

## **Fosamprenavir/ritonavir and Nelfinavir have Comparable Effects on Body Fat Changes in Antiretroviral-naïve Patients: 48-Week Results from the SOLO Study.**

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**Background:** To date, minimal prospective data from cohorts or from randomised, comparative trials on the incidence of body composition changes (BCC) have been presented.

**Methods:** SOLO was a randomized study in antiretroviral therapy-naïve, HIV-infected adults which compared the efficacy and safety of fosamprenavir/ritonavir once-daily (FPV/r, Lexiva®, Telzir®; N=322) with nelfinavir twice-daily (NFV; N=327), each administered with abacavir/lamivudine. BCC were assessed by physician and patient observation using a standardized questionnaire, and anthropometry.

**Results:** Demographic characteristics were well matched in the two groups. Median baseline (BL) CD4: 170 cells/uL, median HIV-1 RNA: 4.81 log<sub>10</sub> copies/mL. A median increase in body weight of 3kg at week (wk) 48 was observed in both groups. There was a median increase from BL in hip and waist circumference of 2 cm in the FPV/r group and 3 cm in the NFV group. Median Waist/hip ratio did not change. 40/322 (12%) and 52/327 (16%) of subjects reported at least one BCC at BL in the FPV/r and NFV groups, respectively, with the majority of these subjects reporting fat wasting (25/322 (8%) and 37/327 (11%), respectively). Of note, 14/30 (47%) and 16/35 (46%) of subjects with BCC at BL did not report any BCC at wk 48, in the FPV/r and NFV groups, respectively. Of subjects with no BCC reported at BL, 36/203 (18%) and 45/220 (20%) reported BCC at wk 48 in the FPV/r and NFV groups, respectively. Of subjects who did not report fat wasting at BL, only 4% (9/215, and 9/232) reported fat wasting at wk 48 in both groups. Of subjects

who did not report fat accumulation (FA) at BL, 15% (33/219) and 18% (44/238) reported signs of FA at wk 48 in the FPV/r and NFV groups.

**Conclusion:** Over 48 wks, a comparable proportion of subjects reported BCC in the FPV/RTV and NFV groups combined with a similar weight gain but no change in waist/hip ratio. The majority of changes were fat accumulation. Of note, in both groups a low rate of fat wasting was observed which may relate to abacavir/lamivudine.

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