Study Nickname: Complera Switch

Full Name: A Phase III, Randomized, Double-Blind Switch Study to Evaluate the Safety and Efficacy of Emtricitabine/Rilpivirine/Tenofovir Alafenamide (FTC/RPV/TAF) Fixed-Dose Combination (FDC) in HIV-1 Positive Subjects Who Are Virologically Suppressed on Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate (FTC/RPV/TDF or Complera)

Participant Overview: This study is designed for adults who are HIV-positive and virologically suppressed on the single-tablet regimen FTC/RPV/TDF (Complera). Participants will be randomized to stay on Complera or switch to an investigational single-tablet regimen that contains the pro-drug tenofovir alafenamide (TAF) instead of tenofovir disoproxil fumarate (TDF), a component of Complera. A bone density monitoring substudy is available but not required.

Major Eligibility Criteria:

- At least 18 years old and currently receiving ARV therapy consisting solely of FTC/RPV/TDF (Complera) continuously for at least 6 months
- Viral load: <50 copies/mL for at least 6 months
- Adequate renal function
- Have no documented resistance to any of the study agents at any time in the past
- Hepatitis B negative
- Absence of active hepatitis C infection (subjects with HCV antibody but no detectable viral load are eligible to enroll)

Description:
This is a Phase III, randomized, double-blind switch study. Study participants must be HIV-1-positive adults who are virologically suppressed on a regimen consisting only of FTC/RPV/TDF (Complera). All subjects will be randomized in a 1:1 ratio to either maintain the FTC/RPV/TDF with a placebo-to-match FTC/RPV/TAF, or switch to FTC/RPV/TAF with a placebo-to-match FTC/RPV/TDF. After 48 weeks, all participants will be given the option to receive FTC/RPV/TAF in an open-label extension.

Both FTC/RPV/TDF (Complera) and FTC/RPV/TAF are supplied by the study. Labs, bone mineral density testing, and exams are provided through the study at no cost. Study participants are also eligible for a stipend in the amount of $75 per study visit.

For more information:
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