


HIVCare News

SEPTEMBER / OCTOBER
2009
CLINICAL RESEARCH
OPPORTUNITIES
See Pages 2, 3, & 4

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


PHARMACEUTICAL UPDATES

♦ Isentress Expanded Approval & Safety Changes


 On July 8, 2009 the Food and Drug Administration (FDA) expanded approval of integrase inhibitor Isentress (raltegravir) to include ARV treatment-naïve individuals. Previously, Isentress had been approved for treatment-experienced individuals only. New approval was based on a 48-week trial result, which showed that raltegravir plus tenofovir/emtricitabine was not inferior to efavirenz plus tenofovir/emtricitabine in treatment-naïve patients. Dosing is 400-mg. twice daily, without regard to food for ARV-experienced or ARV-naïve individuals.

In August, safety label changes were made to include a significant warning about severe skin and hypersensitivity reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, a life-threatening separation of the top and second layers of skin, which have been recently reported in a small number of individuals. These reactions may begin with rash, malaise, fever or nausea and may include liver dysfunction. Reactions usually start within the first six weeks and should be reported to physicians immediately.

♦ Aptivus Safety Label Changes

 On June 19, 2009 the FDA approved revisions to the safety labeling for protease inhibitor Aptivus (tipranavir), first approved in 2005, to warn of potential blood coagulation and platelet aggregation concerns. Aptivus, taken as either capsule or oral solution, should be used with caution by anyone who may be at risk for increased bleeding following surgery or trauma; anyone taking medications known to increase the risk of bleeding such as anticoagulants or antiplatelet agents; and anyone taking supplemental high doses of vitamin E. The new warning is based in part on data from animal studies, showing that use of tipranavir alone can cause increases in coagulation parameters, bleeding events, and death.

♦ FDA Alters Rules for "Expanded Access"

 On August 12, 2009 the FDA announced two changes to the rules governing access to experimental new drugs. One expands access to experimental drugs for seriously ill patients and the second amends the regulation on charging patients for investigational therapies. Drug companies will now be able to charge for, but not make a profit from, the experimental treatments. According to an FDA spokesperson, these changes are "intended to improve access to investigational drugs for patients with serious

or immediately life-threatening diseases or conditions who lack other therapeutic options and who may benefit from such therapies, and balance access to promising new therapies against the need to protect patient safety, and seek to ensure that expanded access does not discourage participation in clinical trials or otherwise interfere with the drug development process."


CONFERENCE UPDATES

♦ 5th International AIDS Society Conference



The 5th IAS Conference on HIV pathogenesis, treatment and prevention was held in Cape Town, South Africa, with nearly 5500 delegates from around the world in attendance. Attention focused on treating HIV in resource-limited countries worldwide. The conference also included updates of the most recently FDA-approved ARVs, including Isentress and Intelence, a focus on the importance of adherence, the value of regular monitoring, and an increasing awareness of bone health issues and earlier treatment. A report on the FOTO study, (Five-days-On-Two-days-Off) showed a benefit to continuous therapy with fewer adverse events compared to interrupted therapy, consistent with the results of the SMART study. For those with computer access, complete conference coverage can be found at <http://www.ias2009.org/>.

♦ Unlocking the Mysteries of the HIV Controller

 How some HIV+ individuals are able to suppress HIV naturally without the use of medications, and what science can learn from studying these HIV controllers will be discussed at unique one-day symposium to be held October 13, 2009 in San Francisco. Additional topics will include how psychosocial issues can play a role in HIV disease progression, as well as a presentation by Shanti L.I.F.E. Institute staff on ways to support immune functioning. Attendance at this symposium is free of charge, but space is limited and advance registration is recommended. Contact Tiko Lieou at 415-674-4718 or visit www.shanti.org/life. Breakfast and lunch provided. The symposium will be at 347 Dolores Street and is scheduled from 8:30 AM until 4 PM. (See related CD8+ cell study on Page 3, Other UCSF-Sponsored Studies)

Yoga of the Breath for People Living with HIV

No Fee!!!

8 Sessions ~ September 4-11, 2009

415-337-4591 ~ mwonders@gmail.com

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 31st Street, Oakland, CA 94602 **510-437-4888**

♦ **SWIFT Study:** a 48-week study to evaluate the safety and efficacy of switching from Epzicom (Ziagen/Epivir) to Truvada (Viread/Emtriva) for those currently on a suppressed regimen containing Epsicom and a boosted protease inhibitor. Compensation provided.

♦ **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.



BAART PROGRAMS **This Study Ending Soon!!**

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 **415-255-0744**

♦ A study to examine characteristics of the immune system of HIV+ people to further research on HIV therapies and vaccines. Participants must be HIV+ for at least 1 year and never received HIV medications. Compensation to \$285 for 2 visits.

♦ A Phase I study of the TUTI-16 tat vaccine for treatment of HIV. Must be HIV+ for at least six months, no viral load between 3,000 and 100,000 and CD4+ count >400. Compensation is \$35 per visit, up to \$280 for study completion.

EAST BAY AIDS CENTER (EBAC)

3100 Summit Street, 2nd Floor
Oakland, CA 94609 **510-869-8490**
http://www.altabates.com/clinical/aids_scvs.html

♦ A Phase III 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.

HEALTH MANAGEMENT INSTITUTE

45 Castro Street, Suite 415
San Francisco CA 94114 <http://hmii.org/> **415-565-6288**

♦ **SWIFT Study:** a 48-week study to evaluate the safety and efficacy of switching from Epzicom (Ziagen/Epivir) to Truvada (Viread/Emtriva) for those currently on a suppressed regimen containing Epsicom and a boosted protease inhibitor. Compensation provided for study and screening.

KAISER PERMANENTE MEDICAL GROUP-SF

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

♦ A 48-week study of Taimed Biologics monoclonal antibody ibalizumab for those who are treatment-experienced, have a VL >1000, and have susceptibility to at least one active ARV.

♦ 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 of 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.

METROPOLIS MEDICAL GROUP

2351 Clay Street, Suite 512
San Francisco, CA 94115 **415 292-5477**
All studies provide free labs, study drugs & compensation between \$500 & \$750

♦ **QUAD Study** comparing Atripla to Quad, a new one-pill-a-day co-formulation of an investigational integrase inhibitor, an investigational booster and Truvada for ARV-naïve individuals.

♦ A head-to-head comparison of an investigational booster versus ritonavir in combination with Truvada and Reyataz for ARV-naïve individuals.

♦ A comparison of two integrase inhibitors in treatment-experienced individuals with detectable virus. Background regimen is individualized.

♦ **Swift Study:** A switch from Epsicom to Truvada for those with undetectable virus currently on a protease inhibitor.

QUEST CLINICAL RESEARCH

2300 Sutter Street, Suite 202
San Francisco, CA 94115



www.questclinical.com

415-353-0800

- ♦ A 96-week study of a new integrase inhibitor which does not require boosting, for treatment-naïve individuals with a CD4+ cell count >100 and a viral load >1,000. Compensation is \$50 per visit.
- ♦ Hepatitis C: Volunteers needed for multiple studies with a variety of inclusion criteria. Please call site for details.
- ♦ A 48-week study of Taimed Biologics monoclonal antibody ibalizumab for those who are treatment-experienced, have a viral load >1000, and have susceptibility to at least one active ARV. Compensation is \$35 per visit.
- ♦ 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.

UCSF/ADULT AIDS CLINICAL TRIALS UNIT

995 Potrero Avenue, Bldg 80, Ward 84
San Francisco, CA 94110

415-514-0550, ext. 353

http://php.ucsf.edu/rsrch_trials.shtml

All AACTG studies provide compensation

- ♦ Start HIV meds on a 2+ year randomized study comparing Reyataz vs. Prezista vs. Isentress. (A5257)
- ♦ A study for HIV+ women to see if HPV vaccine Gardasil may fight off HPV disease. (A5240)
- ♦ A study for HIV+/HCV+ people with insulin resistance and HCV genotype 1 who have failed HCV treatment in the past. (A5239)
- ♦ A study for those with a viral load >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 (A5241)

UCSF / POSITIVE HEALTH PROGRAM / SFGH

http://php.ucsf.edu/rsrch_trials.shtml#anc2

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

♦ Maraviroc Intensification Study: Do you have a low CD4 cell count despite undetectable viral load on HAART? A randomized, controlled trial is adding CCR5 inhibitor maraviroc to current HAART to see if intensifying therapy increases CD4+cell counts. Compensation provided. **415-476-4082 x104**

♦ A pulmonary hypertension (PH) study is now recruiting for HIV+ individuals with suspected PH or diagnosed PH. 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. **415-353-8892**

♦ Hepatitis C and HIV Co-infection: A new 24-week treatment study for those infected with HCV within the past six months. No CD4+ or viral load restrictions. Compensation provided. **415-476-4082 x556**

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

♦ Volunteers are needed for a study evaluating the effects of integrase inhibitor raltegravir (Isentress) 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 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**

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 each study.

♦ Help researchers find the CD8+ cell anti-HIV factor (CAF) that naturally protects infected people from disease. If you are not taking ARVs or have been on treatment for less than one year you can volunteer for this blood draw study. **415-476-4071**



Other UCSF-Sponsored Studies, continued on Page 4

Other UCSF-Sponsored Studies, continued

♦ Volunteers are needed for a study examining the effects of labeled water (D₂O) on the activity of T-cells and flow of molecules in the CNS. Participants must be willing to drink labeled water 2-3 times daily for either 12 days or 6 weeks and undergo 3 spinal taps and 4 blood draws in 12 days or 4 spinal taps and 5 blood draws in 6 weeks. Compensation provided.

415-206-4328 or 415-215-0202

♦ Cognitive health study for those over 60 years of age to determine if insulin resistance is involved in the cognition process. Participants may not have had a brain infection. Study includes annual follow-up. Compensation is \$50 for the initial visit and \$50 for an MRI.

415-476-5485

♦ 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. Compensation is provided.



415-597-9322

♦ NUCLEOMAXX: A 2-month study to evaluate the effects of uridine supplementation for those who are taking, or have recently taken AZT, (Zidovudine Retrovir, Combivir or Trizivir) or D4T (stavudine or Zerit) and have a viral load between undetectable and 10,000 copies. Compensation is provided.

415-206-4090

♦ OPTIONS Project for those recently exposed to HIV and experiencing acute retroviral syndrome or those who have sero-converted within the past six months. Compensation is provided.



415-502-8100

♦ The 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 ARVs. Compensation is provided.



415-632-5030

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. This study is open to those who are HIV+, HCV+ or co-infected, whether you intend to begin treatment or not. Compensation is \$20 per visit.

SF VETERANS ADMINISTRATION MEDICAL CENTER

4150 Clement Street
San Francisco, CA 94121

415-221-4810 ext. 3763

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

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

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

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/>

♦ A phase III, randomized, open-label trial comparing 3 drug regimens in ARV-naïve patients. The study will compare Isentress vs. boosted Atazanavir vs. boosted Prezista, plus Truvada. (A5257)

♦ A study of a two dose regimen of Zostavax, a herpes zoster vaccine, for those with CD4+ >200 and undetectable viral load on current ARVs. (A5247)

♦ 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 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 12 weeks. Must have a CD4+ cell count >100 and a viral load > 5000 copies.

♦ A study to explore whether adding CCR5-antagonist maraviroc (Selzentry) to an existing regimen will 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+ persons whose current HIV medicines are not working. (A5241)

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Diane Cenko, Editor



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HIVCare at Saint Francis Memorial Hospital is an
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