

## PHARMACEUTICAL UPDATES

### ◆ Ritonavir Precautions and Cardiac Issues



In August 2008 the Food and Drug Administration (FDA) approved changes to the product label for Ritonavir (norvir) reflecting new information about electrocardiogram changes and cardiac arrhythmias. The label now states that norvir should be used with caution in patients with underlying structural heart disease, preexisting conduction system abnormalities, cardiomyopathies, or ischemic heart disease, as these individuals may be at increased risk for developing cardiac conduction abnormalities.

### ◆ Reyataz Safety Label Changes



In August 2008 the FDA announced significant updates to the Reyataz (atazanavir) package insert regarding new drug-drug interaction information, specifically the administration of Reyataz (with or without ritonavir) and nevirapine (Viramune), efavirenz (Sustiva), all hormonal contraceptives, midazolam, H<sub>2</sub>-receptor antagonists, and drugs that are substrates of cytochrome P450 2C8. Cytochrome P450 2C8 is involved in the metabolism of drugs such as paclitaxel, rosiglitazone, and cerivastatin, among others.

According to this new information, Reyataz should not be administered with nevirapine because nevirapine decreases Reyataz exposures resulting in risk for nevirapine toxicity. With regard to efavirenz, co-administration results in decreased Reyataz exposure. For treatment-experienced patients it is recommended that Reyataz not be combined at all with efavirenz for this reason. For treatment-naïve patients, dosing adjustment is recommended using Reyataz 400 mg with ritonavir 100 mg and efavirenz 600 mg once daily.

For more information on Reyataz label changes, check with a pharmacist or the following FDA web site:

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label.ApprovalHistory>

### ◆ New Safety Information for Tenofovir Combos



In July 2008 the FDA approved safety label changes for those using fixed-dose ARV medications containing tenofovir (Viread) to advise of the potential risk of renal (kidney) impairment. A previous alert had been issued for tenofovir alone.

In addition, the safety labeling cautions about risk for the worsening of hepatitis B (HBV) infection in those co-infected with HIV/HBV and the potential for performing complex behaviors while asleep after taking certain sedating medications concurrently with tenofovir-containing medications.

### ◆ Label Change Adds Pre-testing for Abacavir HSR



Use of the NRTI abacavir (Ziagen) has been associated with a serious hypersensitivity reaction (HSR), estimated to occur in 2-8 % of exposed individuals. This sometimes-fatal reaction is a multi-organ syndrome that can include fever, rash, gastrointestinal symptoms, respiratory symptoms and generalized malaise, fatigue or myalgia. At the time of original approval, it was not possible to identify those who might be at greatest risk for developing the HSR. A screening test has been available for some time to identify those who carry a particular genetic allele, called HLA-B\*5701, which is associated with the serious HSR. The FDA has now approved safety label changes recommending that before initiating or restarting Ziagen *all* individuals undergo specific HLA screening, using the Trofile assay. Those who are positive for HLA-B\*5701 should consider alternative therapies.

## CONFERENCE UPDATE

### XVII International AIDS Society Conference

Mexico City was the site of the XVII International AIDS Conference, August 3-8, with a theme of



"Universal Action NOW." More than 22,000 researchers, policymakers, and treatment advocates attended the event.

Among the topics covered were the timing of antiretroviral therapy (early vs. late), metabolic complications, and details on potential cardiovascular risk factors. Other Conference highlights included the following:

◆ Dr. Anthony Fauci, MD, of the National Institutes of Health raised the possibility of a cure during a session on the future of the HIV epidemic. He later stated he was not suggesting a theoretical goal, but a real scientific possibility that is under study.

◆ A late breaker session review of studies of sero-discordant couples where the HIV-positive partner was on antiretroviral treatment could neither confirm nor disprove the recent Swiss declaration of a negligible risk of HIV transmission from a person on treatment with undetectable viral load.

◆ Kidney toxicity is most likely to occur in patients taking tenofovir if they are controlling high blood pressure with potentially kidney-toxic drugs, while also taking protease inhibitors.

◆ For complete conference details see the official Conference website: <http://www.aids2008.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**

- ♦  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.
- ♦  IRISS Study Intervention for Recently Informed of Sero-positive Status: A 5-week intervention to increase positive affect in newly diagnosed. 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 to the study participant. 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 study of a new NRTI, apricitabine, for those who are resistant to 3TC or FTC. Participants must have a VL >2,000 and currently be taking FTC or 3TC. Resistance testing will be provided. Compensation is \$35 per visit.
- ♦ 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 \$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-Hayward**

27400 Hesperian Blvd  
Hayward, CA 94545 **510-784-6499**

*No studies are currently enrolling at this site.*


**KAISER PERMANENTE MEDICAL GROUP-SF**

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

- ♦ A study of a new NRTI, apricitabine, for those who are resistant to 3TC or FTC. Participants must have a VL >2,000 and currently be taking FTC or 3TC. Resistance testing will be provided.
- ♦ A Phase III placebo-controlled study to evaluate  crofelemer, a unique twice-daily treatment for HIV-related diarrhea. Must be on stable ARVs for at least 4 weeks, have a CD4+ count >100 and be experiencing diarrhea on a daily basis.

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

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

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

**QUEST CLINICAL RESEARCH**

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



**415-353-0800**

- ♦ A two-week, dose-escalating study of an investigational new integrase inhibitor for those either ARV-naïve or not 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. Compensation up to \$1500 for a total of 14 study visits.


*Quest Clinical, continued on Page 3*

*Quest Clinical, continued*

- ♦ Phase III study of a new once-daily NNRTI, TMC278, versus Sustiva both with abacavir and 3TC in ARV-naïve individuals. Compensation to \$480.
- ♦ Hepatitis C (without HIV) Volunteers are needed for a 15-day study of an experimental oral medication to treat hepatitis C. Compensation to \$2,100.

**RIDER RESEARCH GROUP**

40 Hillway Avenue  
San Francisco, CA 94117 **415-682-2430**

- ♦ A Phase III placebo-controlled study to evaluate a  unique twice-daily treatment for HIV-related diarrhea, crofelemer. Must be on stable ARVs for at least 4 weeks, have a CD4+ count >100 and be experiencing diarrhea on a daily basis.

**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.

- ♦  **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 be on a stable ARV regimen containing tenofovir in combination with 3TC or FTC. Compensation is provided. **415-476-9296, ext 309**
- ♦ Do you have a low CD4 cell count despite HAART? A randomized, controlled trial adding integrase inhibitor raltegravir to current HAART to see if intensifying therapy with raltegravir will lead to further decrease in viral load and immunologic benefit. Compensation is provided. **415-476-4082 x122**
- ♦ 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. **415-206-5461**
- ♦ Volunteers are needed for a study evaluating the effects of 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**

- ♦ **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**

- ♦ 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**

- ♦ Anal HPV Study for HIV-positive African American men who are at risk for HPV, the virus that causes genital warts. You may qualify whether or not you have ever had genital warts or been told you have had HPV. Compensation is provided. **415-353-2463**

- ♦ 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**

- ♦ 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**

- ♦ **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**

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

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

- ♦ A Phase II study of DR-COP therapy for newly-diagnosed, previously untreated AIDS-associated B-cell non-Hodgkin's lymphoma at any stage. (AMC 047)
- ♦ 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)

**UCSF/COMMUNITY CONSORTIUM**

510 Treat Avenue (between Folsom & Harrison)  
San Francisco, CA 94110 **415-476-9554 ext. 315**

- ♦ Opioid and Cannabinoid PK interaction study for those who have been on stable pain medication for chronic pain. Uses vaporized cannabis. Call site for details. Compensation to \$520

**OTHER UCSF- SPONSORED STUDIES**

*Locations and phone numbers vary with study*

- ♦ 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 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**
- ♦ NUCLEOMAXX Study to evaluate the effects of uridine supplementation for those with a viral load <10,000, taking AZT or D4T for the past year. Compensation provided.
- ♦ 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**
- ♦ CHAI (Coping with HIV and Affect Interview) for anyone recently diagnosed with HIV; includes 7 interviews to identify how a new diagnosis affects one's life. Compensation is \$30 per visit **415-353-4299**  
[http://www.osher.ucsf.edu/Research/abstract\\_chai.aspx](http://www.osher.ucsf.edu/Research/abstract_chai.aspx)

**SF VETERANS ADMINISTRATION MEDICAL CENTER**

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

- ♦ POEM Study: A 5-year study to monitor the safety of long-term use of CCR5 antagonist maraviroc in a larger and more diverse patient population. Those who do not have R5 tropism will not be given Maraviroc, but will be only observed in the study.
- ♦ Do you have a low CD4 cell count despite HAART? A randomized, controlled trial adding integrase inhibitor raltegravir to current HAART to see if intensifying therapy with raltegravir will lead to further decrease in viral load and immunologic benefit.



**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/>

- ♦  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 new integrase inhibitor GS144, boosted with ritonavir, 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 two weeks. Must have a CD4+ cell count >100 and a viral load > 5000 copies.
- ♦  A study to explore whether adding maraviroc (Selzentry) 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, given in 3 separate doses, 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-infected persons whose current HIV medicines are not working (A5241)

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HIVCare at Saint Francis Memorial Hospital  
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