

HIVCare News

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

JANUARY / FEBRUARY

2009

CLINICAL RESEARCH
OPPORTUNITIES

See Pages 2, 3, & 4

PHARMACEUTICAL UPDATES

♦ The State of HAART 2009: Transformation



The Jan 15, 2009 issue of *Clinical Infectious Diseases* provides timely insight into the current state of Highly Active Antiretroviral Therapy (HAART). Drs. Lucy Wilson and Joel Gallant state: "The recent approval of new antiretroviral agents within existing and novel classes has ushered in a *transformation* of the HIV treatment landscape." Some examples of this transformation include the following. For treatment-experienced individuals with extensive drug resistance and previously untreatable virus, there now may be multiple new options for suppressive therapy. Also, revised U.S. and international treatment guidelines now state that the goal of therapy is virological suppression to <50 copies/mL for *everyone* being treated, not only for those on an initial regimen.

According to Wilson & Gallant, these developments "represent a major step forward" and also "create new challenges for clinicians, who must be knowledgeable about the use and interpretation of a variety of types of resistance and tropism assays, who must understand the issues of pharmacokinetics and drug interactions, and who must keep abreast of the expanding treatment armamentarium." Additionally, the sequencing of therapy options, consideration of side effects and even financial considerations impact HAART decisions, further transforming therapy options.

While only one new ARV was approved in 2008, NNRTI Intelence, the previous year's approvals of CCR5 antagonist Selzentry and integrase inhibitor Isentress increased both the range and complexity of HIV treatment options. Clinicians now weigh the pros and cons of ten protease inhibitors, seven NRTIs, four NNRTIs, two entry inhibitors and an integrase inhibitor, with an investigational maturation inhibitor and a monoclonal antibody likely to be added to the mix.

2008 treatment transformation has also come from data gathered through the S.M.A.R.T Study that showed the disappointing results of treatment interruptions for almost everyone. Other studies reported during the year tended to support a trend toward initiating HAART earlier than previously suggested. And finally, recommendations from the Centers for Disease Control (CDC) now firmly encourage both an increase in routine testing for HIV and initiation of testing in Emergency Rooms that will allow for earlier identification and treatment of the estimated 250,000 individuals in the U.S. who are HIV-positive but unaware of their status.

♦ Selzentry Gets Full Approval & Label Changes



Based on data from two 48-week studies, the Food and Drug Administration (FDA) on November 25, 2008, granted full (traditional) approval to CCR5 antagonist Selzentry (maraviroc) for treatment-experienced individuals with CCR5-tropic HIV. Limited approval of Selzentry had originally been granted in August 2007. Label changes include a requirement for tropism testing before prescribing Selzentry and caution if considering use in anyone with hepatic (liver) impairment since this condition may result in increased levels of maraviroc. During the most recent Phase III studies with Selzentry, it was revealed that 11 subjects (1.3%) had cardiovascular events, including myocardial ischemia and/or infarction, while no subjects who received placebo experienced such events. The new label reports this but makes no recommendations for restricted use.

CONFERENCE HIGHLIGHTS

9th International Congress of Drug Therapy in HIV Infection



Held in Glasgow, Scotland and attended by nearly 3000 delegates from 80 countries, this conference has become recognized as a significant scientific event. Among the highlights presented were the following:

- ♦ People who begin HAART with a higher CD4 count are more likely to achieve complete immune recovery but HAART has significant clinical benefits even if treatment is started late.
- ♦ Significant drug-drug interactions appear in about 20% of people taking ARVs and can result in unexpected increases or decreases in ARV levels.
- ♦ One study suggested that Atripla users might someday be able to take weekend treatment breaks.


See: <http://www.hiv9.com/index.asp> for details.

RWF for Surplus Medication & Supplies

Founded in 2000, Rainbow World Fund (RWF) is an international relief agency that, among other projects, collects unused medical supplies and surplus medications for distribution to clinics in Central America and Mexico. Dr. Lisa Capaldini, MD, oversees medical assistance projects. To arrange for medication pick up, call **415-563-2219**. Medications and supplies may also be dropped off at 4111 18th Street, San Francisco, 94114. For more info see www.rainbowfund.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 31st Street, Oakland, CA 94602 **510-437-4888**

- ◆ 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.
- ◆ 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.

CONANT MEDICAL GROUP CLINICAL RESEARCH

470 Castro Street, Suites 202-204
San Francisco, CA 94114
ceden@conantmedical.org **415-255-0744**

- ◆  A Phase I study of the TUTI-16 tat vaccine for treatment of HIV. Participants must have been HIV-positive for at least six months, had no prior HIV medications within the previous six months, and have viral load between 3000 and 100,000 and CD4 count 400 or above. Compensation is provided.
- ◆ 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**



- ◆ A two-week, dose-escalating study of an 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.
- ◆ Hepatitis C (without HIV) Volunteers needed for a 15-day study of an experimental oral medication to treat HCV. Compensation to \$2100.

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



Rider Research, Continued on Page 3

Rider Research, continued

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

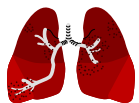
- ♦ A study for those with a VL >1000 on a PI-containing regimen with two other ARVs. The purpose of this study is to determine the benefit of adding an NRTI to a new anti-HIV drug regimen based on the most recently approved ARVs. (A5241)
- ♦ A study for those diagnosed with recent tuberculosis infection 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)

♦ 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 study

♦ **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**

OTHER UCSF-SPONSORED STUDIES, continued

Locations and phone numbers vary with study



- ♦ 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**

- ♦ A Phase III study for treatment-experienced adults to compare experimental integrase inhibitor GS0144 elvitegravir with raltegravir (Isentress) each with background regimen.
- ♦ **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 phase III, randomized, open-label trial comparing 3 drug regimens in ARV-naïve patients. The study will compare raltegravir vs. boosted Atazanavir vs. boosted darunavir plus Truvada. (ACTG 5257)
- ♦ 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 experimental integrase inhibitor GS 0144 eltegravir, 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)

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. Additional compensation is also provided.



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