48-week pooled analysis of DUET-1 and DUET-2: the impact of baseline characteristics on virologic response to etravirine

Pedro Cahn, 1 Jean-Michel Molina, 1 William Towmer, 1 Monika Peeters, 1 Johan Vingerhoets, 1 Greet Boets, 1 Benny Baeten, 4 Goedele De Smedt 1

1 Fundación Huelsped, Buenos Aires, Argentina; 2 Assistance Publique Hôpitaux de Paris and University of Paris, Paris, France; 3 Kaiser Permanente, Los Angeles, CA, USA; 4 Tibotec BVBA, Mechelen, Belgium

Abstract

Background

48-week pooled analysis from the ongoing, randomized, double-blind, placebo-controlled DUET-1 and DUET-2 studies demonstrated the efficacy and safety of etravirine (ETR; TMC125) in treatment-experienced patients.

Methods

Treatment-experienced patients with documented NRTI resistance, ≥2 primary protease inhibitor (PI) mutations and one wild-type (<300 copies/ml), were randomized 1:1 to receive ETR (200 mg) or placebo bid, plus background and salvage RNIs, during with low-dose ritonavir (300 mg), optimized NRTI, and an antiretroviral (ARV) primary endpoint was the percentage of patients with confirmed viral load (<50 copies/ml, intent-to-treat [ITT]; population: time-to-loss of virologic response [TLOVR]; logistic regression model). Subgroup analyses assessed the effect of baseline characteristics on response to ETR.

Results

One thousand, two hundred and three patients were included in the pooled analysis: 398 and 405 patients in the ETR and placebo groups, respectively. Baseline characteristics and demographics were comparable between treatment groups: male (83% vs 91%), median age (53 years), Caucasian (68% vs 75%), and viral load (4.7 log10 copies/ml). CD4 cell count (119 cells/mm3) and hepatitis B and C coinfection (0% vs 13%). The effect of baseline characteristics on virologic response is shown below.

Conclusions

ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48. ETR + BR demonstrated superior virologic responses than placebo + BR in treatment-experienced patients at week 48.

Acknowledgments

The authors report no conflicts of interest. This study was supported by Tibotec BVBA.

Supported by Tibotec

Presented at the XVIIth International AIDS Conference, Mexico City, Mexico, August 3–8 2008.

This poster is available on-line at www.tibotec.com