Racially and Gender Diverse Aptivus Study Underway

June 14, 2007 By Tim Horn

Boehringer Ingelheim, manufacturer of the protease inhibitor Aptivus® (tipranavir), has announced that it is now enrolling patients into its SPRING study. The company says that it will be one of the largest racially and gender diverse international studies of highly treatment-experienced HIV-positive patients.

The goal of the SPRING study is to enroll 200 women and 200 men who are HIV positive and highly treatment-experienced. A racially and ethnically diverse population including, but not limited to, White, Black, Hispanic, Asian and American Indian patients will be recruited.

The study will also be the largest controlled trial conducted to date evaluating the utility of therapeutic drug monitoring (TDM) in treatment-experienced HIV patients.

The SPRING study will enroll patients in 72 sites in the United States, Canada, Mexico, Germany, Italy, Spain, Argentina and Brazil. Patients are required to be 18 years of age or older and have received prior treatment from at least three classes of antiretroviral agents and have documented resistance to at least one protease inhibitor.

Patients' CD4 count must be at least 50 upon entering the study; their viral load must be at least 1,000 copies.

All 400 patients entering the study will take 500mg Aptivus (500 mg) with 200mg Norvir® (ritonavir), both twice a day, in combination with an optimized background regimen of drugs. Two hundred patients will undergo TDM – a lab test that measures drug concentrations in the blood – and have their Aptivus or Norvir doses adjusted if necessary. The other 200 study volunteers will remain on the standard Aptivus/Norvir doses for all 48 weeks of the trial.

Additional information regarding the Boehringer Ingelheim SPRING study is available on the National Institutes of Health's ClinicalTrials.gov.