

HIVCare News

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

NOVEMBER / DECEMBER


2008

CLINICAL RESEARCH
OPPORTUNITIES

See Pages 2, 3, & 4


PHARMACEUTICAL UPDATES

◆ Expanded Use of Prezista Approved

 On October 22, 2008 the Food and Drug Administration (FDA) approved expanding the use of protease inhibitor Prezista (darunavir, TMC114) to include ARV-naïve individuals. Prezista originally received accelerated approval in 2006 for ARV-experienced individuals, targeting those who had failed previous protease inhibitor-containing regimens.


Recommended dosing for treatment-naïve individuals differs from that of the treatment-experienced and has been set at 800 mg (two 400 mg tablets) boosted with 100 mg of ritonavir *once* daily. For treatment-experienced adults, the dosing remains at 600 mg boosted with 100 mg ritonavir *twice* daily. Prezista should be taken with food in all cases. It is recommended that Prezista not be combined with indinavir (Crixivan), lopinavir/ritonavir (Kaletra), saquinavir (Invirase) or pravastatin (Pravachol). The new 400 mg tablets should be available in pharmacies by early November 2008.

◆ More Changes to Reyataz Prescribing Information

 On September 30, 2008 the FDA authorized a revised packet insert for Reyataz (atazanavir) to include alternative dosing for treatment-naïve individuals. Recommended dosing has now been established at 300 mg once daily boosted with 100 mg of ritonavir, taken with food. For treatment-naïve individuals who are unable to tolerate ritonavir, atazanavir 400 mg once daily, with food, is recommended.

Updated information about the occurrence of rash now indicates that up to 20% of those treated with Reyataz have experienced a rash within 7 weeks of starting the drug. Average rash duration was 1.3 weeks. Less than 2% discontinued therapy because of the rash.

◆ Raltegravir and Symptoms of Depression

 A report in the September 12 issue of *AIDS* suggests that the addition of raltegravir (Isentress) to the treatment regimen of someone who is taking antidepressants or antipsychotics may result in a short-term increase of depressive symptoms. As a result of four case reports from Canadian physicians, all involving men between the ages of 40 and 55 who had a history of depression or bipolar mood disorders, it was reported that within a month of initiating treatment with raltegravir, all four experienced exacerbated (worsening) symptoms and one had to be hospitalized. However, dose adjustments of the antidepressant/antipsychotic medications ultimately resulted in dissipation of symptoms.

HARNESSING AN INNATE ANTI-HIV ENZYME



An enzyme that exists in every human cell, called APOBEC-3G, appears to be capable of stopping HIV replication at the initial step in the process, when retroviral RNA is transcribed into viral DNA. Scientists have studied this enzyme for several years, but until recently it wasn't apparent how it might be used to control HIV. A report published in the October 12 issue of the online journal *Nature* indicates that researchers have now identified what is described as the "atomic structure of the active portion" of APOBEC-3G, suggesting how and where the enzyme binds to viral DNA, mutating and destroying it. In the human body, APOBEC-3G is thwarted in its effort to control HIV because HIV has evolved to "encode the protein *Vif*, known as a virulence factor, that blocks APOBEC-3G." Results from this research suggest important clues about this binding that could ultimately be used to design drugs that would allow APOBEC-3G to function against HIV. "This would unlock humans' innate ability to fight HIV. We were born with it, and it's there waiting," commented researcher Xiaojiang Chen of the University of Southern California where this research was done. "Mapping the structure of APOBEC-3G at the atomic level is a goal that has been sought after worldwide because of its significance," Chen stated.

<http://www.sciencedaily.com/releases/2008/10/081012164445.htm>

UNIQUE IMMUNOLOGIC STUDY AT NIH



The National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID) in Bethesda, MD, has initiated a unique study to evaluate the immunologic and virologic response of certain HIV "progressors" following an infusion of lymphocytes from "elite long-term non-progressors." The study will infuse cells obtained from an HIV-positive non-progressor who has been able to control HIV replication without medication into a progressor who has failed at least two standard regimens of HIV therapy.

The study is seeking both donors and recipients. Up to 3 donors and 3 recipients will be eligible to participate. Donors will be compensated. Transportation is generally provided to all participants in NIAID studies. For additional enrollment information contact study coordinator Rocco Caldararo at 301-402-3481 or caldararor@niaid.nih.gov.

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**

- ♦ **IRISS Study:** The IRISS Study is exploring different ways to help people cope with a new HIV diagnosis. If you have been recently diagnosed with HIV you may be eligible. 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 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 **415-255-0744**

- ♦ 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, 2nd Floor
Oakland, CA 94609 **510-869-8490**
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**

- ♦ **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 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.
- ♦ Do you have HIV-related diarrhea? A 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 28th Street Study: **510-508-4477**
Oakland, CA 94609 Office: **510-835-5000**
<http://www.hivaidszimbabwe.com/clinics/scott.php>

- ♦ Do you have HIV-related diarrhea? A 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 **415-353-0800**



- ♦ **Attachment Inhibitor,** combined with optimized background, for those with limited ARV options, comparing two different doses (no placebo) of an inhibitor that interferes with co-receptor binding for both CCR5 and CXCR4.
- ♦ 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 Research, continued from Page 2

- ♦ 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**

- ♦ Do you have HIV-related diarrhea? A 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.

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

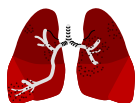
All AACTG studies provide compensation

- ♦ 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
Locations and phone numbers vary with study.

- ♦  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**
- ♦ Raltegravir Intensification 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. 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**
- ♦ **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 be on a stable ARV regimen containing tenofovir in 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**

- ♦ 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**

- ♦ 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**

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

AAM Clinical Trials Consortium, continued from Page 3

- ♦ 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

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

- ♦  **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 antiretroviral medications. Compensation is provided. **415-632-5030**



- ♦ **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. **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**

- ♦ **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.

- ♦ **Raltegravir Intensification 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, 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-infected persons whose current HIV medicines are not working. (A5241)

HIVCare News is made possible

through the generosity of the Saint Francis Foundation
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



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