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Poster presentation

Safety and tolerability of etravirine (ETR; TMC125) in hepatitis B and/or C co-infected patients in DUET-1 and DUET-2: pooled 48-week results

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Purpose of the study

The 48-week efficacy and safety analysis of the next-generation NNRTI etravirine (ETR) in the DUET studies has recently been completed. We report safety results from a planned pooled analysis, according to baseline hepatitis co-infection status.

Methods

HIV-1-infected patients on stable but virologically failing therapy were randomised to receive either ETR 200 mg twice daily or placebo, both in combination with a background regimen (BR) consisting of darunavir with low-dose ritonavir (DRV/r), investigator-selected NRTIs and optional enfuvirtide (ENF). Hepatitis B and/or C virus (HBV and/or HCV) co-infection status was confirmed by hepatitis B surface antigen or HCV antibody and qualitative HCV ribonucleic acid (RNA). Co-infected patients were eligible if they were clinically stable, with aspartate aminotransferase (AST) and alanine aminotransferase (ALT) levels <5 × the upper limit of normal and did not require anti-hepatitis treatment. Adverse events (AEs) and laboratory parameters were analysed.

Summary of results

At baseline, HBV and/or HCV status was known for 1,129 HIV-1-infected patients. Of these, 139 patients (12.3%) were co-infected with HBV and/or HCV; the sample size was too small to compare HBV and HCV groups separately. Median treatment duration for this analysis was 52.3 vs. 51.0 weeks in the ETR + BR and placebo + BR groups, respectively. In co-infected patients, grade 3 or 4 AEs, serious AEs and deaths were less frequent with ETR than with placebo. Grade 3 or 4 AST/ALT elevations were more frequent in co-infected patients receiving ETR, however, the differences between the ETR and placebo groups was small. The incidence of grade 3 or 4 hepatic AEs was similar in both treatment groups. See table in Figure 1.

Conclusion

In general, the incidence and severity of AEs with ETR was similar to placebo, irrespective of co-infection status. The incidence of hepatic AEs and grade 3 or 4 AST/ALT elevations was higher in co-infected patients than in non-co-infected patients in both treatment groups, consistent with the underlying chronic hepatitis condition. ETR did not increase hepatic toxicity in patients with hepatitis co-infection and was generally well tolerated in all patients.

Incidence. %	HIV and HBV and/or HCV co-infected patients		Non co-infected patients	
	ETR + BR (n=72)	Placebo + BR (n=67)	ETR + BR (n=495)	Placebo + BR (n=495)
Any AEs	95.8	97.0	95.8	95.8
Grade 3 or 4 AEs	31.9	44.8	32.9	33.3
Discontinuation due to AEs	8.3	9.0	6.7	5.1
Serious AEs	26.4	34.3	18.2	21.8
Deaths	2.8	4.5	1.4	2.8
Hepatic AEs[A]	12.5	9.0	5.5	6.1
Grade 3 or 4 hepatic AEs	6.9	7.5	2.4	2.4
Discontinuation due to hepatic AE	1.4	3.0	0.8	0.4
Selected treatment-emergent grade 3 or 4 laboratory parameters				
ALT	11.1	7.5	2.4	1.4
AST	9.7	6.0	2.2	1.4

HBV and/or HCV status was not recorded in 42 placebo- and 32 ETR-treated patients. *Data also includes hepatic laboratory abnormalities reported as AEs

Figure 1