

# 13th Conference on Retroviruses and Opportunistic Infections



Denver, Colorado - February 5-8, 2006

## EFFICACY AND SAFETY OF ATAZANAVIR-BASED THERAPY IN ANTIRETROVIRAL NAÏVE HIV-1 INFECTED SUBJECTS, BOTH WITH AND WITHOUT RITONAVIR: 48-WEEK RESULTS FROM AI424-089

*Conf Retrovir Opportunistic Infect 2006 Feb 5-8;13:abstract no. 107LB*

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**BACKGROUND:** Atazanavir (ATV) is a potent, generally well tolerated once-daily protease inhibitor that has been extensively studied without ritonavir (RTV) in ART-naïve, and when boosted with RTV, in treatment-experienced patients; however, data on the use of ATV with RTV (ATV/r) in ARV-naïve subjects are limited.

**METHODS:** Study AI424-089 is a 96-week, randomized, open-label, prospective study comparing the efficacy and safety of ATV/r 300 mg/100 mg with ATV 400 mg, both in combination with lamivudine (3TC) and extended-release stavudine (d4T), all given once daily, in ART-naïve subjects. The primary endpoint was the proportion of subjects with HIV RNA <400 copies/mL through week 48; planned secondary assessments included proportion with HIV RNA <50 copies/mL, CD4 count change, and safety parameters.

**RESULTS:** We randomized 200 subjects, of whom we treated 199. At baseline, the mean CD4 count was 235 cells/mm<sup>3</sup>, the mean HIV RNA 4.95 log<sub>10</sub> copies/mL, the mean total cholesterol 161 mg/dL, and the mean triglyceride level 145 mg/dL. Discontinuations prior to week 48 were few: ATV/r, 12%; ATV, 10%. The rate of drug-related adverse events of at least moderate intensity was comparable between arms. Adverse events-related discontinuations occurred more commonly in the ATV/r arm (8%) than the ATV arm (1%); these were primarily protocol-mandated for persistent hyperbilirubinemia. Jaundice and scleral icterus (all grades) were more common in the ATV/r arm (22%; 23%) than the ATV arm (7%; 13%). Mean increase in total cholesterol was 15% for the ATV/r arm vs 6% for the ATV arm (p <0.01); mean increase in triglycerides was 26% for ATV/r

vs -3% for ATV (p <0.01); a shift of  $\geq 1$  NCEP triglyceride category occurred in 16% for ATV/r vs 11% for ATV.

<b>Week 48 Efficacy Results</b>	<b>ATV/r</b>	<b>ATV 400</b>	<b>Difference Estimate (95% CI) (ATV/r - ATV400)</b>
<b>HIV RNA (Intent to Treat, TLOVR)</b>	<i>n</i> = 95	<i>n</i> = 105	
% with <400 copies/mL	86	85	1.5 (-8.2, 11.1)
% with <50 copies/mL	75	70	5.0 (-7.0, 17.0)
<b>HIV RNA (On Treatment)</b>	<i>n</i> = 84	<i>n</i> = 94	
% with <400 copies/mL	93	93	0.2 (-7.4, 7.8)
% with <50 copies/mL	87	76	11.2 (-0.2, 22.6)
<b>Mean CD4 <math>\uparrow</math> from Baseline (cells/mm<sup>3</sup>)</b>	189	224	-21.1 (-48.9, 6.6)*

\*Time-averaged difference through Week 48

**CONCLUSIONS:** In this study in ART-naïve HIV+subjects, ATV, with or without RTV, demonstrated a high rate of virologic response through 48 weeks. Both arms were generally safe and well tolerated, although subjects on ATV/r had a higher rate of hyperbilirubinemia. These results support additional studies using ATV/r in ART-naïve subjects.

2006-02-05  
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