



Treatment-Naïve Trials

CCTG 589

Nucleoside-sparing combination therapy with Lopinavir/ritonavir + Raltegravir vs. Efavirenz + Tenofovir Disoproxil Fumarate + Emtricitabine in Antiretroviral naïve patients (48 weeks)

- CD4 >50 cells
- HIV Viral Load >5,000 copies
- No chronic Hep C or chronic/active Hep B
- Viral dynamics (5 visits in 2 weeks)

Treatment-Experienced Trials

GS-US-183-0144

Phase 3, double blind, double-dummy, study of Elvitegravir/rtv vs Raltegravir each administered with a background regimen in HIV-1 infected, treatment-experienced patients

- Currently on stable ARV therapy
- HIV Viral load \geq 1000 copies/ml
- No CD4 cell restriction
- Must be able to receive one of the fully active ritonavir-boosted Protease Inhibitors
- Resistance to two classes of ARVs or 6 months experience with two or more different classes of ARVs

TMB-202

Phase 2b, multicenter, randomized, double blind study to evaluate the effectiveness and safety of ibalizumab for 48 weeks

- Given intravenously every 2 weeks along with a background regimen
- HIV Viral load \geq 1000 copies/ml
- Resistance to at least one NRTI, NNRTI, and PI
- On stable HAART regimen for at least 8 weeks before screening OR in the past 8 weeks have failed their ARV regimen and are off therapy
- No CD4 restrictions

GS-US-164-0216

Phase 4 open label study to evaluate the rationale of switching from Epzicom to Truvada in virologically suppressed patients maintained on a ritonavir-boosted protease inhibitor

- Two consecutive <50 copies of HIV viral load prior to screening
- Must be on Epzicom for \geq 6 months
- No CD4 requirements

BI.1100.1526

An open label, phase IIIb, randomized parallel group study to assess the efficacy and safety of switching HIV-1 infected patients successfully treated with a Nevirapine IR based regimen to Nevirapine XR 400 mg QD or remaining on Nevirapine IR 200 mg BID based regimen

- Treatment with **Viramune** regimen for at least the preceding 18 weeks (must be taking Viramune BID)
- Background therapy with **3TC/ABC** (Kivexa® in EU; Epzicom in US), **FTC/TDF** (Truvada™) or **3TC/AZT** (Combivir®)
- An HIV viral load < 50 copies/mL in preceding 3 months and at screening

Upcoming (April 2009)

GS-US-236-0104

A Phase 2, double-blind study of the safety and efficacy of Elvitegravir/Truvada/GS-9350 vs. Atripla in naïve patients

GS-US-216-0105

A Phase 2, double-blind study of the safety and efficacy of GS-9350 boosted Reyataz compared to Ritonavir boosted Reyataz in combination with Truvada in naïve patients