

HIVCare News

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

JULY / AUGUST
2008
CLINICAL RESEARCH
OPPORTUNITIES
See Pages 2, 3, & 4

PHARMACEUTICAL UPDATE

◆ HIV Treatment Options Grow in Number & Complexity While A Cure Remains Elusive



Since 1989, when the first drug to treat HIV was approved by the U.S. Food & Drug Administration (FDA), the total number of antiretroviral drugs has grown to 23 individual and five fixed-dose combination ARV medications. Five new ARVs been approved since June 2006. All the current antiretroviral drugs work by preventing viral replication. Currently there are six classes of FDA-approved antiretrovirals: nucleoside analogs, nonnucleoside analogs, protease inhibitors, two entry inhibitor classes (fusion and CCR5 antagonist) and an integrase inhibitor. It is anticipated that a seventh new class, maturation inhibitor, may be approved in the near future if and when production issues are resolved.

Each class of drugs works at a different stage of the virus life cycle. While this provides a beneficial array of treatment options, particularly for the highly ARV-experienced individual, there is need, greater than ever before, to know how to sequence and combine these drugs to provide the maximum viral suppression for the longest period of time. Even at this early juncture, physicians are beginning to report individuals with resistance to all six approved drug classes. For the newly diagnosed individual, the choice of an initial therapy regimen can be critical to the prospects for long-term, durable viral suppression

For those with Internet access, the publication *Positively Aware* provides an annual HIV Drug Update, complete with pictures and analysis from the points of view of the pharmaceutical company, the treating physician and the AIDS activist. The publication is also available in hard copy.

http://positivelyaware.com/2008/08_01/drug_guide.html

Without question, HIV therapies have proven to be lifesavers, but the risks of resistance, and short- and long-term side effects render them an imperfect solution to the HIV epidemic. Medical literature seldom mentions the “C” word—cure, but in the case of HIV, the cure must be vigorously pursued.

A recent quote *Project Inform* states, “The only real solution is a cure. While some may discount its possibility, we do not. Many promising approaches are under study, as well as a resurgence in community activism aimed at cure research. A conscientious program mounted by academia, industry, government and community is necessary to reach this goal.”

CONFERENCE UPDATE

◆ The XVII International Drug Resistance Workshop



held in June in Sitka, Spain, was the first opportunity for physicians and researchers to focus on potential resistance problems of the most recently approved ARVs. Much attention was focused on integrase inhibitor, Raltegravir, and newly revealed resistance pathways that might influence other integrase inhibitors currently in development. Also of special interest was data presented on potentially heightened susceptibility to both novel NNRTI Intelence and PI Aptivus in the presence of other viral mutations. How this hypersusceptibility will affect long-term durability of a new regimen is unknown and will require further study.

<http://www.natap.org/2008/ResisWksp/ResisWksp.htm>

STUDY UPDATE

◆ Following an unexpected laboratory test result, Koronis Pharmaceuticals has suspended the national Phase II clinical trial of KP-1461, which offered a unique approach to anti-HIV therapy.



KP-1461 was theorized to work by speeding up the rate of mutation that is natural in HIV, thereby rendering the virus less fit to either replicate or infect new cells. Unlike traditional antiretrovirals, KP-1461 used a method of Viral Decay Acceleration to push the “viral mutation rate beyond the allowable range of diversity, thus extinguishing the population.” In early lab tests, this theory appeared to work as predicted, but in an attempt to replicate the earlier findings, as required by the FDA, the results did not show significant measurable antiviral activity. In addition, in the clinical trials of KP-1461, begun in late summer 2007, have to this point not demonstrated the expected reduction in viral replication. Koronis emphasized that there is no safety concern around KP-1461, but that expected results just aren’t there.


HIV AND AGING



Dr. Lisa Capaldini, M.D., well-known San Francisco physician, will lead a presentation on *HIV & Aging*

on Tuesday, July 8, 2008 at 6:30 PM in The Auditorium at Davies Medical Center, Castro & Duboce Streets. A light dinner will be provided to the audience. While the presentation is free of charge, organizers request an RSVP to Laila Hinkle at 415-600-5045 or hinkleL@sutterhealth.org from those planning to attend.

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**

- ♦ A 48-week study of CCR5 entry inhibitor vicriviroc for ARV-experienced individuals. Compensation provided.
- ♦ CHAI (Coping with HIV and Affect Interview) for anyone diagnosed with HIV within the past one month; includes 7 interviews to identify how a new diagnosis affects one's life. 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 a new NRTI, apicitabine, 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, 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 \$20 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, apicitabine, 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 28th Street
Oakland, CA 94609 **510-508-4477**
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, Study Coordinator.

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 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.
- ♦ Phase III study of a new once-daily NNRTI, TMC278, versus Sustiva both with abacavir and 3TC in ARV-naïve individuals. Compensation to \$480.

Quest Clinical Research, continued on Page 3

Quest Clinical, continued

♦ 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

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

♦ 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**

♦ GENE TRANSFER: A study to evaluate the effects of gene transfer treatment using blood stem cells to fight HIV for those with a CD4+ cell count >100 and a viral load between 400 and 100,000 copies m/L. Participants will be reimbursed for their time. **415-353-2463**

♦ 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/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

According to the U.S. Centers for Disease Control and Prevention (CDC), roughly a quarter of the 1.2 million Americans who are HIV positive do not know they are infected.

**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

♦ **STAYING WELL STUDY- ENDING AUGUST 2008!**

Are you HIV + and not on meds? We are seeking participants for a study on the effects of meditation-based stress management and education groups on health and well-being. A study for those not on ARVs, with CD4+ cell count >250, and VL > 100. Compensation provided.

LAST CHANCE TO ENROLL.
www.stayingwellstudy.org **415-353-9744**

♦ 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. **415-206-3319**

♦ **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

SF VETERANS ADMINISTRATION MEDICAL CENTER

4150 Clement Street
San Francisco, CA 94121

415-221-4810 ext. 3763

- ♦ **Poem study:** A multicenter, prospective, observational, comparative study to monitor the safety of long term use of CCR5 antagonist maraviroc in a larger and more diverse patient population. Patients

who do not have the R5 tropism will not be given Maraviroc, but will be only observed in the study. The study will last 5 years. (A4001067)

- ♦ 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.



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 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)

♦ **Ral-eve study:** This is a study looking for people with undetectable viral loads who are currently on T-20, and switching them from injectable T-20 to oral raltegravir.



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.

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.