



Record 1 of 1



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COMPLETED ⓘ

Study to Evaluate Safety, Pharmacokinetics, and Antiviral Activity of Bictegravir (GS-9883) in Human Immunodeficiency Virus (HIV)-1 Infected Participants

ClinicalTrials.gov ID ⓘ **NCT02275065**

Sponsor ⓘ Gilead Sciences

Information provided by ⓘ Gilead Sciences (Responsible Party)

Last Update Posted ⓘ 2020-11-09



Record History Tab

Compare

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	2014-10-23	• None (earliest version on record)
☐	2	2014-10-27	• Recruitment Status • Study Status • Contacts/Locations
☐	3	2014-11-04	• Study Status • Contacts/Locations
☐	4	2014-11-13	• Study Status • Contacts/Locations
☐	5	2014-11-21	• Study Status • Contacts/Locations
☐	6	2014-11-30	• Study Status

	Version	Date submitted (YYYY-MM-DD)	Changes
			• Contacts/Locations
☐	7	2015-02-06	• Recruitment Status • Study Status • Study Design Results Submission Events (1)
☐	8	2020-09-14	• Study Status • Outcome Measures • Study Identification • Oversight • Study Description • Study Design • Arms and Interventions • Eligibility • Contacts/Locations • Participant Flow • Baseline Characteristics • Adverse Events • More Information
☐	9	2020-10-16	• Study Status • Outcome Measures



Version 7: 2015-02-06

Study Details

Study Identification

Unique Protocol ID	GS-US-141-1219
Brief Title	Safety, Pharmacokinetics, and Antiviral Activity of GS-9883 in HIV-1 Infected Subjects
Official Title	A Phase 1b Randomized, Double-Blinded, Sequential Cohort Placebo-Controlled Study of the Safety, Pharmacokinetics, and Antiviral Activity of GS-9883 in HIV-1 Infected Subjects
Secondary IDs	

Study Status

Record Verification	2015-02
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Overall Status	Completed
Study Start	2014-10
Primary Completion	2015-01 [Actual]
Study Completion	2015-01 [Actual]
First Submitted	2014-10-23
First Submitted that Met QC Criteria	2014-10-23
First Posted	2014-10-27 [Estimated]
Last Update Submitted that Met QC Criteria	2015-02-06
Last Update Posted	2015-02-10 [Estimated]

Sponsor/Collaborators

Sponsor	Gilead Sciences
Responsible Party	Sponsor
Collaborators	

Oversight

U.S. FDA-regulated Drug	
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U.S. FDA-regulated Device	
Data Monitoring	No

Study Description

Brief Summary	This study will investigate the short-term antiviral potency, safety, plasma pharmacokinetics (PK), and the PK/pharmacodynamic (PD) relationship (the dose-response relationship) of GS-9883 at multiple doses in antiretroviral (ART) treatment-naïve adult subjects and subjects who are ART-experienced but are currently off of ART therapy. Up to 32 participants will be enrolled in the study.
Detailed Description	

Conditions

Condition	HIV-1 Infection
Keywords	HIV-1 Infected Adults Treatment Naive

Study Design

Study Type	Interventional
Primary Purpose	Treatment
Study Phase	Phase 1
Interventional Study Model	Parallel Assignment
Number of Arms	4
Masking	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation	Randomized
Enrollment	23 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Cohort 1 GS-9883 1 × 25 mg tablet (or placebo to match) for 10 days.	Drug: GS-9883 - GS-9883 tablet(s) administered orally once daily Drug: GS-9883 Placebo - Placebo to match GS-9883 administered orally once daily

Experimental: Cohort 2 GS-9883 1 × 100 mg (or placebo to match) for 10 days.	Drug: GS-9883 - GS-9883 tablet(s) administered orally once daily Drug: GS-9883 Placebo - Placebo to match GS-9883 administered orally once daily
Experimental: Cohort 3 GS-9883 5 mg or 10 mg (1 × 5 or 2 × 5 mg tablet) (or placebo to match) for 10 days.	Drug: GS-9883 - GS-9883 tablet(s) administered orally once daily Drug: GS-9883 Placebo - Placebo to match GS-9883 administered orally once daily
Experimental: Cohort 4 GS-9883 50 mg or 75 mg (2 × 25 or 3 × 25 mg tablet) (or placebo to match) for 10 days.	Drug: GS-9883 - GS-9883 tablet(s) administered orally once daily Drug: GS-9883 Placebo - Placebo to match GS-9883 administered orally once daily

Outcome Measures

Primary Outcome Measures	1. DAVG11 in plasma HIV-1 RNA (log10 copies/mL) DAVG11: time-weighted average between the first postbaseline value and the last available value up to Day 11 minus the baseline value. [Time Frame: Up to 11 days]
Secondary Outcome Measures	1. Incidence of adverse events and graded laboratory abnormalities Overall safety profile will be characterized by number of participants experiencing adverse events or laboratory abnormalities. [Time Frame: Up to 11 days] 2. Maximum reduction from baseline through Day 11 in plasma HIV-1 RNA (log10 copies/mL) The maximum reduction will be calculated as the lowest up to Day 11 postbaseline value minus the baseline value. [Time Frame: Up to 11 Days] 3. PK parameters of GS-9883 following single- and multiple-dose administration, and the correlation between AUCtau of GS-9883 and DAVG11 in plasma HIV-1 RNA DAVG11: time-weighted average between the first postbaseline value and the last available value up to Day 11 minus the baseline value. AUCtau: concentration of drug over time PK measurements will include: AUCinf, AUC0-last, and Cmax for single-dose administration; and

AUCtau, Cmax, and Ctau for multiple-dose administration.

- PK/PD measurements will include Pearson correlation between AUCtau of GS-9883 and DAVG11 in plasma HIV-1 RNA

[Time Frame: Predose and postdose on Days 1 and 10]

4. Initial viral decay slope in plasma HIV-1 RNA (copies/mL)
The ratio of the mean slopes between treatment pairs of interest will be calculated.

[Time Frame: Up to 11 days]

Eligibility

Minimum Age	18 Years
Maximum Age	65 Years
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	Inclusion Criteria: • No current or prior anti-HIV treatment, including antiretroviral medications received for prevention (preexposure prophylaxis [PrEP]), or postexposure prophylaxis (PEP) within 12 weeks of screening

- Must be between 18 and 65 years of age, inclusive on the date of the screening visit
- Plasma HIV-1 RNA $\geq$ 10,000 copies/mL but $\leq$ 400,000 copies/mL at screening
- CD4+ cell count $>$ 200 cells/mm³

Exclusion Criteria:

- Anticipated to start HIV-1 therapy during the study period
- Active participation in another study of investigational or approved antiretroviral agents
- A new AIDS-defining condition diagnosed within the 30 days prior to screening
- Subjects with positive hepatitis C antibody at screening
- Chronic hepatitis B virus (HBV) infection
- Active, serious infections (other than HIV-1 infection) requiring parenteral antibiotic or antifungal therapy within 42 days prior to Day 1 (baseline)

Contacts/Locations

Central Contact Person	
Study Officials	• Name Hal Martin - Role Study Director - Affiliation Gilead Sciences

Location

- **Berkeley, California, United States**
- **Davis, California, United States**
- **Long Beach, California, United States**
- **Los Angeles, California, United States**
- **San Francisco, California, United States**
- **Washington, District of Columbia, United States**
- **Fort Lauderdale, Florida, United States**
- **Orlando, Florida, United States**
- **Vero Beach, Florida, United States**
- **West Palm Beach, Florida, United States**
- **Atlanta, Georgia, United States**
- **Berkley, Michigan, United States**
- **Newark, New Jersey, United States**
- **Santa Fe, New Mexico, United States**
- **Dallas, Texas, United States**
- **Seattle, Washington, United States**

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