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O415 Efficacy and safety of 48-week maintenance with QD ATV vs ATV/r (both + 2NRTIs) in patients with VL <50 c/mL after induction with ATV/r + 2NRTIs: study AI424136

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Purpose of the study

Once-daily (QD) atazanavir/ritonavir (ATV/r) + 2NRTIs has proven efficacy with favourable lipid and GI profiles in treatment-experienced and -naive HIV patients (pts). Data are needed on effective simplified treatment strategies.

Methods

AI424136 (INDUMA) is a randomised, open-label, multicentre study to assess non-inferiority (15% margin) of 48-week maintenance phase (MP) with ATV 400 mg QD vs. ATV/r 300/100 mg QD (1:1), both + 2NRTIs (excl. TDF), in patients with confirmed HIV-1 RNA <50 c/mL after a 26–30 week induction phase (IP) with ATV/r + 2NRTIs in treatment-naive pts. Primary end-point was proportion of pts with HIV-RNA <50 c/mL through week 48 of MP. Secondary end-points included, percent with HIV RNA <400 c/mL, CD4 cell count change, and safety of MP.

Summary of results

252 pts entered IP (median CD4 245 cells/mm3; median HIV-RNA 4.95 log10 c/mL), during which 30 pts discontinued (nine for AEs). At the end of IP (EoI), 50 were not suppressed and were continued on ATV/r regimen (not described here), and 172 were randomised to MP. Demographics and EoI subject characteristics for MP were well-balanced: median CD4 390 cells/mm3; half of pts were on 3TC+ABC. Through week 48 of MP the ATV arm demonstrated similar (non-inferior) efficacy compared to the ATV/r arm. (Table 1.)

During MP, mean change in CD4 cell count at week 48 was +92 (SE = 18.1) cells/mm3 for ATV/r and +100 (SE = 14.7) cells/mm3 for ATV; discontinuations prior to week 48 were: ATV/r 14%; ATV 8%. Seven pts on ATV/r and 11 on ATV experienced virological rebound, none had emergence of PI resistance. AEs led to discontinuation in 5% and 1% of pts on ATV/r & ATV, respectively. Lab grade 3–4 total bilirubin was reported in 47% and 14% on ATV/r & ATV, respectively. Mean percent triglyceride change from EoI to week 48 of MP was +9.8 vs. -27.0 for ATV/r & ATV, respectively. The percent of pts who shifted into higher NCEP categories from EoI to week 48 of MP was higher in ATV/r than ATV for total cholesterol (23 vs. 10) and triglycerides (20 vs. 3).

Conclusion

These results are consistent with the proven efficacy of atazanavir in naive pts and suggest that for those pts who have achieved undetectability under ATV/r, switching to

Table 1:

Proportion of pts with HIV RNA <50/400 c/mL through Wk 48 of MP (ITT)	ATV/r (N = 85)	ATV (N = 87)	Difference Estimate (95%CI) (ATV – ATV/r)
% <50 c/mL	75	78	2.9 (69.8, 15.5)
% <400 c/mL	81	86	

unboosted ATV may be an option that results in simplification of treatment regimen.