

# HIVCare News

NOVEMBER / DECEMBER

2009


CLINICAL RESEARCH  
OPPORTUNITIES

See Pages 2, 3, & 4

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

### PHARMACEUTICAL UPDATES

- **Correction: Intelence, not Isentress, Update**

 A printing error in the September/October issue of *HIVCare News* attributed safety label changes regarding severe skin reactions intended for **Intelence** (etravirine) to Isentress (raltegravir) instead.

While reactions have been recorded for both drugs, more severe reactions and a special warning now exist for Intelence. Please note here the correct safety label information:

In August 2009, The Food and Drug Administration (FDA) announced **Intelence** safety label changes 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, recently reported in a small number of individuals. Reported reactions may begin with flu-like symptoms, including rash, malaise, fever or nausea and may progress to include serious liver dysfunction. Reactions usually start within the first six weeks after beginning the drug and should be reported to a primary care provider immediately.

- **Viramune Co-Pay Program Now Available**



Boehringer-Ingelheim Pharmaceuticals, Inc. has announced the launch of a Viramune (nevirapine) Co-Pay Savings Program, a program that will allow patients to save up to \$50 on their health insurance co-payment on every monthly refill of a Viramune prescription for up to one year. Any patient with a Viramune prescription who has health insurance coverage requiring a patient co-payment is eligible for the program. The Viramune Co-Pay Savings Card is available directly from healthcare providers. Additional information about the program is available at [www.viramune.com](http://www.viramune.com).

- **Drug Levels Decrease with Tobacco, Marijuana**



A small study reported at the 49<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in September demonstrated that tobacco smoking and marijuana can significantly decrease blood levels of protease inhibitor atazanavir (Reyataz). Researchers obtained levels of atazanavir, viral loads and CD4+ cell counts for 32 HIV-positive people who acknowledged substance abuse problems and 35 people without such disorders. For those who used marijuana and tobacco regularly, trough atazanavir levels (lowest level between medication dosing) were significantly lower than among

those who did not use these substances. Alcohol, cocaine, and opioid use were also assessed, but these substances did not appear to affect atazanavir concentrations. Researchers theorized that liver enzymes involved in drug metabolism may be more active in the presence of certain substances, including cigarette smoke, and that this might account for decreased levels of atazanavir. As this was a small, preliminary study, researchers suggest that additional studies are needed to confirm or refute the association found here and should explore the mechanism that may have caused these lower blood levels and examine whether others ARVs may be similarly affected. This study has highlighted the need to be careful not just about interactions of prescription and nonprescription drugs, but also other compounds that those taking antiretrovirals may be using.

### SURVIVING THE FLU EPIDEMIC



The Conant Foundation invites attendance at an important Community Forum on the topic of how the influenza epidemic may affect those living with HIV. The latest information on the H1N1 virus, the seasonal flu and the avian flu, with updates on prevention, vaccination and treatment will be presented by an expert panel including Dr. Marcus Conant, M.D., Dr. Drew Lawrence, M.D., Dr. Jay Lalezari, M.D. and Alan McCord of Project Inform. There is no charge for attendance.

Date: Tuesday, November 10, 2009

Time: 6:30 to 8:30 PM

Place: LGBT Center, 1800 Market Street, at Octavia

### NEW UNDER ONE ROOF STORE @ WESTFIELD



Under One Roof has announced the opening of a Christmas store at the Westfield San Francisco Center on Market Street. The store will open on November 2, 2009 and will be located on the Dome Level. Holiday-inspired gifts, ornaments and unique San Francisco mementos will be among the many offerings.

Under One Roof is one of the largest providers of unrestricted grants to AIDS Service Organizations in the San Francisco Bay Area. As a volunteer-driven organization they will need help at the Westfield location and at the established store location at 518 Castro Street. Anyone interested in becoming a volunteer for this holiday season can get more information by calling 415-503-2300 or by visiting [www.underoneroof.org](http://www.underoneroof.org).

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**

♦  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 Epzicom and a boosted protease inhibitor. Compensation provided.

♦ 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.



**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**

♦  Got the flu and <500 T Cells? A study of an investigational new flu treatment for those 18 to 65 with flu and a fever over 100 degrees, plus cough, sore throat, muscle ache *or* headache. Compensation provided

♦ A Phase I study of the TUTI-16 tat vaccine for treatment of HIV. Must be HIV+ for at least six months, 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, @nd Floor  
Oakland, CA 94609 **510-869-8490**  
[www.altabates.com/clinical/aids\\_scvs.html](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 Epzicom and a boosted protease inhibitor. Compensation provided for study and screening.

**HENNE GROUP**

[www.hennegroup.com](http://www.hennegroup.com) **866-808-8109 ext 251**

♦  A 60-minute research interview to discuss health issues that face people living with HIV. The interview will take place in Oakland on Tuesday, November 17, 2009 with \$100 compensation.

**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*

♦  INROADS Study: A new once-daily combination of Intelence and Prezista (total of 5 tablets) without nucleosides for those who have detectable virus on a current regimen.

♦  RALPIR study: A switch study from Viread or Truvada to Isentress for people with protein in the urine and no detectable virus.

♦ 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 Epzicom 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](http://www.questclinical.com)

**353-0800**

- ♦ Got the flu and <500 T cells? A study of an investigational new flu treatment for those 18 to 65 with flu and a fever over 100 degrees, cough, sore throat, muscle ache *or* headache. Compensation provided.
- ♦ Gene Therapy study using zinc-finger modified CCR5 receptors on CD4+ cells to make them resistant to HIV infection. For those who have been fully suppressed for at least 18 months and have CD4+ cells between 200-500. Compensation to \$1875 for completion of study.
- ♦ HCV-HIV Co-infection study using a new HCV protease inhibitor teleprivir for those NOT on current ARVs with a CD4+ cell count >500 OR those on ARVs with a CD4+ cell count > 300 and undetectable VL. Compensation to \$750 for completion.
- ♦ Pneumococcal Vaccine study to evaluate immune response in HIV+ individuals. This study is for those with prior pneumococcal vaccination and CD4+ cells >200. Compensation up to \$450
- ♦ 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.
- ♦ 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.
- ♦ Hepatitis C: Volunteers needed for multiple studies with a variety of inclusion criteria. Please call site for details.

**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](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](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.
- ♦ A study to evaluate changes in brain structure and chemistry using MRI and magnetic resonance spectroscopy. 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**
- ♦ HCV 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**

Please Notify HIVCare if your mailing address has changed.

**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. This study 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**
- ◆ 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**
- ◆ Volunteers are needed for a study examining the effects of labeled water (D<sub>2</sub>O) 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**
- ◆ 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**  
<http://www.ucsf.edu/options/>
- ◆ 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 with boosted darunavir (Prezista) 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/>

- ◆ 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 without R5 tropism will not be given maraviroc but will be observed in the study.
- ◆ 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)
- ◆ A phase III, randomized, open-label trial comparing 3 drug regimens in ARV-naive 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)
- ◆ A study adding maraviroc (Selzentry) to an existing regimen to see if it will help to increase CD4+ cell count in those with current count <350 and viral load <50 copies.
- ◆ 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)

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Subscriptions are free of charge by mail or email.

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HIVCare is an ADAP Enrollment Site