Etravirine in Treatment-Experienced Patients

Study TMC125-C223
**Etravirine (formerly TMC125) in Patients with Highly Resistant HIV**

**Study TMC125-C223: Study Design**

**Study Design: TMC125-C223**

**Background**: Randomized, controlled, partially-blind, phase 2b trial evaluating the safety and efficacy of phase 2b formulation of etravirine combined with optimized background therapy (OBT) compared with a standard-of-care regimen.

**Inclusion Criteria (n = 199)**
- Adults
- HIV RNA >1,000 copies/mL
- ≥3 NNRTI resistance mutations

**Treatment Arms**
- OBT + *Etravirine 400 mg bid* (old formulation*)
  - (n = 77)
- OBT + *Etravirine 800 mg bid* (old formulation*)
  - (n = 78)
- OBT + Control
  - (n = 40)

*Old formulation of etravirine 800 mg equivalent to 200 mg of FDA-approved formulation of etravirine

Etravirine (formerly TMC125) in Patients with Highly Resistant HIV Study TMC125-C223: Results

Week 48: Change in HIV RNA Level

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Week 48: Change in HIV RNA, by Baseline Etravirine Mutations

Week 48: Virologic Response (Intent-to-Treat Analysis)

Conclusion: “Etravirine demonstrated higher efficacy than control, irrespective of the number of detectable nonnucleoside reverse transcriptase inhibitor resistance-associated mutations.”

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