Impact of etravirine on hospitalizations and hospital-related costs: 48-week findings from pooled DUET trials

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Abstract

Background
DUET-1 and DUET-2 are two identically designed, ongoing, randomized, double-blind, placebo-controlled, Phase III trials, which have demonstrated efficacy of etravirine (ETR; TMC125) + background regimen (BR; darunavir/low-dose ritonavir [DRV]/NRTIs) and optional antiretroviral (ART) versus placebo + BR in HIV-1-infected, treatment-experienced patients. Efficacy and safety results from DUET-1 and DUET-2 have been reported recently. Hospitalization events and duration of hospital stay were recorded for each patient.

Methods
This analysis evaluated, at 48 weeks, differences in hospitalizations and days hospitalized to examine the cost implications between ETR + BR and placebo + BR in the pooled DUET trial population. Hospitalization rates were analyzed by negative binomial regression, examining the effect of baseline CD4 cell count strata. Daily hospital costs were assigned over the range of published estimates of US$1308–2441 (excluding antiretroviral treatment), which had been inflated to 2006 costs.

Results
One thousand, two hundred and three patients were included: 596 vs 604 in the ETR versus placebo groups. Baseline characteristics and average follow-up were comparable between arms. The number (%) of patients hospitalized was 105 (17.5%) vs 139 (23.0%) for ETR + BR versus placebo + BR, respectively (p=0.0006). Hospitalization rates and number of hospitalization days increased with decreasing baseline CD4 cell counts in both arms. For patients with <50 cells/mm³ CD4 cell count at baseline, ETR + BR showed a statistically significant decrease in the hospitalization rate versus placebo + BR (p<0.0001). Total hospital days observed during the 48-week follow-up period were 1702 vs 2747 for ETR + BR versus placebo + BR. Hospital costs were estimated to be $23.4 million for ETR + BR vs $36.6–7 million for placebo + BR.

Conclusions
At Week 48, ETR + BR provided a statistically significant reduction in overall hospitalization rates versus placebo + BR. The reductions in the number of hospitalizations and time spent in the hospital represent a significant clinical benefit to the patients and significant savings in hospital-related costs to the healthcare system.

Please note the abstract has been updated since submission.

Introduction
The number of hospitalizations and hospital stays has been shown to increase over time in patients undergoing antiretroviral treatment (ART). This analysis examines the effect of baseline CD4 cell count strata on hospitalization rates and hospital-related costs in patients enrolled in two identical HIV-1 treatment trials (DUET-1 and DUET-2) with etravirine (ETR; TMC125) + background regimen (BR; darunavir/low-dose ritonavir [DRV]/NRTIs) versus placebo + BR. Daily hospital costs were assigned over the range of published estimates of US$1308–2441 (excluding antiretroviral treatment), which had been inflated to 2006 costs.

Methods
Pooled 48-week data from the DUET trials show that ETR + BR provided a statistically significant reduction in overall hospitalization rates and days hospitalized versus placebo + BR.

Results
Hospitalization rates were analyzed by negative binomial regression, examining the effect of baseline CD4 cell count strata. Daily hospital costs were assigned over the range of published estimates of US$1308–2441 (excluding antiretroviral treatment), which had been inflated to 2006 costs. Total hospital days observed during the 48-week follow-up period were 1702 vs 2747 for ETR + BR versus placebo + BR. Hospital costs were estimated to be $23.4 million for ETR + BR vs $36.6–7 million for placebo + BR.

Conclusions
Pooled 48-week data from the DUET trials show that ETR + BR provided a statistically significant reduction in overall hospitalization rates and days hospitalized versus placebo + BR.

Acknowledgments
This research was supported by Tibotec. Presented at the XVIIth International AIDS Conference, Mexico City, Mexico, August 3–8 2008.

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