Abstract

Objectives: DUET-1 and DUET-2 are identical designed, ongoing, randomized, double-blind, placebo-controlled, Phase III trials, investigate TMC125 versus placebo in HIV-1-infected, treatment-experienced patients. The trials differ only by geographical location. We report findings from a planned, pooled analysis of safety in DUET-1 and DUET-2 when all patients had reached Week 24 or discontinued.

Methods: Patients on stable virologically-failing treatment, with documented NNRTI resistance (historical and/or at study entry) and ≥3 primary protease inhibitor (PI) mutations were randomized 1:1 to TMC125 200mg or placebo twice daily (each with darunavir/ritonavir [DRV/r], optimal NNRTIs and optional enfuvirtide [ENF]). Pooled intent-to-treat (ITT) analyses of rash, nervous system, psychiatric and hepatic adverse events (AEs) were by Fisher's exact test.

Results: 1,203 patients were treated (89.3% male; 69.8% Caucasian; 58.4% CDC C); 1,195 patients were evaluable. TMC125 was generally well-tolerated. Most common overall AEs (>0.5% incidence in TMC125 group) were rash, hepatotoxicity, lipemia, and rash.

Conclusions: TMC125 is generally well-tolerated, as safety and tolerability findings are summarized in the tables.

Conclusions

• Safety and tolerability of TMC125 was generally comparable to placebo, except for the incidence of rash.

• Overall, most AEs were of low severity and infrequently led to discontinuation.

• Neuro-psychiatric events were generally of low severity and similar between TMC125 and placebo groups.

• Rash, the only AE to occur more frequently with TMC125, was generally mild-to-moderate and self-limited, and the only AE to occur more frequently than placebo was rash.

A note for those that have been updated following submission of this abstract.

Overview of AEs

baseline characteristics and treatment duration

Hospitalisations

Grade 3 and 4 AEs

Treatment-emergent laboratory abnormalities

Baseline characteristics

DUET-1

DUET-2

Treatment-emergent laboratory abnormalities

Baseline characteristics and treatment duration

Overview of AEs

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