Antiretroviral Naïve - (Never Treated Before)

**A5257: A Phase III Comparative Study of Three Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-Sparing Antiretroviral Regimens for Treatment-Naïve HIV-1-Infected Volunteers**

**Purpose:** To compare the virologic efficacy and tolerability of combination regimens that include FTC/TDF plus RAL, ATV/r, or DRV/r for treatment of ARV-naïve subjects.

**Main Requirements:** ARV Naïve; HIV Viral Load >=1000; Various medical and medication restrictions

**Treatment:** At entry subjects will be randomized to one of the following:

- **Arm A:** ATV 300 mg QD + RTV 100 mg QD + FTC/TDF 200/300 QD
- **Arm B:** RAL 400 mg BID + FTC/TDF 200/300 mg QD
- **Arm C:** DRV 800 mg QD + RTV 100 mg QD + FTC/TDF 200/300 mg QD

**Drug(s) Provided by the Study:** All study medications are provided with the exception of RTV which must be obtained through a physician. Participants will be reimbursed for the cost of the RTV co-payment.

**Gilead US216-0114: A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9350-boosted Atazanavir Versus Ritonavir-boosted Atazanavir Each Administered with Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults.**

**Purpose:** To evaluate the efficacy of a regimen containing GS-9350-boosted Atazanavir versus Ritonavir-boosted Atazanavir each administered with Truvada as determined by the achievement of HIV-1 RNA < 50 at Wk 48.

**Main Requirements:** ARV Naïve; HIV Viral Load >=5000; Various medical and medication restrictions

**Treatment:** At entry subjects will be randomized to one of the following:

- **Arm 1:** GS-9350 150mg + Atazanavir 300mg + Truvada 500mg + Placebo to match Ritonavir 100mg QD
- **Arm 2:** Ritonavir 100mg + Atazanavir 300mg + Truvada 500mg + Placebo to match GS-9350 150mg QD

**Drug(s) Provided by the Study:** All study medications are provided.
Salvage - Resistant to Current Therapy

**A5241**: The Optimized Treatment that Includes or Omits NRTIs (OPTIONS) Trial: A Randomized Strategy Study for HIV-1-Infected Treatment-Experienced Subjects Using the cPSS to Select an Effective Regimen

**Purpose**: To compare treatment success (defined as the probability of not experiencing virologic failure or discontinuation of NRTI strategy by week 48) between subjects taking a new regimen of more than two active agents (defined by a cPSS >2.0) that includes versus excludes NRTIs.

**Main Requirements**: Triple class experienced or 1 mutation in both the NRTI and NNRTI class; Current PI regimen; HIV RNA >= 1000 copies/mL; Various medical and medication restrictions

**Drug(s) Provided by the Study**: Enfuvirtide, Maraviroc, Raltegravir, Darunavir, Tipranavir, and Etravirine will be provided by the study. Neither RTV nor any NRTI's will be provided by the study.

**Experimental Therapeutics**

**Sangamo SB728T**: A Phase I Study of Autologous T-Cells Genetically Modified by Zinc Finger Nucleases SB-728 for Reduced CCR5 Expression in HIV-Infected Patients with Detectable Plasma HIV RNA who have Developed Resistance to Highly Active Anti-Retroviral Therapy (HAART).

**Purpose**: To test the following hypothesis: Autologous CD4+ T cells genetically modified at CCR5 gene by Zinc Finger Nucleases SB-728 will be safe and tolerable in HIV-1 positive subjects.

**Main Requirements**:
- **Cohort 1**: RNA levels ≥2000 copies/mL and <150,000 copies/mL and CD4+ T cell counts ≥200 cells/mm3, patients who have been on two or more HAART regimens and have failed due to resistance or tolerance. Patients must be CCR5 tropic.
- **Cohort 2**: RNA levels <50 copies/ml and CD4+ T cells counts ≥450 cells/mm3; and a documented CD4 nadir of not lower than 300 cells/mm, and patients who have a recorded viral load set point prior to starting therapy.
- **Cohort 3**: RNA levels <50 copies/ml for at least 2 years and peripheral CD4+ T cell counts >200 cells/mm3 and <500 cells/mm3.

**Drug(s) Provided by the Study**: Autologous CD4 T cells genetically modified at CCR5 gene with zinc finger nucleases SB-728.

**Adaptimmune**: A Pilot, Open Label, Multiple Arm, Single Center Study to Evaluate the Safety and Tolerability of Escalating Doses of Autologous T Cells Modified with Lentiviral Expressing a High Affinity Gag-Specific TCRS in HLA-A*02 Patients with HIV

**Purpose**: To determine optimal dose and to evaluate the safety and tolerability of the modified Autologous T Cells.

**Main Requirements**: HIV infection, ≥ 18 years with undetectable HIV-1 RNA levels and CD4+ T Cell counts ≥ 450.

**Observational Studies**

**Pfizer A4001067 POEM**: An International, Multicenter, Prospective Observational Study of the Safety of Maraviroc Used with Optimized Background Therapy in Treatment-Experienced HIV-1 Infected Patients

**Purpose**: The purpose of the study is to estimated the incidence rates of Category C OI’s, viral encephalitis, liver failure and rhabdomyolysis in treatment-experienced HIV-1 infected patients receiving maraviroc during time of use and for up to six months following the discontinuation of treatment.

**Drug(s) Provided by the Study**: None - A Tropism assay will be performed if needed

**NOTE**: Study is open to anyone needing a Tropism. Patient can go onto study if they receive Maraviroc or
### A5240: A Phase II Study to Evaluate the Immunogenicity and Safety of a Quadrivalent Human Papillomavirus Vaccine in HIV-1-Infected Females

**Purpose:** To determine the development of titers in each CD4+ cell count stratum of antibodies to HPV 6, 11, 16, and 18 above a level of type-specific seropositivity after the quadrivalent HPV recombinant vaccine series.

**Main Requirements:** Females ≥13 to ≤45 years of age. CD4+ cell count ≤350 cells/mm³. No prior vaccination with a HPV vaccine.

**Drug(s) Provided by the Study:** GARDASIL - quadrivalent HPV (types 6, 11, 16, 18) recombinant vaccine.

### A5247: A Phase II, Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Evaluate the Safety, Tolerability, and Immunogenicity of ZOSTAVAX® (Zoster Vaccine Live) in Human Immunodeficiency Virus (HIV)-1-Infected Adults on Potent Combination ART with Conserved Immune Function

**Purpose:** Evaluate the Immunogenicity of ZOSTAVAX®(Zoster Vaccine Live) in HIV-infected

**Main Requirements:** Men and women ≥18 years of age who have never received Varicella or Zoster vaccine, are receiving potent ART, have been previously infected with VZV (but not within the year immediately prior to study entry), have a CD4 count ≥200 and have an undetectable HIV viral load. Currently looking for CD4 counts 200-349

**Drug(s) Provided by the Study:** ZOSTAVAX or placebo

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**Questions??**

**Contact us**

**Phone Numbers:**

215-349-8091/8092/8093

Ask for a Study Nurse to help you.