Etravirine versus Protease Inhibitor in ARV-Experienced

TMC 125-C227
Etravirine versus Protease Inhibitor in ARV-Experienced TMC125-C227: Study Design

**Study Design: TMC125-C227**

- **Background:** Randomized, controlled, open-label phase 2 trial evaluating the safety and efficacy of etravirine (formerly TMC125) in PI-naïve patients with NNRTI resistance

- **Inclusion Criteria (n = 116)**
  - Age >18 years
  - HIV RNA >1,000 copies/mL
  - Documented genotypic NNRTI resistance
  - PI naïve

- **Treatment Arms**
  - Etravirine 800 mg bid + 2NRTIs
  - Investigator-selected PI + 2NRTIs

*Note: Old formulation of 800 mg bid equivalent to FDA-approved etravirine dose of 200 mg bid. Initial study planned for 48 weeks, but enrollment stopped prematurely and etravirine treatment discontinued after median 14.3 weeks due to suboptimal virologic response.*

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Prevalence of Baseline NNRTI Resistance Mutations

Etravirine in Patients with Highly Resistant HIV
TMC125-C223: Results

Weeks 12 and 24: Change in HIV RNA

Etravirine *versus* Protease Inhibitor in ARV-Experienced TMC125-C227: Results

Week 24: Mean Change of HIV RNA From Baseline (observed data)

Etravirine *versus* Protease Inhibitor in ARV-Experienced TMC125-C227: Results

Week 24: Proportion of Patients with HIV RNA Less than 50 copies/mL

Conclusions: “In a PI-naive population, with baseline NRTI and NNRTI resistance and NRTI recycling, TMC125 (etravirine) was not as effective as first use of a PI. Therefore the use of TMC125 (etravirine) plus NRTIs alone may not be optimal in PI naive patients with first-line virological failure on an NNRTI-based regimen. Baseline two-class resistance, rather than pharmacokinetics or other factors, was the most likely reason for suboptimal responses.”
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