Emerald Web Summary

Trial Nickname: Emerald

Full Name: A Phase III, randomized, active-controlled, open-label study to evaluate the efficacy, safety and tolerability of switching to a darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) once-daily single-tablet regimen versus continuing the current regimen consisting of a boosted protease inhibitor (bPI) combined with emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) in virologically-suppressed, human immunodeficiency virus type 1 (HIV-1) infected subjects

Participant Overview: This study is designed for adults who are HIV-positive and virologically suppressed on an antiretroviral regimen consisting of a boosted protease inhibitor combined with FTC/TDF (Truvada) for at least 6 consecutive months.

Major Eligibility Criteria:

- At least 18 years old
- 6 consecutive months or longer preceding screening on a stable ARV regimen consisting of Truvada (or emtricitabine and tenofovir) plus one of three boosted protease inhibitors:
    - Kaletra (lopinavir) with ritonavir
    - Prezista (darunavir) with ritonavir or cobicistat
    - Reyataz (atazanavir) with ritonavir or cobicistat
- Undetectable viral load for the year prior to the screening visit

Description:
This is a Phase III, randomized, active-controlled, open-label study. All participants will be randomized in a 2:1 ratio to either switch to an experimental once-daily single-tablet regimen (darunavir/cobicistat/emtricitabine/tenofovir alafenamide, or D/C/F/TAF) or continue taking their current regimen. TAF is an investigational novel pro-drug of first-line agent tenofovir that has demonstrated high antiviral efficacy and an improved renal and bone safety profile from earlier treatments.

All study medications are supplied by the study. Labs and exams are provided through the study at no cost. The study is 48 weeks long, after which all participants will be given the option to receive the D/C/F/TAF regimen in an extension phase. Study participants are also eligible for a stipend in the amount of $75 per study visit.

A subset of participants may be eligible to participate in a bone density (DEXA) substudy.

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