

Poster presentation

## Efficacy and safety of switching from lopinavir/r to atazanavir/r in suppressed patients receiving a LPV/r-containing HAART: ATAZIP 96-week results

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### Purpose of the study

To compare the efficacy and safety of switching from lopinavir/r (LPV/r) to atazanavir/r (ATV/r) in suppressed patients vs. continuing a LPV/r HAART at 2 years.

### Methods

Randomized, open-label 96-week trial including patients with virological suppression (<200 copies/ml; ≥ 6 months) on a LPV/r-containing HAART. Patients were randomized 1:1 to either continue LPV/r or switch to ATV/r. Patients with >4 PI-associated mutations and/or failed to >2 PI-containing regimens were excluded. Primary endpoint: proportion of patients with treatment failure (ITT switching = failure) at 48 weeks. Virologic failure: two consecutive viral load >200 copies/ml (OT).

### Summary of results

248 patients were assigned to continue LPV/r (n = 127) or to switch to ATV/r (n = 121). Baseline characteristics were balanced, including age, sex, risk for HIV infection, liver enzymes, fasting lipid profile, time on prior ARV, previous exposure to PI-containing regimens, and median CD4 (around 450 cells/mm<sup>3</sup>). 30% had available evidence of harboring one or more PI-associated mutations (with 10% showing at least one major mutation, IAS defini-

tion). Treatment failure occurred in 30% (40/127) in the LPV/r arm and in 25% (33/121) in the ATV/r arm (difference -4.2%; 95% CI from -15.6% to 7.1%). Virological failure occurred in 9% (12/127) in the LPV/r arm and in 8% (11/121) in the ATV/r arm (difference -0.36%; 95% CI from -7.6 to 6.9%). Median CD4 changes from baseline were 100.5 and 40 cells/mm<sup>3</sup> in the LPV/r and ATV/r arm, respectively. Adverse events leading to study drug discontinuation occurred in 6% in the LPV/r arm and 5% in the ATV/r arm. Fasting TG and total cholesterol decreased significantly in the ATV/r arm, -53 and -24 mg/dL, respectively. Changes in ALT/AST were similar in both arms and significant total bilirubin elevations were frequently seen in the ATV/r arm.

### Conclusion

Switching to ATV/r in virologically suppressed patients who were receiving a LPV/r-containing HAART provided comparable and durable efficacy with improved lipid parameters.