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

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Abstract

The 48-week efficacy and safety analysis of the next-generation NNRTI etravirine (ETR; TMC125) in the DUET studies has recently been completed. We report safety results from a planned pooled analysis, according to baseline hepatitis co-infection status. HIV-1-infected patients on stable, virologically failing therapy were randomised to receive either ETR 200mg bid or placebo, both in combination with a background regimen (BR) consisting of tenofovir and emtricitabine (FTC), raltegravir (RAL), and investigator-selected NNRTIs and optional enfuvirtide (ENF). Hepatitis B and/or C virus (HBV and/or HCV) co-infection status was confirmed by hepatitis B surface antigen (HBsAg) and qualitative HCV-RNA. Co-infected patients were eligible if they were clinically stable, with aspartate aminotransferase (AST) and alanine aminotransferase (ALT) levels <5 x the upper limit of normal and did not require antiviral treatment. Adverse events (AEs) and laboratory parameters were analysed.

Baseline demographics

In general, the incidence and severity of AEs with ETR was similar to placebo, irrespective of coinfection status. The incidence of hepatitis A and grade 3 or 4 AST/ALT elevations were more frequent with ETR than with placebo. Grade 3 or 4 AST/ALT elevations were more frequent in co-infected patients receiving ETR, however the difference between the ETR and placebo groups was small. The incidence of grade 3 or 4 hepatic AEs was similar in both treatment groups.

Conclusions

- In general, the incidence and severity of AEs with ETR + BR was similar to placebo + BR, irrespective of hepatitis coinfection status.
- Grade 3 or 4 AST/ALT elevations were more frequent with ETR than with placebo. Grade 3 or 4 AST/ALT elevations were more frequent in co-infected patients receiving ETR, however the difference between the ETR and placebo groups was small. The incidence of grade 3 or 4 hepatic AEs was similar in both treatment groups.

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