

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

PHARMACEUTICAL UPDATES

◆ **Videx Safety Label Changes**



The Food and Drug Administration (FDA) has approved new safety labeling for Videx EC (didanosine, ddI) enteric-coated capsules. For those undergoing therapy for hepatitis C with ribavirin, Videx is contraindicated because of the increased potential for peripheral neuropathy, pancreatitis or fatal liver failure, all of which have been observed in those taking both medications. Additionally, Videx should not be taken in combination with allopurinol, a drug commonly used to treat gout because of an increased risk of didanosine-associated toxicity.

◆ **Mood Changes With Asthma Medications**



On June 12, 2009 the FDA requested that manufacturers of leukotriene modifiers, including Singulair, Accolate, and Zflo include warnings on the drugs' labels about reports of behavior and mood changes. Used for relief of asthma symptoms, these products have been reported to cause neuropsychiatric (mood and behavior) events including agitation, aggression, anxiousness, insomnia, tremor, irritability, restlessness and suicidal thinking and behavior. Although these medications are unlikely to interact with anti-HIV medications, the side effects may be similar to those caused by other medications taken by HIV-positive individuals.

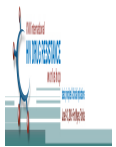
◆ **Caution About a Discontinued Cold Remedy**



On June 16, 2009 the FDA issued an alert on discontinued over-the-counter cold products Zicam Cold Remedy Nasal Gel and Zicam Nasal Swabs, which many people still have in their homes. These products have been reported to be associated with a long-lasting or permanent loss of smell, called anosmia. The FDA recommends that consumers stop using these products and discard them.

CONFERENCE UPDATE

XVIII International HIV Drug Resistance Workshop



Over the past 17 years, this workshop has earned a reputation as a premier meeting on HIV drug resistance. Much information presented finds its way directly into daily clinical practice.

Surprisingly, the topic of this year's keynote address was the potential eradication of HIV from the reservoirs or sequestered cells which are unaffected by antiretroviral therapy. Researchers believe that a cure

will only be possible if all viral reservoirs can be eliminated. Delivering the keynote address, Dr. David Margolis, MD, of the University of North Carolina reported on several approaches to resolving this problem. Intensification of an existing suppressive regimen with ARV drugs, such as entry inhibitors Isentress or Fuzeon, is being studied but not yet been shown to be particularly effective. Also in study is the potential of IL-7 to activate latent reservoirs.

At the workshop itself, one small study of special interest investigated differences in outcomes in resistance to FTC (emtricitabine, Emtriva) or 3TC (lamivudine, Epivir), each used in combination with tenofovir. Both 3TC and FTC are widely used NRTIs which form the backbone of many HAART regimens. The findings in this study showed that patients were less likely to develop the M184V mutation if they failed FTC than if they failed a 3TC-containing regimen. Along with several other studies, this may suggest an advantage for FTC over 3TC with regard to forestalling the development of drug resistance.


More Reasons Not to Interrupt Care



A French study which followed 1007 patients for ten years found that HIV-positive individuals who return to care after a period of being "lost to care" were more than five times more likely to die in the short term than those who remained under the continuous care of their physicians. Reporting in the online journal AIDS (Volume 23, 2009) investigators revealed significant differences between the 135 (13%) patients who failed to see their clinicians regularly and those who maintained regular contact. Seventy-four of the 135 patients (55%) eventually returned to care after an average interruption of 19 months. Of those, 45% had a CD4+ cell count below 200 cells/mm³ and 27% had an AIDS-defining illness.

The patients who had not interrupted their regular care had an average of 369 CD4+ cells/mm³ and no AIDS-defining illnesses. Hospitalizations were significantly increased among those who had interrupted care, with an average stay of 23 days. In addition to the poor prognosis for individuals not in continuous care, investigators suggest that they also "pose an increased risk of HIV transmission since those who interrupt combination antiretroviral therapy cannot benefit from the favorable effect of antiretroviral drugs on infectiousness."

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**

♦  **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 Epsicom and a boosted protease inhibitor. Compensation provided.

♦ **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.



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.



CONANT MEDICAL GROUP CLINICAL RESEARCH

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

♦ A study to examine characteristics of the immune system of HIV+ people to further research on HIV therapies and vaccines. Participants must be HIV+ for at least 1 year and never received HIV medications. Compensation to \$285 for 2 visits.

♦ A Phase I study of the TUTI-16 tat vaccine for treatment of HIV. Must be HIV+ for at least six months, no prior HIV medications within the last six months, have VL between 3000 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**
http://www.altabates.com/clinical/aids_scvs.html

♦ A Phase III 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.

HEALTH MANAGEMENT INSTITUTE

45 Castro Street, Suite 415
San Francisco CA 94114 <http://hmii.org/> **415-565-6288**

♦  **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 Epsicom and a boosted protease inhibitor. Compensation provided for study and screening.

KAISER PERMANENTE MEDICAL GROUP-SF

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

♦ A 48-week study of Taimed Biologics monoclonal antibody ibalizumab for those who are treatment-experienced, have a VL >1000, and have susceptibility to at least one active ARV.

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



♦ A study of apricitabine, a new NRTI for those resistant to 3TC or FTC. Participants must currently be taking FTC or 3TC and have a VL >2000. Resistance testing provided.

QUEST CLINICAL RESEARCH

2300 Sutter Street, Suite 202
San Francisco, CA 94115
www.questclinical.com **415-353-0800**



♦ A 48-week study of Taimed Biologics monoclonal antibody ibalizumab for those who are treatment-experienced, have a VL >1000, and have susceptibility to at least one active ARV. Compensation is \$35 per visit.

♦ A two-week, dose-escalating study of an integrase inhibitor for those either ARV-naïve or who have not been on ARVs for at least 12 weeks. Must have a CD4+ cell count >100 and a viral load >5000. 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.

Quest Clinical, continued on Page 3

Quest Clinical, continued

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

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

- ◆ Start HIV meds on a 2+ year randomized study comparing Rayataz vs Presista vs Isentress. (A5257)
- ◆ Start HIV meds on a 52 week study using Prezista with Isentress. (A5262)
- ◆ Evaluating HIV+ people vaccinated with Zostavax (therapeutic vaccine against shingles). (A5247)
- ◆ 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 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 (A5241)

UCSF / POSITIVE HEALTH PROGRAM / SFGH

http://php.ucsf.edu/rsrch_trials.shtml#anc2

Locations and phone numbers vary with 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**
- ◆ 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. **415-476-4082 x104**
- ◆ 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**
- ◆ SOLID ORGAN TRANSPLANTATION in HIV: A nationwide study to evaluate the safety and effectiveness of kidney and liver transplantation in HIV-positive individuals. **415-353-8892**
- ◆ Hepatitis C and HIV Co-infection: A new 24-week treatment study for those infected with HCV within the past six months. No CD4+ or viral load restrictions. 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 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**

- ◆ Volunteers are needed for a study to evaluate the effects of an antibiotic on cerebrospinal fluid. 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 integrase inhibitor raltegravir, 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 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 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 each study.

- ◆ 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 or have hepatitis C. Study includes annual follow-up. Compensation is \$50 for the initial visit and \$50 for an MRI.

415- 476-5485 or 415- 476-1879

Other UCSF, Continued on Page 4

Other UCSF, Continued from Page 3

♦ **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. **415-597-9322**

♦ **OPTIONS PROJECT** for those recently exposed to HIV 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**



♦ **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**



♦ **NUCLEOMAXX Study** to evaluate the effects of uridine supplementation for those with a viral load <10,000 who are taking or have recently taken Zidovudine (AZT, Retrovir, Combivir or Trizivir) or Stavudine (D4T or Zerit). 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 elvitegravir with raltegravir (Isentress) each with background regimen.

♦ A pilot study to examine if the novel treatment regimen maraviroc, a CCR5 inhibitor, plus boosted atazanavir can be safe and efficacious in treatment naive individuals with a VL >1000. (A4001078)

♦ A Phase II study of maraviroc versus etravirine, each combined with darunavir (Prezista) + ritonavir for treatment-experienced individuals with evidence of NNRTI resistance.

♦ **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.

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. Compensation is \$20 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 52-week open-label study of raltegravir plus boosted-darunavir for treatment-naïve individuals with a VL >5000. (A5262)

♦ A double blind, placebo-controlled study of a two dose regimen of Zostavax, a herpes zoster vaccine, for those with undetectable VL, on current ARVs, and with CD4+ >200. (A5247)

♦ **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 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. (A5257)

♦ 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 12 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 will 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-positive persons whose current HIV medicines are not working. (A5241)

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