



## A Guide to HIV-Related Clinical Research in the San Francisco Bay Area

### PHARMACEUTICAL UPDATES

#### ◆ Isentress Gets Traditional FDA Approval

 On January 29, 2009 the Food and Drug Administration (FDA) granted traditional approval for integrase inhibitor Isentress (raltegravir) in treatment-experienced adults. This approval was based on supplemental data from two 48-week studies. With approval came several product label changes including an adverse reaction report regarding the potential for elevated ALT/AST or total bilirubin in those co-infected with chronic hepatitis B or C. Dosing changes were recommended for co-administration with rifampin and other strong UGT1A1 inducers (like ritonavir) due to reduced raltegravir concentrations.

### CONFERENCE UPDATE

 The 16th Conference on Retroviruses and Opportunistic Infections (CROI 2009) is a scientifically focused meeting of the world's leading researchers working to understand, prevent, and treat HIV/AIDS and its complications. A few examples of the significant presentations this year are the following:

◆ Investigators reported finding no clinical benefit from the increased CD4+ cells that were generated using IL-2 (interleukin) along with standard ARV therapy. Based on recently unblinded information from both the SILCAAT and ESPRIT studies, surprisingly, no significant differences in disease progression or death were found between the groups who received IL-2 and those that did not, in spite of the higher CD4+ cell count of the IL-2 groups.

◆ Controversy has arisen over the best time to initiate antiretroviral therapy. Current ARV guidelines recommend beginning therapy when the CD4+ cells decline to 350, but several studies presented here suggest that beginning HAART when CD4+ cells are 500 or greater is associated with improved survival. Some argued that this data, derived from observational studies, was confounded by too many variables. However, the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT) network is about to launch a multi-center prospective study called the Strategic Timing of AntiRetroviral Therapy (START) to compare immediate versus delayed starting times for initial ARV therapy.

See [www.insight-trials.org/](http://www.insight-trials.org/) for details.

◆ Whether a HAART regimen crosses the blood-brain barrier to penetrate the central nervous system

(CNS) or not may play a role in some observed neurocognitive impairment even in fully suppressed individuals. One study of 300 HIV+ subjects reported that those on a HAART regimen with less CNS penetration had a greater incidence of difficulty with cognitive tests. Other contributing factors included older age, the presence of vascular disease and lower HDL levels. Of note, Atripla, one of the most frequently prescribed HAART regimens, does not have a particularly high CNS penetration.

◆ Two studies, one French and one Canadian, tested a total of 170 men and found that HIV may be detectable in seminal fluids when it is undetectable in blood. In the French study, thirty paired samples out of 145 were found to be discordant, that is undetectable in blood but detectable in seminal fluid. In the Canadian study, discordance ranged from 12% to 36%, depending on when the samples were drawn. While both researchers noted that detectable virus in seminal fluid, called cell-free virus, *may* not be infectious, the Canadian study found that the individual with the level of cell-free virus was in fact infectious.


◆ Reports on new ARV drugs now in development included two maturation inhibitors, bevirimat and MPC-9055, which represent a unique new, drug class. Also discussed were two new integrase inhibitors, Gilead Sciences' elvitegravir and GSK 364735. Two additional NNRTIs are also currently in the drug pipeline as well as CMX 157, an NRTI. PRO140 a monoclonal antibody CCR5-inhibitor which is not available in an oral formulation at this time but which researchers speculate might be useful as a twice-weekly infusion.

◆ Gilead Sciences presented GS9350, a new boosting agent which would act much like ritonavir, but which itself would have no antiretroviral effect. It is speculated that the side-effect profile might be more favorable than that of ritonavir which can cause a variety of metabolic problems. Gilead's new integrase inhibitor (see above) appears to require boosting. Sequoia Pharmaceuticals SPI-452, another booster still in very early trials, is also in the pipeline.

### YOGA OF THE BREATH NO FEE!

A Unique Opportunity for People Living with HIV  
March 13 through 20, 2009  
Quan Yin Healing Arts Center  
455 Valencia Street, SF, 415-337-4591

Studies are listed with brief descriptions only. Additional inclusion and exclusion criteria will apply.  
For additional information, please call the study site directly, or call HIVCare at 415-353-6215.

**ABBREVIATIONS USED:**  = New Study in This Issue or Changes to an Existing Study

ARV = Antiretroviral    > = greater than    < = less than    EAP = Expanded Access Program  
PI = Protease Inhibitor    NRTI = Nucleoside/Nucleotide Analog    NNRTI = Nonnucleoside Analog

**ALAMEDA COUNTY MEDICAL CENTER**

Adult Immunology Clinic at Highland Hospital  
1411 East 31<sup>st</sup> Street, Oakland, CA 94602    **510-437-4888**

- ♦ **IRISS Study:** exploring different ways to help recently diagnosed cope with a new HIV diagnosis. IRISS is a randomized trial that includes 9 interviews over a year. Compensation from \$20-\$50 per visit.
- ♦ **Late Presentation to HIV Care:** A one visit interview for those who have tested HIV+ within the past 9 months or are new to HIV care within the past 3 months. Compensation provided.
- ♦ **GSK Support Study:** comparing Lexiva to Sustiva, each with Epsicom as a first-line, once-daily therapy for ARV-naïve individuals. Compensation provided.

**BAART PROGRAMS**


433 Turk Street  
San Francisco, CA 94109    **415-928-7800, ext 324 or 326**  
<http://www.baartcdp.com/>

- ♦ Volunteers needed for a research study involving treatment of heroin and other opiate addictions. Participants must not be on treatment for addiction within the past 30 days. Addiction treatment will be provided at no cost. Additional compensation is also provided.



**CONANT MEDICAL GROUP CLINICAL RESEARCH**

470 Castro Street, Suites 202-204  
San Francisco, CA 94114  
[ceden@conantmedical.org](mailto:ceden@conantmedical.org)    **415-255-0744**

- ♦  A Phase I study of the TUTI-16 tat vaccine for treatment of HIV. Must be HIV+ for at least six months, no prior HIV medications within the last six months, have VL between 3000 and 100,000 and CD4 count >400. Compensation is \$35 per visit, up to \$280 for study completion.
- ♦ A study of GS-9191, an ointment for the treatment of external genital and perianal warts caused by the human papilloma virus (HPV). Must have a CD4+ count >400 and a viral load <400 copies and at least 2 external anogenital warts. Compensation is \$35 per visit

**EAST BAY AIDS CENTER (EBAC)**

3100 Summit Street, 2<sup>nd</sup> Floor  
Oakland, CA 94609    **510-869-8490**  
[http://www.altabates.com/clinical/aids\\_scvs.html](http://www.altabates.com/clinical/aids_scvs.html)

- ♦ A Phase III randomized, double blind study for ARV-experienced individuals to evaluate the safety and efficacy of ritonavir-boosted integrase inhibitor

elvitegravir versus raltegravir (Isentress) each administered with a background regimen. Compensation is \$35 per visit.

**KAISER PERMANENTE MEDICAL GROUP-SF**

4141 Geary Street  
San Francisco, CA 94115    **415-833-3480**

- ♦ Do you have HIV-related diarrhea? A study to evaluate crofelemer, a unique twice-daily treatment. Must be on stable ARVs for at least 4 weeks, have a CD4+ count >100 and be experiencing diarrhea on a daily basis.
- ♦ A study pf apricitabine, a new NRTI for those resistant to 3TC or FTC. Participants must currently be taking FTC or 3TC and have a VL>2000. Resistance testing provided.



**OFFICE OF DR. ROBERT SCOTT, MD**

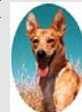
368 28<sup>th</sup> Street    Study: **510-508-4477**  
Oakland, CA 94609    Office: **510-835-5000**  
<http://www.hivaidzimbabwe.com/clinics/scott.php>


- ♦ Do you have HIV-related diarrhea? A study to evaluate crofelemer, a unique twice-daily treatment. Must be on stable ARVs for at least 4 weeks, a CD4+ count >100 and be experiencing diarrhea on a daily basis. Compensation is \$75 per visit.



**QUEST CLINICAL RESEARCH**

2300 Sutter Street, Suite 202  
San Francisco, CA 94115  
[www.questclinical.com](http://www.questclinical.com)    **415-353-0800**



- ♦  A 48-week study of a monoclonal antibody study (TaiMed) for those who are treatment-experienced, have susceptibility to at least one active ARV, and VL >1000. Compensation is \$35 per visit.
- ♦ A two-week, dose-escalating study of an integrase inhibitor for those either ARV-naïve or who have not been on ARVs for at least 12 weeks. Must have a CD4+ cell count >100 and a viral load >5,000. Compensation is \$1,500.
- ♦ Volunteers who have not taken ARVs for at least the past 3 months are needed for study involving an investigational CCR5 inhibitor. Participants should have a CD4+ cell count >250 and a viral load >5000.
- ♦ Hepatitis C (without HIV) Volunteers needed for a 15-day study of an experimental oral medication to treat HCV. Compensation to \$2100.

**UCSF/ADULT AIDS CLINICAL TRIALS UNIT**

995 Potrero Avenue, Bldg 80, Ward 84  
 San Francisco, CA 94110 **415-514-0550, ext. 354**  
[http://php.ucsf.edu/rsrch\\_trials.shtml](http://php.ucsf.edu/rsrch_trials.shtml)

All AACTG studies provide compensation

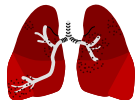
- ♦ A study for those with a VL >1000 on a PI-containing regimen with two other ARVs. The purpose of this study is to determine the benefit of adding an NRTI to a new anti-HIV drug regimen based on the most recently approved ARVs. (A5241)
- ♦ A study for those diagnosed with recent tuberculosis infection to evaluate immediate versus delayed initiation of ARV therapy. Participants must have a CD4+ cell count <200. (A5221)

**UCSF / POSITIVE HEALTH PROGRAM / SFGH**

[http://php.ucsf.edu/rsrch\\_trials.shtml#anc2](http://php.ucsf.edu/rsrch_trials.shtml#anc2)

Locations and phone numbers vary with study.

- ♦  A study to estimate the impact of HIV on those 50 years and older, especially with regard to medication adherence. Compensation to \$50 for a 90-minute interview and possible blood draw. **415-353-2463**
- ♦ Maraviroc Intensification Study: Do you have a low CD4 cell count despite undetectable viral load on HAART? A randomized, controlled trial is adding maraviroc, a CCR5 inhibitor, to current HAART to see if intensifying therapy increases CD4 counts. Compensation is provided. **415-298-4985**
- ♦ A pulmonary hypertension (PH) study is now recruiting for HIV+ individuals with suspected PH or diagnosed PH. Patients with a history of IV drug use may also be eligible. Study participants will receive an echocardiogram. Compensation provided. **415-206-5801**
- ♦ SOLID ORGAN TRANSPLANTATION in HIV: A nationwide study to evaluate the safety and effectiveness of kidney and liver transplantation in HIV-positive individuals.



Visit <http://www.hivtransplant.com/>. **415-353-8892**

- ♦ **Hepatitis C and HIV Co-infection:** A new treatment study for those infected with HCV within the past six months. No CD4+ or viral load restrictions. Treatment regimen is 24 weeks. Compensation provided. **415-476-4082 x556**
- ♦ **Hepatitis B and HIV Co-Infection:** A new 24-week treatment study for those with HIV and chronic hepatitis B. Must have undetectable HIV viral load and combination with 3TC or FTC. **415-476-9296, ext 309**
- ♦ The SCOPE study is recruiting subjects with a viral load less than 2,000 copies/mL off antiretrovirals. This observational study involves an interview and blood draw every 2-4 months. Compensation is provided. **415-476-4082 ext. 140**

♦ Volunteers are needed for a study to evaluate the effects of an antibiotic on cerebrospinal fluid in HIV infection. Participants may not be taking ARV medications and must be willing to have 5 blood draws and 4 lumbar punctures over 14 weeks. Compensation is provided. **415-206-4328**

♦ Volunteers are needed for a study evaluating the effects of integrase inhibitor raltegravir, a new antiretroviral drug, on the central nervous system. Participants must be on a 3-drug regimen for 2 years or longer and must be willing to undergo 4 spinal taps and 5 blood draws over 3 months. Compensation is provided. **415-206-4328**

♦ Recently infected with HIV? Volunteers who have been recently diagnosed with HIV are needed for a study to evaluate changes in the brain and nervous system using MRI, spinal taps and neurological exams over a six-month period. Compensation up to \$495 is provided. **415-206-4328**



♦ A study for those planning an interruption in antiretroviral therapy under the supervision of a doctor. This study will use MRI (magnetic resonance imaging) and magnetic resonance spectroscopy to evaluate changes in brain structure and chemistry. Compensation is provided. **415-206-4328**

**UCSF AIDS-ASSOCIATED MALIGNANCIES CLINICAL TRIALS CONSORTIUM**

400 Parnassus, A502  
 San Francisco CA 94143 **415-476-4126**

- ♦ A Phase II study to evaluate central nervous system penetration of an approved treatment for Burkitt or Burkitt-like lymphoma. Does not provide additional compensation. (AMC 048)

**OTHER UCSF-SPONSORED STUDIES**

Locations and phone numbers vary with study

♦ IRISS Study: Exploring different ways to help those recently diagnosed cope with a new HIV diagnosis. IRISS is a randomized trial that includes 9 interviews over a year. Compensation from \$20-\$50 per visit. **415-353-4299**

♦ The DUO PROJECT is seeking gay men in a couple relationship where at least one person is taking HIV medications. **415-597-9322**

♦ OPTIONS PROJECT for those recently exposed to HIV and experiencing acute retroviral syndrome, those newly diagnosed with HIV infection, or those who have sero-converted within the past six months.

<http://www.ucsf.edu/options/> **415-502-8100**



Other UCSF Studies, continued from Page 3

♦ **PATH PROJECT:** Are you HIV+ and NOT on medication? The PATH project is seeking participants for a UCSF research study. You must be at least 18 yrs of age, HIV+ and not taking antiretroviral medications. Compensation is provided. **415-632-5030**

♦ **NUCLEOMAXX Study** to evaluate the effects of uridine supplementation for those with a viral load <10,000, taking zidovudine (AZT, retrovir, Combivir or Trizivir) or Stavudine (D4T or zert) for the past year. Compensation provided. **415-206-4090**

♦ **RED PLUS Study:** A one-year study of a cognitive counseling intervention with focus on thoughts, attitudes and beliefs of HIV+ men who have unprotected sex with men. Compensation provided at each visit. (AHP) **415- 502-8500**

**SF VETERANS ADMINISTRATION MEDICAL CENTER**  
4150 Clement Street  
San Francisco, CA 94121 **415-221-4810 ext. 3763**

♦  A pilot study to examine if the novel treatment regimen maraviroc plus boosted atazanavir can be safe and efficacious in treatment naive individuals with a VL >1000. (A4001078)

♦  A Phase II study of maraviroc versus etravirine, each combined with duranavir + ritonavir for treatment-experienced individuals with evidence of NNRTI resistance.

♦ A Phase III study for treatment-experienced adults to compare experimental integrase elvitegravir with raltegravir (Isentress) each with background regimen.

♦ **Raltegravir Intensification Study:** Do you have a low CD4 cell count despite HAART? A randomized trial adding raltegravir to current HAART to see if intensifying therapy with raltegravir will lead to further decrease in viral load and immunologic benefit.

♦ **POEM Study:** A 5-year study to monitor the safety of long-term use of CCR5 antagonist maraviroc in a large and diverse patient population.

**STANFORD UNIVERSITY** Department of Psychiatry  
401 Quarry Road, Stanford, CA 94305 **650-724-7025**

♦  **STRESS/R.I.S.E. Study:** to determine the best way to treat stress in men and women living with HIV. Participants must be at least 18 and sexually active. Study includes a total of 13 visits. Study sites are throughout the Bay Area. Compensation to \$325 for completion. **650-724-7025**

**PALO ALTO VETERANS HEALTHCARE CENTER**  
3801 Miranda Avenue  
Palo Alto, CA 94304 **650-496-2510**

♦ **Hepatitis C (HCV) and / or HIV:** A study to determine whether HCV treatment or HIV treatment

makes the immune system respond differently. Open to those who are HIV+, HCV+ or co-infected, whether you intend to begin treatment or not, as determined by discussion with primary care provider. Compensation is \$20.00 per visit.

**STANFORD AIDS CLINICAL TRIALS UNIT**  
Hoover Pavilion 211 Quarry Road, N229  
Palo Alto, CA 94304-5714 **650-723-2804**  
Compensation is provided for travel and meals for most studies.  
<http://actu.stanford.edu/>

♦  **POEM Study:** A 5-year study to monitor the safety of long-term use of CCR5 antagonist maraviroc in a large and diverse patient population. Those who do not have R5 tropism will not be given maraviroc but will be observed in the study.

♦ A phase III, randomized, open-label trial comparing 3 drug regimens in ARV-naive patients. The study will compare raltegravir vs. boosted Atazanavir vs. boosted darunavir plus Truvada. (ACTG 5257)

♦ A study to determine the best way to treat stress in men and women living with HIV/AIDS. **650-724-7025**

♦ A Phase III study of experimental integrase inhibitor GS 0144, elvitegravir versus raltegravir (Isentress), each with background regimen for treatment-experienced individuals.

♦ A two-week, dose-escalating study of an investigational new integrase inhibitor (Progenics) for those who are either ARV-naïve or not on ARVs for at least we weeks. Must have a CD4+ cell count >100 and a viral load > 5000 copies.

♦ A study to explore whether adding maraviroc, a CCR5-antagonist, to an existing regimen with help to increase CD4+ cell counts in those with current count <350 and viral load <50 copies. (AmFAR)

♦ A study for HIV+ women to evaluate the effect of the HPV vaccine, on the body's ability to produce an immune response to the vaccination. (A5240)

♦ A study to look at whether newer anti-HIV drugs are safe and effective in a group of HIV-positive persons whose current HIV medicines are not working. (A5241)

*HIVCare News* is made possible through the generosity of Saint Francis Memorial Hospital. Subscriptions are free of charge by mail or email. **Please notify HIVCare if your address has changed or if you would prefer an email subscription.**

Diane Cenko, Editor  
HIVCare News, 900 Hyde Street #404  
San Francisco, CA 94109  
415-353-6215 or [dcenko@chw.edu](mailto:dcenko@chw.edu)

HIVCare at Saint Francis Memorial Hospital is an AIDS Drug Assistance Program (ADAP) Enrollment Site

