Trial Nickname: Integrase STR

Full Name: A Phase III, 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

Participant Overview: This study is designed for adults who are HIV-positive and have not yet received HIV treatment.

Major Eligibility Criteria:

- At least 18 years old
- Viral load ≥ 500 copies/mL at screening visit
- Have never taken HIV treatment before ("antiretroviral treatment naïve"), except for the use of PrEP (pre-exposure prophylaxis) or PEP (post-exposure prophylaxis

Description:
This is a Phase III, randomized, double-blind study evaluating the safety and efficacy of an investigational fixed-dose combination HIV medication. Participants will be randomized in a 1:1 ratio to receive a fixed dose combination of either the investigational HIV medication regimen GS-9883/emtricitabine/tenofovir alafenamide (GS-9883/F/TAF) or the approved medicines dolutegravir + emtricitabine/tenofovir alafenamide (DTG + F/TAF).

All study medications and study-required labs and exams are provided through the study at no cost. The study is 96 weeks long, after which all participants will be given the option to receive the experimental GS-9883/F/TAF regimen for an additional 48 weeks. Study participants may be eligible for a modest stipend for time and travel per completed study visit.

Study Sponsor: Gilead Sciences, Inc.

For more information, please contact:
Joanne Delaney at 617.502.1707 or jdelaney@crine.org