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Atazanavir is safe and efficacious in HBV and HCV co-infected patients: results of AI424138 (CASTLE)

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Background

Chronic HBV and HCV infections are common co-morbidities that can complicate antiretroviral treatment in HIV-infected patients. Information on efficacy and safety are necessary to better define optimal therapeutic options in this population.

Methods

Randomized, open-label prospective study comparing once-daily ATV/r with twice-daily LPV/r, both in combination with once-daily fixed dose combination tenofovir/emtricitabine in antiretroviral-naive HIV-1 infected subjects. Proportion of subjects with HIV RNA <50 c/mL (confirmed virologic response/CVR), changes in CD4 cell count and lipids from baseline, and adverse events (AEs) through 48 weeks are presented among chronic HBV- and/or HCV-infected (Hep+) subjects.

Summary of results

At baseline, 13% of subjects were Hep+ (5% HBV+; 8% HCV+). Overall 9% of females, 14% males, 25% Asians, 15% Blacks, 5% others, and 13% of Whites were Hep+. (Table 1.)

Grade 2–4 treatment related hyperbilirubinemia (15% vs. 0) and jaundice (3% vs. 0) were more common on ATV/r. Nausea (8% vs. 2%) and diarrhea (14% vs. 0) were more common on LPV/r. Few SAEs were reported among Hep+ in either treatment arm. Grade 3–4 elevations in liver function tests were reported among the following: 5/60, 8% (ALT), 5/60, 8% (AST) and 23/60, 38% (total bilirubin) in the ATV/r arm and 3/50, 6% (ALT), 0% (AST); 0% (total bilirubin) in the LPV/r arm. (Table 2.)

Conclusion

Virologic and immunologic response was comparable in Hep+ treated with ATV/r or LPV/r. ATV/r had a more favorable lipid profile (TC, non-HDL, LDL, TG) and fewer gastrointestinal adverse events among Hep+ subjects than LPV/r. While the overall rates of transaminitis in Hep+ were low in this study compared to those observed in other clinical trials, a small number of subjects in the ATV/r and none on LPV/r had grade 3–4 AST elevations. The cause of this higher proportion in the ATV/r treatment arm among this limited number of subjects is unclear. With close monitoring of liver function tests, ATV/r can be considered as part of HAART among treatment-naive Hep+ patients.

Table 1:

Efficacy at Week 48	ATV/r N = 61	LPV/r N = 51
HIV RNA<50 c/mL, CVR (Non-Completer = Failure), n/N (%)	42/61 (69)	37/51 (73)
Mean CD4 Cell Count Change from Baseline (SE), cells/mm3	196 (26.1)	228 (21.7)

Table 2: Lipid Mean % Change (+/- SE) from Baseline at Week 48 – As Treated Subjects

	ATV/r N = 60	LPV/r N= 51
Total Cholesterol (TC)	12 (9.4, 15.3)	23 (20.1, 26.4)
HDL	28 (24.2, 32.4)	42 (32.3, 53.1)
Non-HDL	7 (3.1, 10.9)	17 (14.2, 20.9)
LDL	12 (6.4, 16.9)	21 (14.6, 27.8)
Triglycerides (TG)	18 (9.8, 27.1)	45 (33.2, 58.2)

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