



Florida/Caribbean AIDS Education and Training Center

# HIV CareLink

A Newsletter for HIV/AIDS Primary Care Providers

## ABOUT US

The Florida/Caribbean AIDS Education and Training Center provides state-of-the-art HIV education, consultation, and resource materials to health care providers in Florida, Puerto Rico and the US Virgin Islands.

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## Conference Update: Joint Meeting 48<sup>th</sup> Annual ICAAC/IDSA 46<sup>th</sup> Annual Meeting October 25-28, 2008 Washington, DC



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The 48<sup>th</sup> Annual Interscience Conference on Antimicrobial Agents and Chemotherapy and the 46<sup>th</sup> Meeting of the Infectious Diseases Society of America took place in Washington, DC October 25-28<sup>th</sup>, 2008. Below is a list of selected HIV-related abstract presentations from this conference along with a link to a detailed summary of each listed abstract. Note: *You must have a log in for [www.clinicalcareoptions.com](http://www.clinicalcareoptions.com) in order to access information from this site.* Also, in order for the hyperlinks below to function properly, you must be logged in when you click the link.

### Existing Antiretrovirals

- Safety and efficacy of raltegravir-based versus efavirenz-based combination therapy in treatment-naïve HIV-1 infected patients: STARTMRK Protocol 021. ([Abstract H-896a](#); [Lennox J, et al.](#))
- Reanalysis of the MERIT Study with the Enhanced Trofile assay (MERIT-ES). ([Abstract H-1232A](#); [Saag M, et al.](#))
- Efficacy and Safety of darunavir 800/100mg once daily vs lopinavir/ritonavir in treatment-naïve, HIV-1 infected patients at 96 weeks: ARTEMIS (TMC114-C211). ([Abstract H-1250c](#); [Mills A, et al.](#))
- Atazanavir/ritonavir vs lopinavir/ritonavir in antiretroviral-naïve HIV-1-infected patients: CASTLE 96 week efficacy and safety. ([Abstract H-1250d](#); [Molina JM, et al.](#))
- Simplification of Antiretroviral Therapy with Efavirenz/emtricitabine/tenofovir DF Single Tablet Regimen vs. Continued Unmodified Antiretroviral Therapy in Virologically-suppressed, HIV-1-Infected Patients. ([Abstract H-1234](#); [DeJesus, E, et al.](#))
- Reduction in AIDS defining events/death (ADE/D) with etravirine (ETR) compared to placebo (PL): pooled DUET 48 week results. ([Abstract H-1239](#); [Haubrich R, et al.](#))
- 96 Week Efficacy/Safety Data Comparing Two Doses of Ritonavir (r) to Boost Once-daily Fosamprenavir (FPV), Used in Combination with Abacavir (ABC)/Lamivudine (3TC). ([Abstract H-1246](#); [DeJesus E, et al.](#))
- CD4+ Cell Increases at 48 Weeks in the Maraviroc Treatment-naïve MERIT Trial. ([Abstract H-1248](#); [Lazzarin A, et al.](#))

- 48-wk safety and efficacy of darunavir/ritonavir (DRV/r) in treatment-experienced children and adolescents in DELPHI. ([Abstract H-894](#); [Blanche S, et al.](#))

### Resistance

- Analysis of resistance to the HIV-1 integrase inhibitor raltegravir: results from BENCHMRK 1 and 2. ([Abstract H-898](#); [Miller M, et al.](#))
- Cross resistance between HIV-1 integrase strand transfer inhibitors (INSTIs) raltegravir, elvitegravir and second generation INSTIs. ([Abstract H-1232](#); [Witmer M, et al.](#))

### New Drugs

- Response to vicriviroc (VCV) in HIV-infected treatment-experienced subjects using an enhanced Trofile HIV co-receptor tropism assay: reanalysis of ACTG 5211 results. ([Abstract H-895](#); [Su Z, et al.](#))
- A phase 2 safety and efficacy study of bevirimat (BVM) in heavily treatment experienced HIV+ patients identifies the target phase 3 study profile. ([Abstract H-891](#); [Lalezari J, et al.](#))
- Antiviral activity and tolerability of 5 mg/kg and 10 mg/kg doses of PRO 140, a humanized monoclonal antibody to CCR5. ([Abstract H1269a](#); [Jacobson J, et al.](#))

### Complications of ART

- Substitution of nevirapine (NVP) for efavirenz toxicity in ACTG A5095. ([Abstract H-1236](#); [Schouten J, et al.](#))

For more information,  
please visit our website:

[www.FCAETC.org](http://www.FCAETC.org)

To request clinical consultation, please call the  
National Clinicians' Consultation Hotline:

**1-800-933-3413**

- Toxicity is Not Related to CD4+ Cell Counts in 221 Patients Switching to Nevirapine (NVP) Due to Simplification or Substitution Strategies (Toscana Study). (Abstract H-2296; Antela A, et al.)
- Renal Function after Use of Tenofovir as Part of the Initial ART Regimen. (Abstract H-2297; Moore RD, et al.)
- Comparison of renal function on NNRTI vs boosted PI based tenofovir regimens. (Abstract H-2298; Short WR, et al.)
- Limb and trunk fat changes by total body DEXA after 96 weeks of treatment with once-daily (QD) fosamprenavir (FPV) boosted with either 100 mg or 200 mg of ritonavir (r) plus abacavir (ABC)/lamivudine (3TC): COL100758. (Abstract H-2302; Wohl D, et al.)
- Coronary plaque volume by CT angiography correlates with duration of antiretroviral therapy. (Abstract 2311; Hadigan C, et al.)

#### Co-morbid Conditions and Complications of HIV

- Comparative analysis of HIV+ and HIV- interaction with testosterone on bone mineral density. (Abstract H-2299; Raghunathan R, et al.)
- Hemoglobin A1c does not accurately reflect glycemia in HIV patients on HAART. (Abstract H-2304; Kim P, et al.)
- HIV infection and the risk of diabetes mellitus. (Abstract H-2306; Butt AA, et al.)
- QT interval as a marker of premature atherosclerosis in HIV infected patients. (Abstract H-2308; Mangill A, et al.)
- Prevalence of pulmonary hypertension in asymptomatic HIV-infected patients receiving antiretroviral therapy. (Abstract H-2312; Byers DK, et al.)
- Continuous antiretroviral therapy decreases bone mineral density: results from the SMART study. (Abstract 2312a; Grund B, et al.)

#### Hepatitis and other Opportunistic Infections

- Varicella vaccine protects children with perinatal HIV infection against zoster. (Abstract H-460; Son M, et al.)
- Community associated methicillin resistant *S. aureus* (CA MRSA) infections in hospitalized HIV patients (pts). (Abstract L-775; Popovich, KJ et al.)
- Community associated methicillin resistant *S. aureus* (CA MRSA) and HIV-intersecting epidemics. (Abstract L-776; Popovich KJ, et al.)
- Methicillin-resistant *Staphylococcus aureus* infection (MRSA-I) in HIV-infected (HIV+) and HIV-uninfected (HIV-) in the Veterans Aging Cohort Study (VACS). (Abstract L-777; Graber CJ, et al.)

- Efficacy of tenofovir plus emtricitabine in treatment of HIV/HBV coinfecting patients. (Abstract V-1626; Engell CA, et al.)
- Progression of liver fibrosis in HIV/HBV coinfecting patients undergoing anti-HBV active antiretroviral therapy. (Abstract H-2315; Teixeira T, et al.)

#### Drug Interactions

A Drug Interaction Report summarizing the drug interaction studies presented at the 2008 joint meeting of ICAAC and IDSA is available on [hiv-druginteractions.org](http://hiv-druginteractions.org) (click link above).

- Drug interaction studies presented include: etravirine and oral contraceptives, lopinavir/ritonavir and gemfibrozil, darunavir/ritonavir and raltegravir, darunavir/ritonavir and rifabutin, raltegravir and rifampin, maraviroc and raltegravir, tipranavir/ritonavir and buprenorphine/naloxone



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## Conference Update: XVII International AIDS Conference August 3-8, 2008 Mexico City, Mexico

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 Clinical Director, Florida/Caribbean AETC

The XVIII International AIDS Conference was held in Mexico City, Mexico August 3-8, 2008. The following are summaries of selected abstracts presented at the conference. For full conference coverage, visit their website at <http://www.aids2008.org>

**GS 903E** Original GS903 trial compared (3 year, double-blind) TDF vs d4T in combination with 3TC/EFV. TDF found non-inferior to d4T and with better lipid and body fat profiles. At study end this open label extension phase allowed those on d4T to switch to TDF + 3TC/ EFV.

Current analysis - 7 yr. f/u of 86 pts from South America on TDF, 3TC/EFV since onset of GS903.

**Results:**

- 80% HIV VL < 50 copies/mL
- 4 virologic failures (none with K65R)
- Mean CD4 increase of +459 cells/mm<sup>3</sup>
- No renal AE, Fanconi syndrome, no change in PO<sub>4</sub>
- Grade 1 ↑ in serum creatinine in 2 pts.; No significant change in estimated GFR
- BMD change from baseline -2.6% (hip) and -1.5% (spine); Spine BMD ↓ 1.5%. Neither clinically significant
- Median limb fat ↑ significant

*Cassetti I, et al. The safety and efficacy of tenofovir DF (TDF) in combination with lamivudine (3TC) and efavirenz (EFV) in antiretroviral-naïve patients through seven years. Abstract TUPE0057*

**HEAT: ABC/3TC Non-inferior to TDF/FTC at Week 96**

- Similar design to ACTG 5202 except LPV/r was 3<sup>rd</sup> agent in each arm
- VF occurred in 14% of patients in each arm
- Similar CD4 increase in both arms
- Similar proportion in each arm achieved VL < 50 at 96 wk

*Smith, K, et.al, Similarity in efficacy and safety of abacavir/lamivudine (ABC/3TC) compared to tenofovir/emtricitabine (TDF/FTC) in combination with QD lopinavir/ritonavir (LPV/r) over 96 weeks in the HEAT Study. Abstract LBPE1138.*

**RAL vs. EFV in Treatment Naïve Patients 96 Week Update of Protocol 004**

- [RAL (100, 200, 400, or 600 mg bid) vs EFV 600 mg qd] + TDF/3TC
- All RAL pts switched to 400 mg bid at week 48
- Trial inclusion criteria:
  - Patients naïve with VL > 5000 c/mL and CD4 ≥ 100 cells/mm<sup>3</sup>
  - No baseline TDF or 3TC resistance

**Results:**

- Viral suppression sustained at Week 96 of RAL treatment
- Virologic response in RAL-treated pts similar to response in EFV arm
- HIV-1 RNA < 50 copies/mL: 83% RAL vs 84% EFV
- RAL well tolerated, and lipid neutral
- No new RAL mutations identified

*Markowitz, M., et.al. Sustained antiretroviral efficacy of raltegravir as part of combination ART in treatment-naïve HIV-1 infected patients: 96-week data. Abstract TUAB0102*

**Association Between Abacavir Use and CV Events:**

Prior reported D:A:D analysis of associations between NRTIs and CVD revealed recent use of abacavir (ABC) or didanosine (ddI) was associated with a 90% or a 47% ↑ risk of MI respectively. The risk was associated with presence of underlying CV risk factors, and was seen only in recent users of ABC or ddI.  
*Sabin CA, et al. Lancet. 2008;371:1417-1426.*

## An Analysis of the Strategies for Management of Antiretroviral Therapy (SMART)

Pts were divided into 3 groups based on NRTI use:

- those receiving ABC but not ddI
- those receiving ddI plus ABC or other NRTIs
- those receiving NRTIs other than ABC or ddI CV

### Endpoints were:

- MI
- Major CV (clinical and silent MI, stroke, surgery for CAD and CV death)
- Expanded major CV events
- Minor CVD events

**Conclusion:** The hazard ratio of experiencing a CVD outcome was higher with current use of ABC vs current ddI or another NRTI. The ↑ risk of CVD seen with ABC was seen only in patients with ≥ 5 CV risk factors at baseline.

Analysis of SMART Data Consistent With D:A:D Finding That Abacavir is Associated With Increased Risk for Cardiovascular Events. Note: *You must have a log in for [www.clinicalcareoptions.com](http://www.clinicalcareoptions.com) in order to access information from this site. Also, in order for the hyperlink below to function properly, you must be logged in when you click the link. [Capsule Summary](#). [CCO Official Conference Coverage of the 2008 International AIDS Conference](#).*

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