

HIVCare News

JANUARY / FEBRUARY

2010

CLINICAL RESEARCH

OPPORTUNITIES

See Pages 2, 3, & 4

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

PHARMACEUTICAL UPDATES

• Selzentry Now Approved for Treatment-Naïve

In November 2009, the Food and Drug Administration (FDA) approved the expanded use of Selzentry (maraviroc) to include adults starting antiretroviral therapy for the first time. Originally approved in 2007 for treatment-experienced adults only, Selzentry works by blocking HIV from binding to CCR5, one of several identified entry or binding sites. Since not all HIV uses the CCR5 binding site, sensitivity testing using a viral tropism test must precede the approved use of Selzentry.

• Traditional Approval for Intelence Granted

Based on follow-up data from the 48-week DUET study, the FDA granted traditional approval for Intelence (etravirine) in late 2009. Intelence is an NNRTI specifically indicated for use in treatment-experienced adults experiencing virologic failure with other NNRTIs. Accelerated approval had originally been granted to Intelence in January 2008.

Based on this follow-up data, a significant change has been made to the Selzentry safety label regarding potential drug interactions. New information indicates that co-administration of Intelence with drugs that are “substrates of CYP3A, CYP2C9, and /or CYP2C19 (a family of cytochrome P450 enzymes) or are transported by P-glycoprotein may alter the therapeutic effect or side effect profile of the co-administered drug.” Because many commonly prescribed medications, including antibiotic, antifungal and antiseizure drugs, fall into these groups, anyone using Intelence should check with a pharmacist or other health care provider who can access full prescribing information for any potential interactions.

A FOCUS ON ERADICATION RESEARCH



World AIDS Day, December 1, was a time to reflect on gains that have been made in treating HIV and on what remains to be done in the future. Many advances have been made in the basic treatment of HIV. Pharmaceutical companies have continued to produce a supply of new therapeutics. Treatments are finally beginning to reach underdeveloped countries, although often as less expensive generics. But while the effort to develop new drugs to treat HIV has been a research priority, viral eradication, or the search for a cure, has not fared as well. A group of activists would like to see that change and welcome all the support they can get.

“*AIDS Cure Isn’t Out of Reach*” appeared in the Philadelphia Inquirer on World AIDS Day. In this piece, author and long-time policy activist Kate Krauss noted: “There is no special department or organization at the National Institutes of Health dedicated to a cure. There are no editorials in the press calling for more research into HIV eradication, the technical name for a cure. ...There is no annual research update on the subject for the general public or annual prize for the most promising work in the field—even though 33 million people have HIV and 25 million have died from it.”

While some scientists have expressed skepticism that HIV will ever be eradicated, there have been at least two documented cases that may offer some hope for a cure. In 1996, an HIV+ man in Berlin, treated very early in the course of infection with didanosine, hydroxyurea and indinavir, appeared to go into remission after stopping the drugs. His doctors advised him to resume therapy when his viral load rebounded, but it never did. The success of this “Berlin patient” has not yet been replicated, but research using a similar regimen is now ongoing with results to be reported in early 2010.


More recently, a 42-year old man, HIV+ for ten years, underwent a bone marrow transplant, also in Berlin, to treat leukemia. ARVs were stopped at the time of transplant. The marrow donor was chosen because he had a naturally occurring mutation, a CCR5 deletion, which can provide immunity to many strains of HIV. While some individuals have inherited one mutation from one parent, this donor had received the CCR5 deletion mutation from both parents. The patient’s leukemia returned after the first transplant, but following a second one, remission occurred. Now, two years later, the patient has *not* resumed ARV therapy and has *not* experienced viral rebound. His doctors say this could be a “functional cure.” While this specific procedure is not a practical approach for “curing” HIV, new research using artificial zinc-finger-inhibitor modified CCR5 receptors (*see Quest Clinical Research, Gene Therapy, page 2*), may provide a parallel path to a potential “functional cure.” For more information, see:

<http://online.wsj.com/article/SB122602394113507555.html>

To support the AIDS Policy Project in their efforts to stimulate interest in eradication research, see <http://www.aidspolicyproject.org/index.html>

Please Join The AIDS Policy Project on Facebook.

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 = Non-nucleoside 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 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


ceden@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.

♦ A Phase I study of the TUTI-16 tat vaccine for treatment of HIV. Must be HIV+ for at least six months, viral load between 3,000 and 100,000 and CD4+ count >400. Compensation is \$35 per visit, up to \$280 for study completion.

EAST BAY AIDS CENTER (EBAC)

3100 Summit Street, 2nd Floor
Oakland, CA 94609 **510-869-8490**
www.altabates.com/clinical/aids_scvs.html

♦  Do you have HIV-related diarrhea? A study to evaluate crotelemer, 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 crotelemer, 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.

HIVCare is an AIDS Drug Assistance Program (ADAP)
Enrollment Site. For Enrollment Information Call

415-353-6215

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

♦ **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.

♦ **QUAD Study** comparing Atripla to Quad, a new one-pill-a-day co-formulation of an investigational integrase inhibitor, an investigational booster and Truvada for ARV-naïve individuals.

♦ A head-to-head comparison of an investigational booster versus ritonavir in combination with Truvada and Reyataz for ARV-naïve individuals.

♦ A comparison of two integrase inhibitors in treatment-experienced individuals with detectable virus. Background regimen is individualized.


♦ **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
www.questclinical.com



415- 353-0800

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

♦ **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 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 teleprvir 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.

Quest Clinical Research, Continued on Page 3

Quest Clinical Research, continued from Page 2

- ♦ 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.
- ♦ 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, cough, sore throat, muscle ache *or* headache. Compensation provided.
- ♦ 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.
- ♦ 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

All AACTG studies provide compensation

- ♦ 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

Locations and phone numbers vary with each study.

- ♦ 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**
- ♦ 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 increases CD4+cell counts. Compensation provided. **415-476-4082 x104**

- ♦ Solid Organ Transplantation in HIV: A nationwide study to evaluate the safety and effectiveness of kidney and liver transplantation in HIV-positive individuals. <http://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 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)

OTHER UCSF-SPONSORED STUDIES

Locations and phone numbers vary with each study.

- ♦ 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** (pager)
- ♦ A study to evaluate how HIV persists in the body and how treatment with Raltegravir 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**
- ♦ Volunteers are needed for a study evaluating the effects of integrase inhibitor raltegravir (Isentress) 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 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**
- ♦ A study to evaluate changes in brain structure and chemistry using MRI and magnetic resonance spectroscopy. Compensation is provided. **415-206-4328**



Other UCSF, continued on Page 4

Other UCSF, continued from Page 3

♦ 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**



♦ 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**



♦ 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 ARVs. Compensation is provided. **415-632-5030**

♦ 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**

♦ Volunteers are needed for a study examining the effects of labeled water (D₂O) 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 or 415-215-0202**

♦ 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**

♦ 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**

♦ 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**



♦ OPTIONS Project for those recently exposed to HIV and experiencing acute retroviral syndrome or those who have sero-converted within the past six months. Compensation is provided.



<http://www.ucsf.edu/options/> **415-502-8100**

PALO ALTO VETERANS HEALTHCARE CENTER
3801 Miranda Avenue
Palo Alto, CA 94304 **650-496-2510**

- ♦ **Hepatitis C and 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 beginning treatment or not. Compensation \$20 per visit.

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 (Selzentry) in a large and diverse patient population.
- ♦ A Phase II study of maraviroc versus etravirine, each with boosted duranavir (Prezista) for treatment-experienced individuals with evidence of NNRTI resistance.

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 adding maraviroc (Selzentry) to an existing regimen to see if it will help to increase CD4+ cell count in those with current count <350 and viral load <50 copies.
- ♦ 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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