

# 15th Annual Conference of the British HIV Association



1-3 April 2009, Liverpool, UK

## FEWER SUBJECTS SWITCHING TO QD ATV/R HAVE LIMB FAT LOSS VERSUS THOSE CONTINUING BID PI/R: 96 WEEK RESULTS OF THE MULTICENTRE, OPEN-LABEL, RANDOMIZED, PROSPECTIVE REAL STUDY FOR THE MANAGEMENT OF LIPODYSTROPHY

*HIV Med* 2009 Apr 1-3; 10(Suppl. 1):5 (abstract no. O3)

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**BACKGROUND:** Atazanavir (ATV) is a potent, well-tolerated QD PI, extensively studied in naïve and experienced patients. Comparative data have demonstrated similar efficacy with a superior lipid profile versus LPV/r. The ReAL Study evaluated the impact on body composition of switching from any BID PI/r to QD ATV/r in patients with lipohypertrophy while the background of two NRTIs remained unchanged.

**METHODS:** Patients with waist circumference >90 cm and viral load <400 copies/mL were randomized (2:1) to ATV/r versus continuing PI/r. CT was used to quantify visceral, subcutaneous, and total adipose tissue; DEXA was used to assess trunk and limb fat. Primary endpoint: 48 week change in trunk-to-limb fat ratio by DEXA. 96 week results include the study endpoints and a post-hoc analysis on patients who had a week 96 decrease in limb fat of at least 20% from baseline (BL).

**RESULTS:** Two hundred and one patients were randomized (200 treated, 131 ATV/r, 69 PI/r [72% LPV/r]). At week 96, there was no significant difference between regimens in mean change from BL in trunk-to-limb fat ratio (ATV/r: 0.04 versus PI/r: 0.05,  $P=0.73$ ) and other DEXA or CT parameters. However, more patients in the PI/r arm had a decrease of at least 20% in limb fat from BL at week 96. This difference between regimens was more evident in patients receiving thymidine analogs. Viral rebound rate ( $\geq 400$  copies/mL) was 6% on both regimens. Mean percent changes from BL in fasting

lipids (ATV/r versus PI/r): Tot Chol -12.5% versus -0.1% ( $P<0.0001$ ); HDL-Chol -6.8% versus -4.6% ( $P=0.48$ ); LDL-Chol -8.4% versus 3.6% ( $P=0.0171$ ); triglycerides)25% versus -12.2% ( $P=0.0381$ ); Non-HDL-Chol -14% versus 1.2% ( $P<0.0001$ ). Discontinuation rates were 13% on both regimens. Overall AEs were comparable between regimens.

**CONCLUSIONS:** In this 96 week analysis, patients with lipohypertrophy who switched from BID PI/r to QD ATV/r had no demonstrated benefit on lipohypertrophy but less limb fat loss, while maintaining efficacy and significantly reducing atherogenic lipids.

2009-04-01  
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