

# AIDS CLINICAL TRIALS UNIT

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ACTU Website:  
[www.upennactu.org](http://www.upennactu.org)

**Patient Benefits - All studies provide \$20 per visit, some have additional compensation.**

**Physician Benefits - All lab work can be faxed, mailed or emailed. An updated lab flow sheet is also sent .**

## The AIDS Clinical Trials Unit

Update of HIV/AIDS Investigational Therapies

Following is a list of studies . A complete list of all studies enrolling at our ACTU can be found on our website at: [www.upennactu.org](http://www.upennactu.org) Click on the topic below to view related category.

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## Antiretroviral Naïve - (Never Treated Before)

Pending

**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  $\geq 1000$ ; 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.

**A5217:** The SETPOINT Study: A Randomized Study of the Effect of Immediate Treatment with Potent Antiretroviral Therapy versus Observation with Treatment as Indicated in Newly Infected HIV-1-infected Subjects: Does Early Therapy Alter the Virologic Setpoint?

**Purpose:** To compare the virologic setpoint 72 weeks after study entry in individuals with recent but not acute HIV-1 infection who are randomized to receive 36 weeks of ART with individuals who are randomized to not receive ART

**Drug(s) Provided by the Study:** Emtricitabine/Tenofovir DF 200/300 mg orally once daily plus Lopinavir/ritonavir 400/100 mg orally twice daily or 800/200 mg orally once daily.

## CNS - Neuropathy / Cognitive Impairment

**A5235:** Phase II, Randomized, Placebo-Controlled, Double-Blind Study of Minocycline in the Treatment of HIV-Associated Cognitive Impairment

**Purpose:** To examine whether minocycline treatment for 24 weeks improves HIV-associated cognitive impairment.

**Main Requirements:** Receipt of a stable antiretroviral regimen for at least 16 consecutive weeks prior to entry and no plan to change therapy between screening and week 24; Cognitive impairment as evidenced by neuropsychological tests administered at screening; Lumbar punctures are optional but recommended; Various medical and medication restrictions

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

## Experimental Therapeutics

**A5256:** A Pilot Trial of Maraviroc (MVC) for Treatment of Subjects on Antiretroviral Therapy with Suboptimal CD4+ T-cell Count Recovery Despite Sustained Virologic Suppression

**Purpose:** To assess whether 24 weeks of MVC added to a subject's current stable antiretroviral regimen is associated with at least a 20 cell/ $\mu$ L CD4+ T-cell count increase in subjects with suboptimal CD4+ T-cell response despite sustained virologic suppression.

**Main Requirements:** On ART for at least 48 weeks prior to study entry with a regimen that includes three or more antiretroviral medications; Screening CD4+ T-cell count <250; Screening HIV-1 RNA undetectable; No current or prior CCR5 inhibitor use; No tropism criteria.

**Drug(s) Provided by the Study:** Maraviroc (MVC, Selzentry™)

**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  $\geq$ 2000 copies/mL and <150,000 copies/mL and CD4+ T cell counts  $\geq$ 200 cells/mm<sup>3</sup>, 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  $\geq$ 450 cells/mm<sup>3</sup>; 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.

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

**Mecasermin:** An Open Label Trial of Mecasermin For HIV Associated Metabolic Disease

**Purpose:** To test the effects and safety of mecasermin for reversing lipoatrophy, dyslipidemia, and insulin resistance in patients with HIV infection and lipodystrophy syndrome.

**Main Requirements:** HIV infection with a history of lipoatrophy and dyslipidemia.

**Drug(s) Provided by the Study:** Mecasermin

## Dose-Finding Studies

**Emend:** A Phase 1B, Randomized, Placebo-Controlled, Double Blind Study to Determine the Safety, Viral Suppressive Potential, Pharmacokinetics and Immune Modulatory Effects of Treatment With Aprepitant (Emend) in HIV Infected Individuals.

**Purpose:** Evaluate the safety and tolerability of Aprepitant for 2 weeks at two different doses and the response of plasma HIV-1 RNA to two different doses of aprepitant compared with baseline.

**Main Requirements:** Subject is antiretroviral-naive or off therapy within 16 weeks prior to entry.; HIV-1 RNA  $\geq$  2,000; CD4  $\geq$  350; Various medical and medication restrictions

**Drug(s) Provided by the Study:** Aprepitant (Emend) or matching placebo

## Vaccines

**A5232:** Optimizing Vaccine Responsiveness in HIV-1 and HCV Infections and Identifying Determinants of Responsiveness: A Pilot Study

**Purpose:** To evaluate whether baseline DC, B-cell, or T-cell function in HCV-infection, HIV-1-infection, and HCV/HIV-1 coinfection predicts neoantigen or recall antigen responsiveness at week 8, as determined by vaccine-induced T-cell response and B-cell humoral immune response.

**Main Requirements:** Arm A: chronic HCV infection defined as PCR positive without previous HCV based therapy and without the presence of Child's B or C cirrhosis. These participants will be HIV-1 seronegative.

Arm B: antiretroviral treatment naive subjects ( $\leq 7$  days of antiretroviral therapy) with chronic HIV-1 infection; CD4+ T-cell count  $\geq 300$  cells/mm<sup>3</sup>; no prior or current opportunistic infection; and with no indication for or the need for HIV-1 therapy. These participants will be HCV seronegative.

Arm C: HCV/HIV-1 co-infection as defined above in Arms A and B.

**Drug(s) Provided by the Study:** Twinrix® (day 0, 7, 21 administration) and diphtheria/tetanus (day 0) immunizations.

**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  $\geq 13$  to  $\leq 45$  years of age. CD4+ cell count  $\leq 350$  cells/mm<sup>3</sup>. No prior vaccination with a HPV vaccine

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

**PennVax B:** A Phase 1b Partially Randomized Pilot Study Intended to Evaluate the Safety and Immunological Effects of HIV-1 DNA Immunization (PennVax-B) With or Without Co-administration of constructs Containing DNA Encoding For the Expression of Either IL-12 or IL-15 In HIV Infected Individuals

**Purpose:** To determine the safety of HIV-1 DNA constructs (PennVax-B) and to determine the optimal doses of IL-12 and IL-15 adjuvant constructs when given with PennVax-B

**Main Requirements:** CD4  $\geq 400$ , HIV  $\leq 75$ , on stable regimen

**Drug(s) Provided by the Study:** PennVax-B, IL-12, IL-15

Pending

**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:** On stable antiretroviral therapy; CD4 cells  $> = 350$  cells/ $\mu$ l; undetectable HIV RNA; Various medical and medication restrictions

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

## Adherence Studies

**MAPS:** Managed Problem Solving: An HIV Adherence Trial

**Purpose:** The purpose of the study is to determine if an adherence strategy is able to increase adherence to HIV medications. A secondary purpose is to see if the adherence strategy can help lower viral load and improve the CD4 count .

**Drug(s) Provided by the Study:** None - A MEMS bottle will be given out (special pill bottle that will record time and date of pill taking)

## 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  $\geq$  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.

**Gilead GS-US-183-0144:** Phase 3 Study of Safety and Efficacy of Ritonavir-Boosted Elvitegravir (EVG/r) Vs. Raltegravir (RAL) Each Administered With a Background Regimen (BR) in HIV-1 Infected, Antiretroviral Treatment-Experienced Adults

**Purpose:** To assess non-inferiority of regimen containing EVG/r vs RAL each administered with a background regimen as determined by the proportion of subjects achieving and maintaining confirmed HIV-1 RNA  $<$  50 through 48 weeks.

**Main Requirements:** HIV RNA  $\geq$  1000; Stable regimen  $\geq$  30 days to screening; Resistance at least 1 agent from 2 or more classes. No prior HIV-1 integrase inhibitor use.

**Drug(s) Provided by the Study:** Elvitegravir or matching placebo and Raltegravir or matching placebo; Viread if selected as second agent for BR

## PK Studies

**BMS A1443002:** Placebo-controlled, Single Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Antiviral Activity of BMS-791325 in Subjects Chronically Infected with Hep C Virus Genotype 1

**Purpose:** To assess the safety and tolerability of a single dose of 100, 300, 900 and a dose from 10-800 mg of BMS-791325 in subjects with chronic HCV genotype 1 infection.

**Drug(s) Provided by the Study:** BMS-791325



**Phone Numbers:**

**215-349-8091/8092/8093**

**Ask for a Study Nurse to help you.**