 200mg/tenofovir alafenamide 25mg (F/TAF) + Placebo-to-match fixed-dose combination of GS-9883 50mg/emtricitabine 200mg/tenofovir alafenamide 25mg (GS-9883/F/TAF) once daily, without regard to food.

The randomization for this study is in a 1:1 ratio, which means that your chance of being assigned to Study Treatment Group 1 is the same as your chance of being assigned to Study Treatment Group 2.

Following this double-blinded portion of the study, there will be an open-label extension in which all subjects will receive GS-9883/F/TAF. Open-label means you and your study doctor will know what study drugs you will be taking.

GS-9883/F/TAF FDC and DTG + F/TAF FDC will be supplied by Gilead Sciences, Inc., which is also the Sponsor of this study. Your study doctor or study nurse will review the proper storage of all study drugs with you. All study drugs must be taken once a day, at the same time every day, with or without food. It is very important that you take your study drugs every day as instructed by the study doctor.

HOW LONG WILL YOU BE ON THE STUDY?

Taking part in this study will last for a total (Blinded + Open Label) of at least 240 weeks (approximately 55 months) not including the screening period which may last up to 30 days. During this time, you will be required to visit the clinic at least 26 times. The blinded portion of the study will consist of at least 16 visits and it will be followed by an End of Blinded Treatment Visit, which will begin the open-label portion of the study for at least 9 visits.

WHAT ARE YOUR RESPONSIBILITIES?

If you decide to take part in this study, there are some rules you must follow. Some of the rules are listed below. There could be other rules that your study doctor will review with you.

During the entire period of study, you must:

- Not get pregnant or get someone pregnant.
- Tell your study doctors all of the information you know about your health and medications you are taking now or start taking while in the study. If you do not tell the study doctor everything you know you may be putting your health at risk.
- Not use any other medications for the treatment of HIV, other than the study drugs and what is allowed in combination with the study drugs. Your study doctor will also make you aware of any other medications that you will not be allowed to take should you decide to take part.
    - You are not allowed to take the following medications while in this blinded portion of the study: Dofetilide, Phenobarbital, Phenytoin, Carbamazepine, Oxcarbazepine, Rifampin, Rifapentine, Cisapride, St. John's Wort, Echinacea, or any antiretroviral drug that is not part of the study regimen
    - You are not allowed to take the following medications while in the open label portion of the study: Dofetilide, Phenobarbital, Phenytoin, Carbamazepine, Oxcarbazepine, Rifampin, Rifapentine, rifabutin, St. John's Wort, Echinacea, or any antiretroviral drug that is not part of the study regimen
- Bring back all unused study drugs and all study drug containers (even if they are empty or used). Your study doctor or study nurse will count how many doses you have taken. Your study doctor or study nurse will ask about any doses you did not take or if you took any extra doses.
- Follow all instructions given to you while you are taking part in this study. If you do not, you may no longer be able to take part in the study. If you are unsure about what you are supposed to do, ask your study doctor.

WHAT WILL HAPPEN AT EACH STUDY VISIT?

If you agree to take part in the study, you will be asked to come to the clinic for a screening visit. You will have screening tests and procedures to help the Study Doctor decide if you qualify to take part in this study. You will need to be seen at the study center within 30 days before the study starts. The table below shows what will happen each time you visit the clinic. The descriptions of procedures or additional tests are described after the table:

Procedures (what will happen during the Blinded Phase)	**Screening (To see if you qualify for the study)**	**Day 1**	**Wk 4**	**Wk 8**	**Wk 12**	**Wk 24**	**Wk 36**	**Wk 48**	**Wk 60**	**Wk 72**	**Wk 84**	**Wk 96**	**Wk 108**	**Wk 120**	**Wk 132**	**Wk 144**	**Post Week 144/ Every 12 Weeks**	**End of Blinded Study Treatment Visit**	**30-Day Follow-Up**	**ESDD**
Informed Consent	X																			
Review your health history and height	X																			
Review any changes in your health since last visit, including any adverse effects experienced		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Review medications you are taking	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Complete physical examination (may include urogenital/anorectal exam) or symptom-directed physical exam, as needed	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
ECG (recording of your heart)	X	X				X		X				X				X	X (every 48 weeks)	X		X
Measure your vital signs (blood pressure, heart rate, breathing rate, and temperature) and weight	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Take blood and urine samples for laboratory tests (e.g. kidney function, chemistry, hematology, viral load, storage, and blood & urine pregnancy test as applicable for women who are able to have children)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Take blood sample for pharmacokinetic (PK) testing (to know how much study drug is in your body)			X	X	X	X	X													
Take blood sample for Hepatitis C testing	X							X				X				X	X (every 48 weeks)			

Procedures (what will happen during the Blinded Phase)	**Screening (To see if you qualify for the study)**	**Day 1**	**Wk 4**	**Wk 8**	**Wk 12**	**Wk 24**	**Wk 36**	**Wk 48**	**Wk 60**	**Wk 72**	**Wk 84**	**Wk 96**	**Wk 108**	**Wk 120**	**Wk 132**	**Wk 144**	**Post Week 144/ Every 12 Weeks**	**End of Blinded Study Treatment Visit**	**30-Day Follow-Up**	**ESDD**
Take blood for Hepatitis B testing (if negative)	X							X				X				X	X (every 48 weeks)			
Take blood sample for Hepatitis B DNA testing (if positive)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X
Take blood sample for Hepatitis B testing (if positive)	X				X	X		X		X		X		X		X	X (every 24 weeks)			
Estimated total amount of blood in mL that will be drawn up to (5 mL= approx. 1 teaspoon)	71.5	46.5	64	60	72	70.5	60	76	56	58.5	56	68	56	58.5	56	68	56 every 12 weeks/ 58.5 every 24 weeks/68 every 48 weeks	58.5	44	58.5
Fasting		X			X	X		X		X		X		X		X	Every 24 Weeks	X		
Optional Pharmacokinetic (PK) Sub-Study			X	X																
Optional blood sample for pharmacogenomics testing (HLA, UGT1A1 and biomarkers)		X																		
Subject Reported Questionnaires		X	X		X			X												
Optional Peripheral Blood Mononuclear Cell (PBMC) sub-study		X					X				X				X					
Get study drug		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		

Procedures (what will happen in the Open-Label Phase) End of Blinded Treatment Visit	End of Blinded Treatment Visit	End of Week								30-Day Follow-up	Early Study Drugs DC
		12 OL	24 OL	36 OL	48 OL	60 OL	72 OL	84 OL	96 OL		
Estimated total amount of blood in mL that will be drawn up to (5 mL= approx. 1 teaspoon)	58.5	56	58.5	56	68	56	58.5	56	68	44	58.5
Review medications you are taking	X	X	X	X	X	X	X	X	X	X	X
Review any changes in your health since last visit, including any adverse effects experienced	X	X	X	X	X	X	X	X	X	X	X
Complete Physical examination (may include urogenital/anorectal exam) or Symptom-Directed Physical Exam, as needed	X	X	X	X	X	X	X	X	X	X	X
ECG (recording of your heart)	X				X				X		
Measure your vital signs (blood pressure, heart rate, breathing rate, and temperature) and weight	X	X	X	X	X	X	X	X	X	X	X
Take blood and urine samples for laboratory tests (e.g. kidney function, chemistry, hematology, viral load, storage, blood & urine pregnancy test as applicable for women who are able to have children)	X	X	X	X	X	X	X	X	X	X	X
Fasting	X		X		X		X		X		
Take blood sample for Hepatitis C testing					X				X		
Take blood sample for Hepatitis B testing (if negative)					X				X		
Take blood sample for Hepatitis B DNA testing (if positive)	X	X	X	X	X	X	X	X	X		X
Take blood sample for Hepatitis B testing (if positive)			X		X		X		X		
Get study drug	X	X	X	X	X	X	X	X			
Return Study Drug	X	X	X	X	X	X	X	X	X		X

Procedure or Test	**Description**
ECG	You will lie down and have adhesive patches (similar to Band-Aids®) placed on your chest, arms, and legs. In some areas, it may be necessary to shave a small spot of body hair so the adhesive patches can be properly placed on your body. Wires from the machine are then attached to the adhesive patches. These wires record your heart's electrical activity. This test takes about 15 minutes.

Lab Tests and Biologic Sample Collection	**Description**
Blood Samples for Routine Health Testing	Samples of your blood will be tested to check your health. The test will measure: • How well your liver and kidneys are working • If your ability to clot (stop bleeding) is normal If your blood counts, chemistry and fat levels are normal
Pregnancy Test	Females of childbearing potential will have a serum pregnancy test at the Screening visit. A urine pregnancy will be done at each subsequent visit. To take part in this study, the pregnancy test must be negative.
Blood Samples for HIV Viral Load	Blood samples will be taken at every visit to measure how much HIV is in your blood and how your body is reacting against the virus. In addition, the blood samples will be used to look at the genetic sequence of the virus. If the amount of HIV in your blood is too high, the blood samples will be used to see if there are any mutations in certain regions of the HIV-1 gene at screening and throughout the study. Some mutations can prevent certain anti-HIV drugs or drug regimens from reducing the level of HIV-1 in your blood. When this occurs, HIV-1 becomes "resistant" to that drug and possibly other similar drugs.
Hepatitis B and Hepatitis C Virus Testing	Blood samples will be taken to test for the presence of Hepatitis B and Hepatitis C viruses. For subjects who meet the definition of Hepatitis B infection at any visit, the central laboratory will conduct tests to confirm the Hepatitis B every 24 weeks with select tests, and every 12 weeks with select tests.

Lab Tests and Biologic Sample Collection	**Description**
	For subjects who do not meet the definition of Hepatitis B or C infection at any visit, the central laboratory will conduct tests to confirm Hepatitis B or C every 48 weeks, including during the open-label phase.
Urine Sampling	Urine samples will be taken to measure general health, how well your liver and kidneys are working.
Pharmacokinetic (PK) test	Samples of your blood will be tested to see how much study drug is in your body. You will also be asked to complete a diary which will ask questions about the time you took your study drug the day before and if you took your dose of study drug with or without a meal.

Optional Pharmacokinetic (PK) Sub-study	A pharmacokinetic sub-study will be performed at the Week 4 or 8 visit in approximately 30 subjects. The sub-study will include intensive PK sampling and there will be a separate additional Consent Form to review, sign and date for subjects who participate.
Additional non-study test	If you agree, leftover blood from the samples collected during the study may be used to help answer questions that are not part of the main study. If you do not agree, you can still take part in the main study. More information is below.
Optional Peripheral Blood Mononuclear Cell (PBMC) Sub-study	A Peripheral Blood Mononuclear Cell (part of blood cells which fight infection) sub-study will be performed at the Day 1, Week 36, Week 84, and Week 132 Visits in approximately 50 subjects. The sub-study will include an additional blood sample to be collected and there will be a separate additional Consent Form to review, sign and date for subjects to participate.
Optional Pharmacogenomics testing	Pharmacogenomics is the study of how a person's genes affect a person's response to drugs or HIV-1. If you agree, an extra 6mL (about 1 tsp) may be collected at the Day 1 visit for future biomarkers, HLA testing and UGT1A1 testing. HLA is a protein known as human leukocyte antigen. This type of protein is typically used to identify the best donor for an organ transplant recipient. The HLA testing will help us understand how the immune system and HIV-1 interact. UGT1A1 test shows if you have a particular gene. If you do not agree, you can still take part in the main study.

Study Drug	Description
Get study drug	At the visits marked on the table, you will be given study drug to take home with you. Store your study drug as instructed by your study doctor.
Take study drug	Take your study drugs 1 time per day without regard to food at approximately the same time each day.
Bring back study drug and containers	Bring back all unused study drug and all study drug containers (even if they are empty or used). Your study doctor or study nurse will count how many doses you have taken. Your study doctor or study nurse will ask about any doses you did not take or if you took any extra doses.

Additional information about the Day 1, Week 4 to Week 144 and post Week 144 Visits procedures is noted below.

- If you are Hepatitis B positive and enrolled in the study, approximately 6 mL of blood will be collected for additional Hepatitis B testing at all visits. Please note that the blood collection volume for this procedure is already included in the procedures table above.

If any of the test results are found to be abnormal, your study doctor may ask you to come for repeat testing.

End of Blinded Study Treatment Visit
At the End of Blinded Treatment Visit you will discontinue your blinded study drugs and you will begin participation in the open-label extension phase for at least 96 weeks.

Open-Label Extension Visit
Please reference the Study Procedures Table for a listing of procedures that will be performed during these visits. If, after the completion of the 96 weeks of open label extension visit, GS-9883/F/TAF is not available in your country, you will be given the option to continue open label GS-9883/F/TAF.

Early Study Drug Discontinuation (ESDD) Visit
If you are unable to complete your study drug dosing and/or unable to complete the study, you will return to the study clinic for one last visit. Please reference the Procedures Table for a listing of procedures that will be performed at this visit.

30-Day Follow-Up
If you complete the study through the End of Blinded Study Treatment visit and do not wish to participate in the open-label extension, you will be required to return to the clinic 30 days after the completion of study drug for the 30-Day Follow-Up visit. If you prematurely discontinue study drug during the blinded phase or during the open label extension phase and refuse to continue in the study through the Unblinding Visit, you will be asked to return to the clinic 30 days after the completion of the Early Study Drug Discontinuation Visit for the 30 Day Follow-Up Visit. Please reference the Procedures Table for a listing of procedures that will be performed at this visit.

Hepatitis B Management:
If you test positive for Hepatitis B at screening or develop signs or symptoms of active Hepatitis B virus at any time during the study, your study doctor will inform you and discuss all your options with you.

If you are Hepatitis B positive, you will be allowed to participate in this study because F/TAF (which will be given to subjects in both study treatment arms) is active against Hepatitis B. The safety and effectiveness of this study drug in treating your Hepatitis B will be monitored in this study.

If you are infected with Hepatitis B and stop taking your study drug, there is a risk that your hepatitis could get worse.

Hepatitis C Management
If you test positive for Hepatitis C at screening or develop signs or symptoms of active Hepatitis C virus at any time during the study, your study doctor will inform you. Your study doctor will discuss all your options with you if you are Hepatitis C positive. If you and your study doctor decide to treat your Hepatitis C, you may be requested to attend more frequent clinic visits to monitor your Hepatitis C and Gilead will collect this data. Gilead will not be paying for your Hepatitis C treatment.

WHAT RESTRICTIONS ARE THERE DURING THIS STUDY?

The following beverages are restricted during this study:

- Grapefruit juice
- Seville orange juice

Fasting (no food or liquids except water) is required for tests at the Day 1 Visit, Weeks 12, 24, 48, 72, 96, 120, 144, every 24 weeks thereafter, and at the End of Blinded Study Treatment visit. Fasting is also required at the Week 24, 48, 72 and 96 open-label visits. You may not eat or drink (except water) for 8 hours prior to each of those visits. Eating or drinking may affect the results of your urine and blood testing. If you have not fasted, the visit may proceed but you will be asked to return to the clinic within 72 hours in a fasted state.

Concentration of study drug may decrease with antacids. Subjects may not take antacids (e.g., Tums or Rolaids), the ulcer medication sucralfate (Carafate), and vitamin or mineral supplements that contain calcium, iron or zinc for a minimum of 6 hours before and 2 hours after any dose of study drug.

WHAT SAMPLES WILL BE STORED?
WHAT TESTS WILL BE DONE ON THESE SAMPLES?

Some of your blood and urine taken at each visit, except the Screening visit, the 30-Day Follow-up visit, and the Unscheduled visit will be stored. Your stored samples and the information collected about you during the study may be used by the Study Sponsor or its research partners to help answer study questions about the study drug or HIV. At the end of this study, these samples may be held in storage by Gilead Sciences, Inc. for up to 15 years. After 15 years, the samples will be destroyed. You can request that your samples be destroyed at any time by writing to the study doctor at the address listed on the first page of this form.

Viral Infections HIV

Some of your blood drawn at all visits, except the Screening visit, 30-Day Follow-up visit, and Unscheduled visits will be frozen and stored. Your stored samples and the information collected about you during the study may be used by the Study Sponsor or its research partners for additional testing to help answer study questions about the study drugs or HIV. Additional testing may be to test the amount of HIV in your samples as part of the main study, drug levels in your samples, or medical care laboratory data. No human genetic testing will be done without your separate written consent. At the end of this study, these samples may be held in storage by Gilead Sciences, Inc. for up to 15 years.

Viral mutation testing finds changes or “mutations” in parts of the virus being studied. Some mutations can prevent certain drugs or drug treatments from reducing the amount of HIV in your blood and urine. These tests for mutations may be experimental and may not have been approved by the US FDA. The results of these tests are “for research use only”, and the understanding of the test results may not have direct benefit to you.

Blinded Results

Information provided from tests done on your samples will not be given to you or your study doctor. This information will not be placed in your medical records and will have no effect on your medical care.

WHAT ARE THE POSSIBLE RISKS OF BEING IN THIS STUDY?

Common Side Effects for 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 patients 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
- 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).

Dolutegravir (DTG)
Please talk to your study doctor for more details on adverse events or see the Tivicay® package insert for more information.

For female subjects only:
A recent study found that babies born to women taking dolutegravir at the time of becoming pregnant or early in pregnancy may have a higher risk for a type of birth defect called neural tube defects, such as spina bifida. These defects occur early in pregnancy before many women even know they are pregnant. Please speak with your Study Doctor if you have any questions about dolutegravir and the potential risk for neural tube defects.

It is very important while you are in this study that you do not become pregnant. Not having sex is the only certain way to prevent pregnancy.

If you are a woman who chooses to have sex with a male partner, you will be required to use highly effective methods of birth control, throughout the study and for 30 days following the last dose of study drug.
Please speak with your Study Doctor to determine the best method of birth control for you and your male partner during this study.

If you are unable or unwilling to meet the updated requirements for birth control, you will be discontinued from the study.

If you are female and become pregnant or suspect that you have become pregnant while in the study or within 30 days of the last dose of study drug, you will be required to stop taking all study drugs and notify your Study Doctor immediately. You will be discontinued from the study. The Study Doctor will "unblind" your treatment assignment, and report to you which medications you were taking during the study. The Study Doctor will request to track your pregnancy and will report the pregnancy and outcome to Gilead Sciences, Inc., the Sponsor of this study.

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 includes the following adverse reactions identified in two three-year-long clinical studies (GS-US-292-0104 and GS-US-292-0111) in which 866 participants with HIV not previously treated received E/C/F/TAF (another HIV treatment that also contains F/TAF):

Very common (more than or equal to 10%):
- Headache
- Diarrhea
- Nausea
- Fatigue

Common (greater than or equal to 1% and less than 10%):
- Vomiting
- Abdominal pain
- Dyspepsia (indigestion)
- Flatulence (passing gas)
- Rash

Other adverse reactions were identified after approval of F/TAF but were not from clinical studies, so the frequency of occurrence is unknown: hives (urticaria), swelling of the face, lips, tongue or throat (angioedema).

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

Please talk to your study doctor for more details on adverse events or see the F/TAF package insert for more information.

IMMUNE RECONSTITUTION SYNDROME
A condition called immune reconstitution syndrome can happen in some patients with advanced HIV infection (AIDS) when combination anti-HIV treatment is started. Signs and symptoms of inflammation from opportunistic infection that a person has or had

may occur as the medicines work to control the HIV infection and strengthen immune system.

Autoimmune disorders such as Graves' disease (a disease in which the thyroid produces excessive thyroid hormones), polymyositis (a disease caused by inflammation leading to weakness of the muscles), and Guillain-Barre syndrome (a disease that occurs when the body's immune system attacks part of the nervous system, leading to nerve inflammation that causes muscle weakness), have also been reported to occur in the setting of immune reconstitution, however, the time to onset is variable and can occur many months after starting treatment. Call your study doctor right away if you notice any signs or symptoms of an infection after starting study drug.

BLOOD DRAWS
Collecting a blood sample from a vein may cause pain, bruising, lightheadedness, fainting, and very rarely, infection at the site of the needle stick.

ECG
After you have an ECG, you may have mild irritation, slight redness, and itching on your skin where the recording patches are attached. You may have your chest shaved for this procedure.

QUESTIONNAIRES
Some of the questions may seem personal and may make you feel uncomfortable. If you have any questions or concerns while answering these questions, please talk to your study doctor.

FASTING
Fasting could cause dizziness, headache, stomach discomfort, or fainting.

ALLERGIC REACTION
Allergic reaction is always possible with a drug you have not taken. Serious allergic reactions that can be life-threatening may occur. Some things that happen during any allergic reaction to any type of medication are:

- rash
- having a hard time breathing
- wheezing when you breathe
- sudden drop in blood pressure
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

UNKNOWN/UNEXPECTED RISKS AND DISCOMFORTS
There are adverse events that are not known or happen rarely when subjects take these study drugs. You will be told of any new information that might cause you to change your mind about continuing to take part in this study as soon as the information is available.

As with any new drug, extra care has to be taken to monitor the side effects that are not always obvious. If you feel any side effects or unusual symptoms, please notify your study doctor as soon as possible at the phone number listed in this form.

PREGNANCY AND BREAST-FEEDING

Please share this information with your partner if it is appropriate.

The effects of GS-9883/F/TAF and DTG + F/TAF on a developing fetus (unborn baby) as well as on exposed infants are not known in humans. Any female able to become pregnant must have a negative blood pregnancy test to enroll. Females who are breast-feeding will not be enrolled in this study.
It is very important while you are in this study that you do not become pregnant if you are a female, or do not cause others to become pregnant if you are a male. Not having sex is the only certain way to prevent pregnancy.

If you are a man who chooses to have sex with a female partner, you will be required to use effective methods of birth control from the first study drug dose, throughout the study and for 90 days following the last dose of study drug, one of which must be an effective barrier method. Please speak with your Study Doctor to determine the best method of birth control for you and your female partner during this study.

If you cause your female sex partner to become pregnant while you are in the study or within 90 days after your last dose of study drug, the study drug may or may not harm an unborn baby. If you have a female partner who becomes pregnant or suspects that she has become pregnant while you are in the study or within 90 days after your last dose of study drug, you will be required to notify your Study Doctor immediately. As the risk to your partner and unborn baby is not known, it is recommended for your partner to receive appropriate prenatal care. If you agree, your partner will be asked to sign a consent form to allow disclosure of medical information related to pregnancy. Your Study Doctor may need to disclose to your partner details of this study and your taking part in it. The Study Sponsor and the Study Doctor will not be responsible for the costs related to the pregnancy, delivery, or care of your child.

If you are a woman who chooses to have sex with a male partner, you will be required to use effective methods of birth control from the screening visit, throughout the study and for 30 days following the last dose of study drug. Please speak with your Study Doctor to determine the best method of birth control for you and your male partner during this study.

If you are female and become pregnant or suspect that you have become pregnant while in the study and within 30 days of last dose of study drug, you will be required to stop taking all the study drugs and to notify your study doctor immediately. You will be discontinued from the study. The Study Doctor will “unblind” your treatment assignment, and report to you which medications you were taking during the study. The study doctor will request to track your pregnancy and will report the pregnancy and outcome to Gilead Sciences, Inc., the Sponsor of this study.

Other not yet identified side effects could occur to you, your embryo or fetus should you become pregnant during the time you participate in the study or after you have completed the study.

CONDOM USE

It has been proven that condom use decreases the risk of spreading HIV and Hepatitis B between sexually active individuals. To decrease your risk of transmitting the virus to another individual and to decrease the risk of being infected with a different strain of HIV, we recommend that condoms be used for all sexual activity to include oral, vaginal, and anal sexual contact. Condom use is recommended in addition to your current form of birth control. Male subjects must agree to use condoms during heterosexual intercourse and avoid sperm donations while enrolled in the study and for 90 days after administration of the last dose of study drug.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You may not receive benefit from taking part in this study. Studies are a way for doctors to see if a drug is useful in fighting a disease.

Your taking part in this study may help people with HIV-1 infection understand more about the treatment of your disease. By taking part in this study, your health will be monitored closely at study visits.

WHAT ARE YOUR TREATMENT OPTIONS?

Your study doctor will discuss appropriate treatment options and the risks and benefits with you.

You can discuss if you want to have any treatment or if you want to choose other antiretroviral medications (ARVs) to treat your disease, which may include those that are already approved and sold.

WHAT HAPPENS IF YOU DO NOT WANT TO TAKE PART IN THIS STUDY? WHAT HAPPENS IF YOU NO LONGER WANT TO TAKE PART IN THE STUDY?

Your decision to take part in this study is voluntary. You can refuse to take part or stop taking part at any time without giving a reason. If you decide to stop the study at any time, your exit from this study will not affect medical care which you otherwise may receive and you will not be penalized or lose any benefits to which you are otherwise entitled.

Your participation in this study may be stopped at any time by your study doctor, Gilead Sciences, Inc., or regulatory authorities.

Your study doctor may decide for your medical safety to stop your study drug(s) or take you off the study. You may be taken off the study if your study doctor learns you did not give a correct medical history or did not follow instructions for the study. If you are taken off the study, you will no longer receive the study drug(s). If your study drug(s) is stopped, your study doctor will closely monitor your overall health.

HOW MUCH WILLSTUDY TREATMENT COST YOU?

The study drugs used in this study will be given to you at no charge. All study visits and fees for lab tests and procedures that are part of this study will be provided at no cost to you. You or your usual health care payer will be responsible for any other health care costs.

WILL YOU BE PAID TO BE PART OF THIS STUDY?

You will be paid $25.00 for your screening visit. For visits thereafter, Day1 and 10 visits through wk 96 (4, 8, 12, 24, 36, 48, 60, 72, 84 and 96) and every 12 weeks past week 96, you will be paid $40 for every visit you attend. An additional payment of $10 will be made at these visits if you bring back the study drug bottles dispensed at the last visit (empty or with any unused study drugs). Thus if you attend all required visits through week 96, and return your study drug bottles for the study through wk 96, the maximum payment you can receive is $575. If you stop taking study drugs early and complete the Early Study Drug Discontinuation Visit and return the study drug bottles, you will be compensated $50. You will be compensated $50 for the 30-Day Follow-Up Visit that occurs after the Early Study Drugs Discontinuation Visit. You will be paid $50.00 for completed Open-Label Extension Visits and an additional $50.00 for Open-Label Extension Visits that include a DEXA Scan. You will be compensated $25 for any unscheduled visits requested by the study staff. The total payment you will receive for the study depends on how long you participate.

Compensation for the screening visit will be cash; compensation for the other study visits will be given by ClinCard debit card.

Please note that if you receive more than $600.00 compensation in one year for participation in research studies at the University of Pennsylvania, you must provide an Individual Tax Identification Number or Social Security Number for tax purposes.

WHAT HAPPENS IF YOU ARE INJURED?

MEDICAL TREATMENT AND COMPENSATION FOR STUDY-RELATED INJURY

If you become sick or injured as a direct result of taking the study drug and/or following the study procedures, the study site will provide you with medical treatment. The Sponsor, Gilead Sciences, Inc., will reimburse you or the study site for the reasonable and necessary costs of such medical treatment. No other form of reimbursement for study-related injury or illness is offered by the Sponsor. You should immediately contact your Study Doctor at the contact information shown below in the event you experience any study-related illness or injury.

If you receive Medicare benefits, the Sponsor, Gilead Sciences, Inc., is required by law to report payments made to you for treatment, complications, and injuries that arise from this Study. Information that you are taking part in the Study, medical treatments received, Medicare claims, and other personal information about you such as your

name, social security number, and date of birth, will be provided to the Centers of Medicare and Medicaid Services and its agents and/or contractors for this purpose.

You do not give up any legal rights by signing this form. You are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00014040.

WHO WILL HAVE ACCESS TO YOUR MEDICAL RECORDS?

GENERAL STATEMENT ABOUT PRIVACY

Records identifying you will be kept confidential and, to the extent permitted by applicable laws and/or regulations, will not be made publicly available. . Your personal information may be given out if required by law. If you test positive for HIV, Hepatitis B or Hepatitis C, by law we have to report the infection to the City of Philadelphia Health Department/PA Department of Health. We would report your name, gender, racial/ethnic background, and the month and year you were born.

This is to keep track of how many people in the U.S. have HIV infection. It is also to make sure that states get enough money from the federal government to support the medical care of people living with HIV. The Health Department does not share the names of HIV infected people with anyone else. It removes all personal identifiers, such as your name, before giving information on the number of HIV infections to the federal government. Please note that it is likely that this information has been already reported to the PA Health Department as the HIV test being done for this study is not the first test for you. In the event of any publication regarding this study, your identity will remain confidential.

Your coded study information may also be used for additional unanticipated medical and/or scientific research projects in the future relating to your disease or similar diseases and development of the study drug (but at all times in compliance with applicable law and regulation).

Authorization to Use and Disclose Records

The authorization part of the consent gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

What personal health information is collected and used in this study and might also be disclosed?
The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, date of birth
- Social Security Number (if you receive more than $600 for participating in studies at PENN, we will need your SSN for the W-9)
- Personal and family medical history
- Current and past medications or therapies
- Results of physical exams, laboratory tests and procedures you will undergo during this research study

Why is your personal contact and health information being used?
Your personal contact information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are being collected as part of this research study. In some situations, your personal health information might be used to help guide your medical treatment.

Which of our personnel may use or disclose your personal health information?
The following individuals may use or disclose your personal health information for this research study:

The Principal Investigator and the Investigator's study team

Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

Who, outside of UPHS and the School of Medicine, might receive your personal health information?

As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

- Pharmaceutical sponsor (Gilead Sciences): This is the company that supplies drugs for the study. Information regarding safety and adverse effects needs to be collected and monitored.
- Contract Research Organization: Monitors will visit the site on a regular basis to review data and assure accuracy and completeness of information before the data are analyzed.

Regulatory and safety oversight organizations

The Food and Drug Administration and regulatory agencies in other countries

The Office of Human Research Protections

The Study Monitoring Committee

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name or medical record number. Information regarding your health, such as side effects of the study medications you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may UPHS and the School of Medicine be able to use or disclose your personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research repository (database). However, UPHS and the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization to do so
- The University of Pennsylvania's Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place
- As permitted by law

Will you be able to access your records?
Since this is an open-label study, you will be able to access some or all of your medical records after the study is over. The Principal Investigator is not required to release research information to you that is not part of your medical record.

Can you change your mind?
Yes, at any time you may withdraw your approval to allow the use and disclosure of your personal health information as described here. You must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission to use your personal health information, you will also be withdrawn from the research study.

If you withdraw your permission to use any blood or tissue obtained for the study, the Sponsor may need to retain and use any samples that have already been collected to comply with its legal obligations and to maintain the scientific integrity of the study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. You will also be given the UPHS and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your personal health information.

WHAT IS AN ELECTRONIC MEDICAL RECORD?
An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

If you have any questions about the collection and use of information about you, you should ask your Study Doctor.

WHERE CAN YOU FIND MORE INFORMATION ABOUT THIS STUDY?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AGREEMENT TO BE IN THE STUDY

By signing this informed consent form, I acknowledge that:

(1) I have carefully read and understand the information in this form.
(2) The purpose and procedures of this research study have been fully explained to me. I was able to ask questions and all of my questions were answered to my satisfaction.
(3) I have been informed of the drugs and procedures of the study that are being tested. I have been informed of possible risks as a result of taking part in this study that could happen from both known and unknown causes.
(4) I understand that I am free to withdraw my consent and to stop my participation in this study at any time. The possible effect on my health, if any, of stopping the study early has been explained to me.
(5) I understand that stopping the study will not impact my medical care and treatment options.

Subject

Subject Printed Name	Signature	Date

Person Obtaining Consent

Printed Name & Title	Signature	Date

Witness (if applicable)

Witness Printed Name	Signature	Date

Future Research Consent

You are being asked to take part in future research. If you decide to not take part in this future research, you can still take part in the main study.

If you agree to participate in the future research testing, some of your samples may be used for genetic testing.

There are possible non-physical risks associated with the genetic research, such as the risk associated with a breach of privacy or confidentiality. For example, if your genetic research information were disclosed to unauthorized persons, there is the possible risk of discrimination by employers, insurance providers or others.

However, this risk is very low since your research results are subject to doctor-subject confidentiality, and are treated strictly confidentially and steps are taken to keep this risk as small as possible.

A federal law, called the Genetic Information Non-discrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility on premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law. Be aware that his federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

This research may help scientists to better understand:

- How your disease and related diseases work
- The effect of the study drug and/or other medications on the body
- How the study drug is processed by the body
- Who could benefit from the study drug
- Why some people have adverse events

The results of the tests done on your biologic samples will not be given to you or your study doctor. Information from these tests may be printed in a medical journal or presented at scientific meetings. Only a summary of data from all subjects will be used.

The results of this research may lead to an approved product for the treatment, prevention, or confirmation of disease. You understand and agree that by consenting to the storage and testing of your samples for possible future research, you authorize the use of your sample, the by-products of the sample, and any products developed from the sample as described by this form. The Study Sponsor, other researchers, or companies may patent or sell discoveries that result from this research. You will not be paid any money if this happens. You may choose to take part in none, some, or all of the future research, listed below.

If you decide you no longer want to take part in this future testing of your biologic sample(s), your unused sample(s) will be destroyed. The Study Sponsor may continue to use and disclose the results from samples that were tested before you withdrew your consent.

If you decide to no longer take part in the main study or are taken off the main study by your study doctor, the biologic samples you provided for future research will still be kept and may be used for future testing. If you decide you no longer want to take part in this future testing, then your unused sample(s) will be destroyed. You can request that your samples be destroyed at any time by writing to the study doctor at the address listed on the first page of this form.

For this study, you are being asked to let the Study Sponsor store and use the samples listed below for future testing.

Carefully read the sentences below and think about your choice(s).
Check the 'Yes' or 'No' box and initial next to your choice.

1) Store and use your **leftover** blood and urine collected during this study for future research **outside of the main study.** Your samples may be stored and used for up to 15 years after the end of the study.

I agree to allow my leftover blood and urine samples to be stored after the main study testing is complete and used for future research outside of the main study.

☐ Yes_____ *(initial)* ☐ No _____ *(initial)*

Collect, store and use blood sample for pharmacogenomics testing. Pharmacogenomics is the study of how a person's genes affect a person's response to drugs or HIV-1. An additional 6 mL of blood will be collected on Day 1 of the study visit. Your sample may be stored and used for this research for up to 15 years after the end of the study.

I agree to allow my blood sample to be used for pharmacogenomics testing.

☐ Yes_____ *(initial)* ☐ No _____ *(initial)*