Prospective randomised comparison of lopinavir and Atazanavir in HIV-1 infected patients with good baseline virological control combined with Tenofivir DF: Efficacy and tolerability in naive or experienced HIV-1 infected patients: ARTEN Study: week 48 results

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Abstract

Background: lopinavir (LPV) and atazanavir (ATZ) are effective antiretroviral drugs with favourable lipids profiles. The aim of this study was to compare efficacy and safety of ATZ vs. LPV and to compare efficacy of ATZ vs. LPV in combination with tenofovir (TFV)/emtricitabine (FTC).

Methods: At the end of week 48, 576 HIV-infected treatment-naïve patients were randomised 1:1:1 to receive: i) NVP 200 mg BID, ii) NVP 400 mg QD or iii) NVP QD + LPV + FTC, respectively. Primary endpoint was treatment response (TR) defined as the proportion of patients with HIV-RNA (HIV RNA) ≤ 50 copies/mL at two consecutive visits after week 14 (Week 28). Secondary endpoints included virologic failure (VF), treatment response (TR) and safety. Data were only collected from the first 28 weeks in the second treatment arm. Analysis was performed by day 28 using an ITT analysis and by week 48 using an FAS analysis.

Results: Overall, 93.4% of patients with confirmed response at Week 28 achieved and maintained TR at Week 48 with both LPV/FTC and ATZ. LV failure occurred in 5.1% and 0.4% of patients treated with LPV/FTC and ATZ, respectively. Safety results showed no difference in adverse events associated with the two treatment arms. Changes from baseline in laboratory test over time are not shown. Safety results included no increase of adverse events with the addition of ATZ to LPV/FTC. No increase of liver enzymes was observed. Conclusion: LPV + FTC and ATZ + FTC are both highly effective and well tolerated in treatment-naïve patients. This study was supported by Boehringer Ingelheim GmbH.

References