

# HIVCare News

MARCH/ APRIL  
 2009  
 CLINICAL RESEARCH  
 OPPORTUNITIES  
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## Guide to HIV-Related Clinical Research in the San Francisco Bay Area

### PHARMACEUTICAL UPDATES

#### ◆ Heat-Stable Norvir Tablet Approved



The Food and Drug Administration (FDA) has approved a new heat-stable tablet formulation of protease inhibitor Norvir (ritonavir) that does not need to be refrigerated, and can be stored safely at room temperature. The new tablet and the original soft-gel capsule both contain 100 mg of ritonavir, and while the absorption rate is different, the manufacturer claims there is no requirement for dosage change.

#### ◆ New Kaletra Interactions Reported

The FDA has recently approved revisions to the Kaletra (lopinavir/ritonavir) package insert to include new information about interactions with inhaled medicines, including Serevent, Advair and Revatio (sildenafil). The resulting complications vary with each product but are considered serious and may include heart palpitations, hypotension, and visual changes. Anyone currently taking Kaletra and using an inhalant should contact his or her primary care provider to discuss the potential interactions.



#### ◆ Prezista Label Changes Based on New Data



Based on two 96-week studies of protease inhibitor Prezista (darunavir) new safety information has been added to the label for both treatment-naïve and treatment-experienced individuals. Newly identified interactions with Selzentry (maraviroc) indicate that a dose and timing adjustment is advised. In addition, osteonecrosis has been added as an adverse drug reaction.

#### ◆ New Safety Concern for Invirase/Ritonavir

The FDA has announced preliminary data suggesting that Invirase (saquinavir) in combination with Norvir (ritonavir) may have potentially adverse effects on the heart. When used together, the drugs may cause an abnormal heart rhythm or a heart block. Symptoms can include lightheadedness, fainting, or abnormal heart beats and may progress to a life-threatening irregular heart beat known as ventricular fibrillation (VF). Any symptoms should be immediately reported to a primary care provider.



### CONFERENCE UPDATE

- ◆ **CROI 2010:** The 17<sup>th</sup> Conference on Retroviruses and Opportunistic Infections (CROI) was held in San Francisco in February. For the first time in recent memory, the opening session of



the conference included the word “cure.” Dr. John Hoxie, University of Pennsylvania, discussed the HIV-positive man who, following an autologous bone marrow transplant for leukemia has remained free of detectable virus for over 1,000 days without medication. Whether the individual is cured remains to be determined, but this intriguing case provides an incentive to those seeking novel approaches to viral eradication. A few of many conference highlights include the following:

- An increasing recognition of the role of inflammation in endothelial dysfunction and carotid atherosclerosis; whether inflammation is the result of the virus, the treatments, or both, requires more study.
- Starting antiretroviral therapy earlier, with a higher CD4+ cell nadir (lowest count recorded) was associated with improved stiffness in blood vessels.
- Presentation of an updated ranking on brain-penetrating ARVs, with mixed findings on how significant brain penetration actually may be. One study found that those with undetectable HIV levels in the blood are also likely to have undetectable levels in the brain as well. The best penetrators were zidovudine, nevirapine and indinavir/ritonavir.
- Identification of vitamin D deficiency in up to 72% of HIV-positive individuals tested; a low level of vitamin D has been associated with a number of potentially serious illnesses, including osteoporosis, and with increased risk for cardiovascular disease, metabolic syndrome, diabetes, insulin resistance, immune dysfunction and senescence.
- Starting antiretroviral therapy during treatment for opportunistic diseases, not treating the disease alone, in people diagnosed with advanced HIV infection lowered several inflammation markers more than treating the opportunist infection alone, without added ARV therapy.
- HIV-positive men and women are more likely to have decreased bone mineral density compared with HIV-negative people of similar ages.
- There were fewer than usual reports of new ARVs. An exception: Gilead’s Quad, the first-ever 4-drug coformulation containing tenofovir, emtricitabine, experimental integrase inhibitor elvitegravir and experimental boosting agent cobicistat.
- About one of every six new HIV cases diagnosed in 2007 involved virus drug-resistance mutations.
- And, for the first time, CROI sessions are available for viewing on the internet and can be found at [http://retroconference.org/2010/data/files/webcast\\_2010.htm](http://retroconference.org/2010/data/files/webcast_2010.htm).

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 **II**=Integrase Inhibitor **NRTI**=Nucleoside/Nucleotide Analog **NNRTI**= Non-nucleoside 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 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.

◆ **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.

**CONANT MEDICAL GROUP CLINICAL RESEARCH**

470 Castro Street, Suites 202-204  
San Francisco, CA 94114 **415-575-7500**  
[dirby@conantmedical.org](mailto:dirby@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.

**EAST BAY AIDS CENTER (EBAC)**

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

◆ Do you have HIV-related diarrhea? A study to evaluate cfofelemer, 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.


**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 cfofelemer, 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.

**METROPOLIS MEDICAL GROUP**

2351 Clay Street, Suite 512  
San Francisco, CA 94115 **415 292-5477 ext. 486**  
All studies provide free labs, study drugs & compensation between \$500 & \$750

◆  The **QUAD Study:** A comparison of two once-daily options, Atripla or Quad, for HIV+ people who have never taken ARV therapy before.

◆  The cobicistat study comparing a new booster versus Norvir, both in combination with Truvada and Reyataz.

◆ **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.

◆ **SWIFT Study:** A switch from Epzicom to Truvada for those with undetectable virus currently on a protease inhibitor containing regimen.

**QUEST CLINICAL RESEARCH**

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



◆ **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.

◆ 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.

◆ A maturation inhibitor study for those with a viral load > 1000 copies and sensitivity to at least two other ARVs.

◆ 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.

◆ **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 \$45.

◆ **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

- ♦  A study of a two dose regimen of Zostavax, a herpes zoster vaccine, for those with a CD4 count between 200 and 350, with undetectable VL on current ARV. (A5247)
- ♦ A study evaluating the ability of trained staff to conduct an effective oral exam for individuals with <200 CD4 T cells. (A5254)
- ♦ 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 of levels of pro-inflammatory HDL cholesterol for African American men age 50 and older, HIV+ or HIV-negative. **415-353-2463**
- ♦  A study to assess the use of saliva in measuring HIV viral load and oral mucosal disease. Compensation is \$20 per visit. **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 CCR5 inhibitor maraviroc to current HAART to see if intensifying therapy *improves cardiovascular function*. Compensation provided. **415-476-4082 x104**
- ♦  Solid Organ Transplantation in HIV: This study is closed, but *transplants continue as standard of care*. <http://hivtransplant.com/> **415-353-8892**
- ♦ 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**
- ♦ 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**

**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**
  - ♦ 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, HIV+ and not taking ARVs. Compensation provided. **415-632-5030**
- 
- ♦ Are you about to start or re-start HIV medications? Earn up to \$575 in a study of the interaction of alcohol and antiretrovirals. **415-206-3364 or 415-719-5605**
  - ♦ 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**
  - ♦ A study to evaluate how HIV persists in the body and how treatment with Isentress and Truvada changes the distribution of HIV in the body. Participants must be ARV-naïve and have a CD4+ count >350. Compensation to \$220. **415-476-4082 ext 341**
  - ♦ A study to see if adding Raltegravir to a current ARV regimen for 24 weeks will improve cardiovascular function. For those with suppressed viral load for at least one year not currently starting or stopping cholesterol or blood pressure meds in the past 12 weeks. Compensation to \$375. **415-476-4082 ext.341**
  - ♦ 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**
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- ♦ Volunteers are needed for a study evaluating the effects of Isentress on the central nervous system. Participants must be on a 3-drug regimen for 2 years or longer and 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**
  - ♦ 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**

**Would you prefer to receive HIVCare NEWS by email? Reply to [dcenko@chw.edu](mailto:dcenko@chw.edu).**

Other UCSF, Continued from Page 3

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



♦ A study to evaluate changes in brain structure and chemistry using MRI and magnetic resonance spectroscopy. Compensation is provided. **415-206-4328**

♦ 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**

♦ 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**

♦ 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**

♦ OPTIONS Project for those recently exposed to HIV and experiencing acute retroviral syndrome or those who have seroconverted within the past six months. Compensation is provided. **415-502-8100**



**UCSF AIDS-ASSOCIATED MALIGNANCIES**

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)

**UCSF ADOLESCENT TRIALS NETWORK**

3333 California, Suite 248  
San Francisco CA 94118 **415-514-2434**

♦  Several studies are available for 18-24 year old HIV-positive individuals, with detectable virus, no prior ARV therapy, CD4+ count >350, willing to start HIV therapy or defer therapy based on CD4+ counts. Call site for details. Compensation for time and travel is provided.

**PALO ALTO VETERANS HEALTHCARE CENTER**

3801 Miranda Avenue  
Palo Alto, CA 94304 **650-496-2510**

♦ Hepatitis C (HCV) & HIV or Hepatitis C: A one time blood draw for those who have spontaneously cleared hepatitis C without treatment.

♦ Hepatitis C (HCV) and / or HIV: A study to determine whether HCV treatment or HIV treatment makes the immune system respond differently for those who are HIV+, HCV+ or co-infected, whether on treatment or not. Compensation \$20 per visit

**SF VETERANS ADMINISTRATION MEDICAL CENTER**

4150 Clement Street  
San Francisco, CA 94121 **415-221-4810 ext. 3763**

♦  QUAD Study: a comparison of two once-daily options, Atripla or Quad, for HIV+ people who have never taken ARV therapy before.

♦  A study of a new NNRTI, UK453061, in combination with darunavir/ritonavir and an NRTI for ARV-experienced individuals with evidence of NNRTI resistance

♦  A study of an investigational oral flu treatment for those under 65 and diagnosed with influenza.

♦ 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**

1000 Welch Road, Suite 202  
Palo Alto, CA 94304 **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 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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