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Safety and Efficacy of Bictegravir + Emtricitabine/Tenofovir Alafenamide Versus Dolutegravir + Emtricitabine/Tenofovir Alafenamide in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults

ClinicalTrials.gov ID ⓘ NCT02397694

Sponsor ⓘ Gilead Sciences

Information provided by ⓘ Gilead Sciences (Responsible Party)

Last Update Posted ⓘ 2020-04-07



Study Details Researcher View Results Posted **Record History**

Study Record Versions

- This table shows all the versions of this study record arranged in order by submitted date.
- To view one version of the study record, click the submitted date.
- To compare two versions, select them using the check boxes and click "Compare" at the bottom of the list.

	Version	Date submitted (YYYY-MM-DD)	Changes
☐	1	2015-03-20	None (earliest version on record)
☐	2	2015-03-30	- Study Status - Contacts/Locations
☐	3	2015-04-08	- Study Status - Contacts/Locations
☐	4	2015-04-20	- Study Status - Contacts/Locations
☐	5	2015-04-23	- Study Status - Eligibility
☐	6	2015-05-07	- Recruitment Status - Study Status - Contacts/Locations
☐	7	2015-10-27	Study Status
☐	8	2015-11-23	- Study Status - Arms and Interventions
☐	9	2016-06-07	- Study Status - Study Identification - Study Design - Arms and Interventions - Study Description - Outcome Measures
☐	10	2016-08-22	Study Status
☐	11	2016-12-20	- Study Status - Eligibility - Contacts/Locations
☐	12	2017-06-30	- Study Status - Contacts/Locations
☐	13	2018-01-15	- Study Status - Oversight - Contacts/Locations
☐	14	2018-02-27	- Study Status - Contacts/Locations - Study Description - Study Design - Arms and Interventions - Outcome Measures - Participant Flow - Baseline Characteristics - Adverse Events - More Information
☐	15	2019-03-13	Recruitment Status

☐	16	2020-03-25	- Study Status - IPDSharing
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Version 1: 2015-03-20

Study Details

Study Identification

Unique Protocol ID	GS-US-141-1475
Brief Title	Safety and Efficacy of GS-9883 + Emtricitabine/Tenofovir Alafenamide Versus Dolutegravir + Emtricitabine/Tenofovir Alafenamide in HIV-1 Infected, Antiretroviral Treatment-Naive Adults
Official Title	A Phase 2, Randomized, Double-Blinded Study of the Safety and Efficacy of GS-9883 + Emtricitabine/Tenofovir Alafenamide Versus Dolutegravir + Emtricitabine/Tenofovir Alafenamide in HIV-1 Infected, Antiretroviral Treatment-Naive Adults
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Study Status

Record Verification	2015-03
Overall Status	Recruiting
Study Start	2015-03
Primary Completion	2015-12 [Estimated]
Study Completion	2016-05 [Estimated]
First Submitted	2015-03-20
First Submitted that Met QC Criteria	2015-03-20
First Posted	2015-03-25 [Estimated]
Certification/Extension First Submitted	2016-08-22
Last Update Submitted that Met QC Criteria	2015-03-20
Last Update Posted	2015-03-25 [Estimated]

Sponsor/Collaborators

Sponsor	Gilead Sciences
Responsible Party	Sponsor
Collaborators	

Oversight

U.S. FDA-regulated Drug	
U.S. FDA-regulated Device	
Data Monitoring	Yes

Study Description

Brief Summary	This study will evaluate the efficacy, safety and tolerability of GS-9883 + emtricitabine/tenofovir alafenamide (FTC/TAF) fixed dose combination (FDC) versus dolutegravir (DTG) + FTC/TAF in HIV-1 Infected, antiretroviral treatment-naive adults. This study will also evaluate the pharmacokinetic (PK) profile of GS-9883, FTC and TAF.
Detailed Description	

Conditions

Condition	HIV-1 Infection
Keywords	Adult HIV naive

Study Design

Study Type	Interventional
Primary Purpose	Treatment
Study Phase	Phase 2
Interventional Study Model	Parallel Assignment
Number of Arms	2
Masking	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation	Randomized
Enrollment	75 [Estimated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Treatment Arm 1 - Participants will receive GS-9883 + FTC/TAF FDC + placebo to match DTG once daily for 48 weeks. - Following Week 48, participants will continue to take their blinded treatment and attend visits every 12 weeks until treatment assignments have been unblinded. Participants will return for an unblinding visit and be given the option to participate in an open-label rollover extension and receive GS-9883 + FTC/TAF until it becomes commercially available, or until Gilead Sciences elects to terminate the development of GS-9883 or FTC/TAF.	Drug: FTC/TAF - Emtricitabine/Tenofovir Alafenamide (FTC/TAF) 200 mg/25 mg tablet administered orally Drug: GS-9883 - GS-9883 75 mg tablet administered orally Drug: Placebo to match DTG - Tablet administered orally
Active Comparator: Treatment Arm 2 - Participants will receive DTG + FTC/TAF FDC + placebo to match GS-9883 once daily for 48 weeks. - Following Week 48, participants will continue to take their blinded treatment and attend visits every 12 weeks until treatment assignments have been unblinded. Participants will return for an unblinding visit and be given the option to participate in an open-label rollover extension and receive GS-9883 + FTC/TAF until it becomes commercially available, or until Gilead Sciences elects to terminate the development of GS-9883 or FTC/TAF.	Drug: FTC/TAF - Emtricitabine/Tenofovir Alafenamide (FTC/TAF) 200 mg/25 mg tablet administered orally Drug: DTG - Dolutegravir (DTG) 50 mg tablet administered orally Other Names: - Tivicay® Drug: Placebo to match GS-9883 - Tablet administered orally

Outcome Measures

Primary Outcome Measures	1. Percentage of participants with HIV-1 RNA < 50 copies/mL as determined by the FDA-defined snapshot algorithm. [Time Frame: Week 24]
Secondary Outcome Measures	1. Percentage of participants with HIV-1 RNA < 50 copies/mL as determined by the FDA-defined snapshot algorithm. [Time Frame: Week 12] 2. Percentage of participants with HIV-1 RNA < 50 copies/mL as determined by the FDA-defined snapshot algorithm. [Time Frame: Week 48] 3. The change from baseline in log10 HIV-1 RNA and in CD4+ cell count [Time Frame: Weeks 12, 24 and 48] 4. The incidence of treatment-emergent adverse events (AEs) and treatment-emergent laboratory abnormalities. [Time Frame: Up to 1 year] 5. Maximum observed plasma concentration (Cmax) of GS-9883, FTC, and TAF For a subset of participants who enroll in the PK substudy. [Time Frame: Week 4 or 8] 6. Time to maximum observed plasma concentration (Tmax) of GS-9883, FTC, and TAF For a subset of participants who enroll in the PK substudy. [Time Frame: Week 4 or 8] 7. Observed drug concentration at the end of the dosing interval (Ctau) for GS-9883, FTC, and TAF For a subset of participants who enroll in the PK substudy. [Time Frame: Week 4 or 8] 8. Area under the concentration-time curve over the dosing interval (AUCtau) for GS-9883, FTC, and TAF For a subset of participants who enroll in the PK substudy. AUCtau is defined as concentration of drug over time. [Time Frame: Week 4 or 8] 9. Estimate of the terminal elimination half-life (t1/2) of GS-9883, FTC, and TAF

	For a subset of participants who enroll in the PK substudy. [Time Frame: Week 4 or 8] 10. Trough plasma concentrations for GS-9883, FTC, and TAF This endpoint will measure the plasma concentrations of GS-9883, FTC, and TAF. [Time Frame: Weeks 4, 8, 12 and 24]
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Eligibility

Minimum Age	18 Years
Maximum Age	
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	Inclusion Criteria: • Antiretroviral naïve (≤ 10 days of prior therapy with any antiretroviral agent following a diagnosis of HIV-1 infection) except the use for pre-exposure prophylaxis (PREP) or post-exposure prophylaxis (PEP), up to one month prior to screening. • Plasma HIV-1 RNA levels ≥ 1,000 copies/mL at screening. • Screening genotype report provided by Gilead Sciences must show sensitivity to tenofovir (TFV) and FTC. • Adequate renal function as measured by estimated glomerular filtration rate ≥ 50 mL/min according to the Cockcroft-Gault formula • CD4+ cell count > 50 cells/μL at screening. Exclusion Criteria: • A new AIDS-defining condition diagnosed within the 30 days prior to screening as defined in the study protocol • Chronic Hepatitis B Virus (HBV) infection • Hepatitis C infection (Individuals who are hepatitis C virus (HCV) Ab positive, but have a documented negative HCV RNA, are eligible) • Active, serious infections (other than HIV-1 infection) requiring parenteral antibiotic or antifungal therapy within 30 days prior to Baseline • Participation in any other clinical trial without prior approval from the sponsor is prohibited while participating in this trial

Contacts/Locations

Central Contact Person	• Name: Gilead Study Team • Email: GS9883studies@gilead.com
Study Officials	• Name: Hal Martin, MD, MPH • Role: Study Director • Affiliation: Gilead Sciences
Location	• Foster City, California, United States Status: Not yet recruiting • Los Angeles, California, United States Status: Recruiting • Houston, Texas, United States Status: Recruiting

IPD Sharing

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