A5308: Clinician Summary Sheet

Title of Study: A Prospective, Single-Arm, Open-Label Study to Evaluate the Effect of Fixed-Dose Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate on T-Cell Activation, Absolute CD4+ T-Cell Count, Inflammatory Biomarkers and Viral Reservoir in Treatment-Naïve HIV-1 Controllers

Brief Summary: A5308 consists of two steps. Step 1 is an open-label, phase IV, single-arm study in treatment-naïve HIV-1 controllers with any absolute CD4 count to evaluate the effects of antiretroviral therapy (ART) on immune activation and inflammation, absolute CD4 count, viral decay, residual viremia, viral reservoir, and quality of life in situations of low-level viremia. A limited number of subjects will have the option of registering to a viral decay component of the study which will consist of six additional study visits. Step 2 is an optional additional 48 weeks of either open-label ART or no treatment for all subjects who complete Step 1.

Objectives: The primary objective is to evaluate changes from baseline in CD8 immune activation at 24 and 48 weeks after initiation of Complera in treatment-naïve HIV-1 controllers. Secondary objectives include:

- To evaluate changes in plasma viral load and in the viral reservoir after initiation of ART.
- To evaluate changes in CD4 count at 48 weeks after initiation of ART.
- To evaluate changes in CD4 immune activation and systemic inflammatory markers measured by soluble markers after initiation of ART.
- To evaluate safety, tolerability, and changes in quality of life due to study treatment in naïve HIV-1 controllers after initiation of ART.
- To identify the presence of non-nucleoside reverse transcriptase inhibitor (NNRTI) and nucleos(t)ide reverse transcriptase inhibitor (NRTI) resistance mutations from plasma HIV-1 RNA at baseline and at the time of virologic failure.

Twenty of the participants may enroll in a viral decay study. The objective of this is to study the rates of plasma viral decay in HIV-1 controllers.

Inclusion/Exclusion Criteria: The subjects must be 18 years of age or older and have an HIV-1 RNA level of < 500 copies for a period of at least 24 months. They cannot have taken antiretroviral medications in the past.

Treatment: Study treatment is defined as Complera (emtricitabine [FTC]/rilpivirine [RPV]/tenofovir disoproxil fumarate [TDF]). During the 12 week lead-in period subjects will receive no study treatment. At the completion of the 12 week lead-in period subjects will receive treatment with fixed-dose FTC/RPV/TDF for 48 weeks (through week 60 of the study). At the week 60 study visit, all subjects have the option to continue on study and receive open-label ART (FTC/RPV/TDF) or no treatment for an additional 48 weeks.

Duration of Study: Participants will be in this study for up to 108 weeks. Step 1 lasts for 60 weeks and Step 2 lasts for 48 weeks. Step 2 of the study is optional.

For more information contact:
Dale Maddox, RN
404-616-9738