Etravirine in Treatment Experienced

DUET-1 (TMC125-C206)
Etravirine in Treatment Experienced
DUET-1: Study Design

**Study Design: DUET-1**

- **Background**: Randomized, controlled, double-blind, placebo-controlled phase 3 trial evaluating the long-term efficacy, tolerability, and safety of etravirine in treatment-experienced adults with HIV

- **Inclusion Criteria (n = 612)**
  - Age ≥18 years
  - On stable ARV regimen for ≥8 weeks
  - HIV RNA >5000 copies/mL
  - ≥3 primary PI mutations
  - ≥1 NNRTI resistance-associated mutation

- **Treatment Arms**
  - Etravirine 200 mg BID + OBT*
  - Placebo + OBT*

*OBT = NRTIs, Darunavir/r, +/- Enfuvirtide

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DUET-1: Results

Week 24: Virologic Response (ITT-TLOVR*)

![Bar chart showing virologic response at Week 24 for HIV RNA <400 copies/mL and <50 copies/mL.]

- **HIV RNA <400 copies/mL**
  - Etravirine + OBT: 225/304 (74%)
  - Placebo + OBT: 157/308 (51%)

- **HIV RNA <50 copies/mL**
  - Etravirine + OBT: 170/304 (56%)
  - Placebo + OBT: 119/308 (39%)

*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response.*

Etravirine in Treatment Experienced DUET-2: Results

Week 24: Virologic Response (ITT-TLOVR*)

*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response.

Etravirine in Treatment Experienced DUET-1: Results

Week 24: Virologic Response (ITT-TLOVR*)

Week 24: Virologic Response (ITT-TLOVR*)

Reusing or Not Using Enfuvirtide

Using Enfuvirtide de novo

HIV RNA <50 copies/mL (%)

*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response.

Etravirine in Treatment Experienced DUET-1: Results

Week 24: Virologic Response (ITT-TLOVR*)

Interpretation: “In treatment-experienced patients with NNRTI resistance, treatment with TMC125 (etravirine) achieved better virological suppression at week 24 than did placebo. The safety and tolerability profile of TMC125 (etravirine) was generally comparable with placebo.”

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