AIDS Weekly Plus

Study Findings from University of Puerto Rico School of Medicine Provide New Insights into AIDS/HIV Research

Staff Writer

January 7, 2013

2013 JAN 7 (NewsRx) -- By a News Reporter-Staff News Editor at AIDS Weekly -- Investigators discuss new findings in AIDS/HIV Research. According to news reporting from San Juan, Puerto Rico, by NewsRx journalists, research stated, "Antiretroviral (ARV) therapy during pregnancy is recommended to reduce the risk of mother-to-child transmission (MTCT). Physiologic changes during pregnancy can affect PK."

The news correspondents obtained a quote from the research from the University of Puerto Rico School of Medicine, "We present the PK of total and unbound (pharmacologically active) DRV in HIV-1-infected pregnant women receiving twice-daily (bid) DRV/ritonavir (rtv). This Phase IIIb study enrolled HIV-1-infected pregnant women=18 years old in the 2nd trimester of pregnancy receiving DRV/rtv 600/100 mg bid and other ARVs. DRV (total and unbound) and rtv (total) plasma concentrations were obtained predose and 1, 2, 3, 4, 6, 9 and 12 hours postdose during the 2nd and 3rd trimesters and postpartum. Total DRV and rtv plasma concentrations were determined using a previously validated HPLC-MS/MS assay (lower limit of quantification 5.00 ng/mL). Unbound DRV was determined by fortifying plasma samples with 14-C DRV and separating total and unbound DRV using ultrafiltration. Total and unbound 14-C DRV were measured using liquid scintillation counting. Total and unbound PK parameters were derived using a noncompartmental analysis. Safety and efficacy were investigated at each visit and summarized using descriptive statistics. Sixteen women (10 black, 4 Hispanic, 2 white) were enrolled; 11 had evaluable PK data. Total DRV AUC12h was 24% and 17% lower during 2nd and 3rd trimesters, respectively, vs postpartum (Table). Unbound DRV AUC12h was unchanged during 2nd and 3rd trimesters vs postpartum. Total and unbound DRV Cmin increased by 43% and 10%, respectively, during 2nd trimester and by 86% and 14%, respectively, during 3rd trimester vs postpartum. Unbound DRV was above the EC50 (27.5 ng/mL) for PI-resistant HIV in all patients. Albumin and a1-acid glycoprotein (AAG) concentrations were 22%-29% lower during pregnancy vs postpartum. Viral load decreased and CD4+ count increased over time. One serious adverse event was reported (increased transaminase). Three of 12 infants were born prior to 37 weeks (30, 36 and 36 weeks), and all 12 infants were HIV-1-negative by standard PCR testing. Total DRV and rtv PK decreased during pregnancy likely due to pregnancy-related dilution of albumin and/or AAG. No clinically relevant change in unbound DRV AUC12h and Cmin occurred during pregnancy, and there was no MTCT; therefore no dose adjustment is required for DRV/rtv 600/100mg bid in pregnant women."

According to the news reporters, the research concluded: "This ongoing trial will further evaluate the

effects of pregnancy on DRV/rtv once daily, etravirine and rilpivirine PK."

For more information on this research see: Total and unbound darunavir (DRV) pharmacokinetics (PK) in HIV-1-infected pregnant women. Journal of the International Aids Society, 2012;15(6):18340. (BioMed Central - www.biomedcentral.com/; Journal of the International Aids Society - www.jiasociety.org)

Our news journalists report that additional information may be obtained by contacting C. Zorrilla, University of Puerto Rico School of Medicine, San Juan, Puerto Rico (see also AIDS/HIV Research).

Keywords for this news article include: Antiinfectives, Antiretrovirals, Antivirals, Pharmaceuticals, Drugs, Therapy, San Juan, HIV/AIDS, Darunavir, Pregnancy, Obstetrics, Puerto Rico, RNA Viruses, Retroviridae, HIV Infections, Women's Health, Pharmacokinetics, AIDS/HIV Research, Vertebrate Viruses, Protease Inhibitors, Primate Lentiviruses.

See the topic on aegis.org