

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

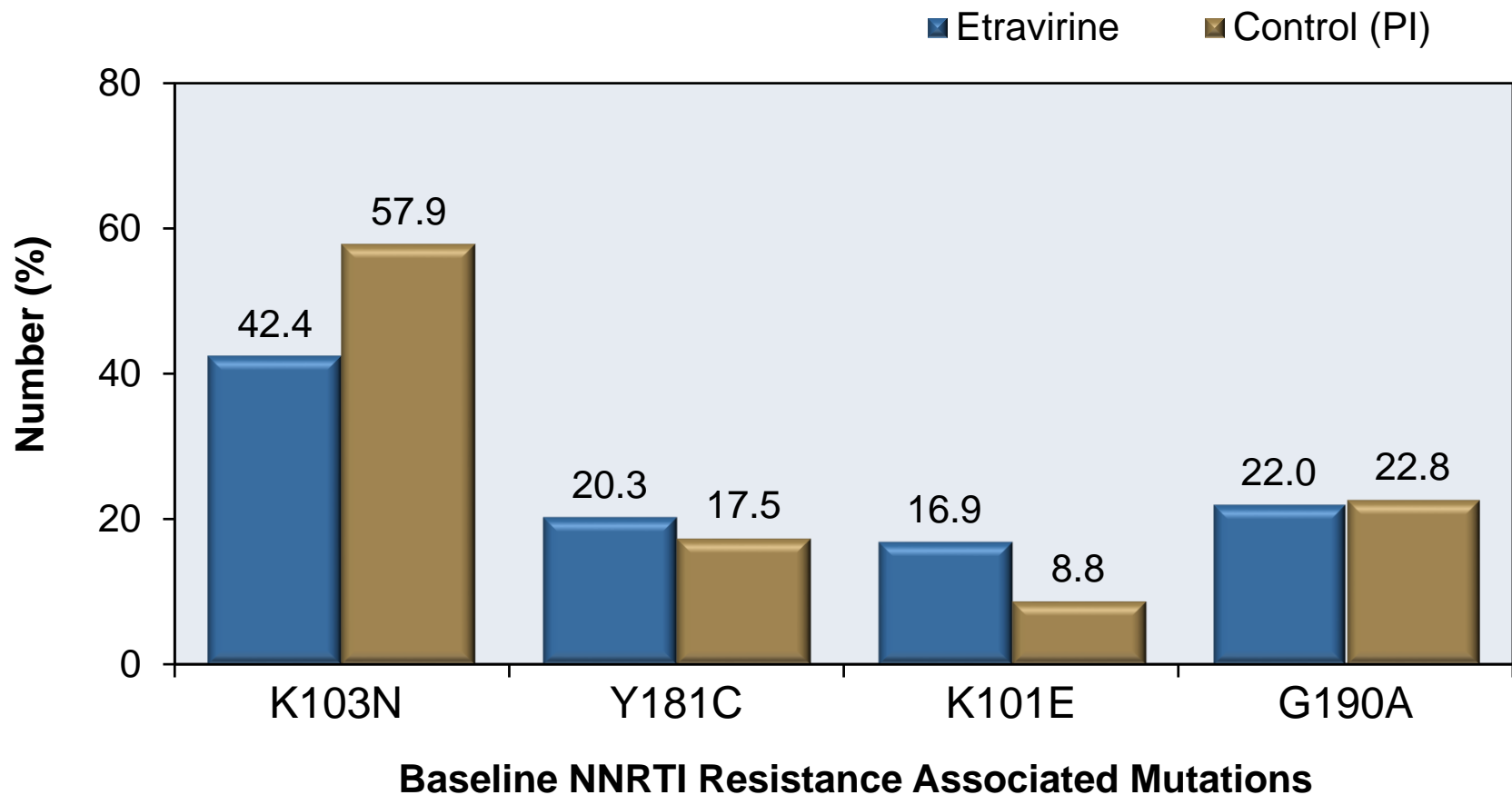
Etravirine 800 mg bid
(old formulation*)
+ 2 NRTIs
(n = 59)

**Investigator Selected
Protease Inhibitor**
+ 2 NRTIs
(n = 57)

*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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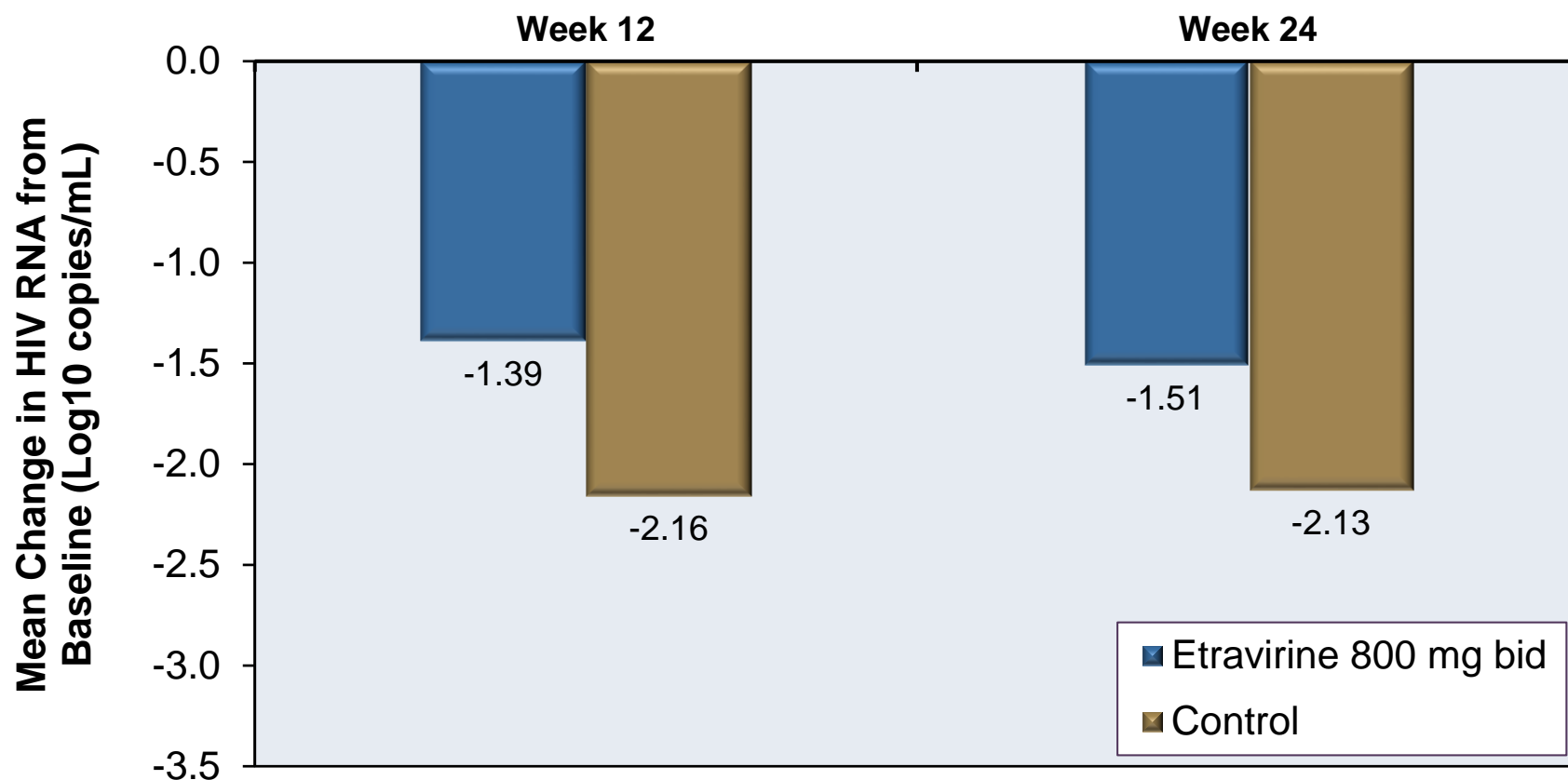
Prevalence of Baseline NNRTI Resistance Mutations



Etravirine in Patients with Highly Resistant HIV

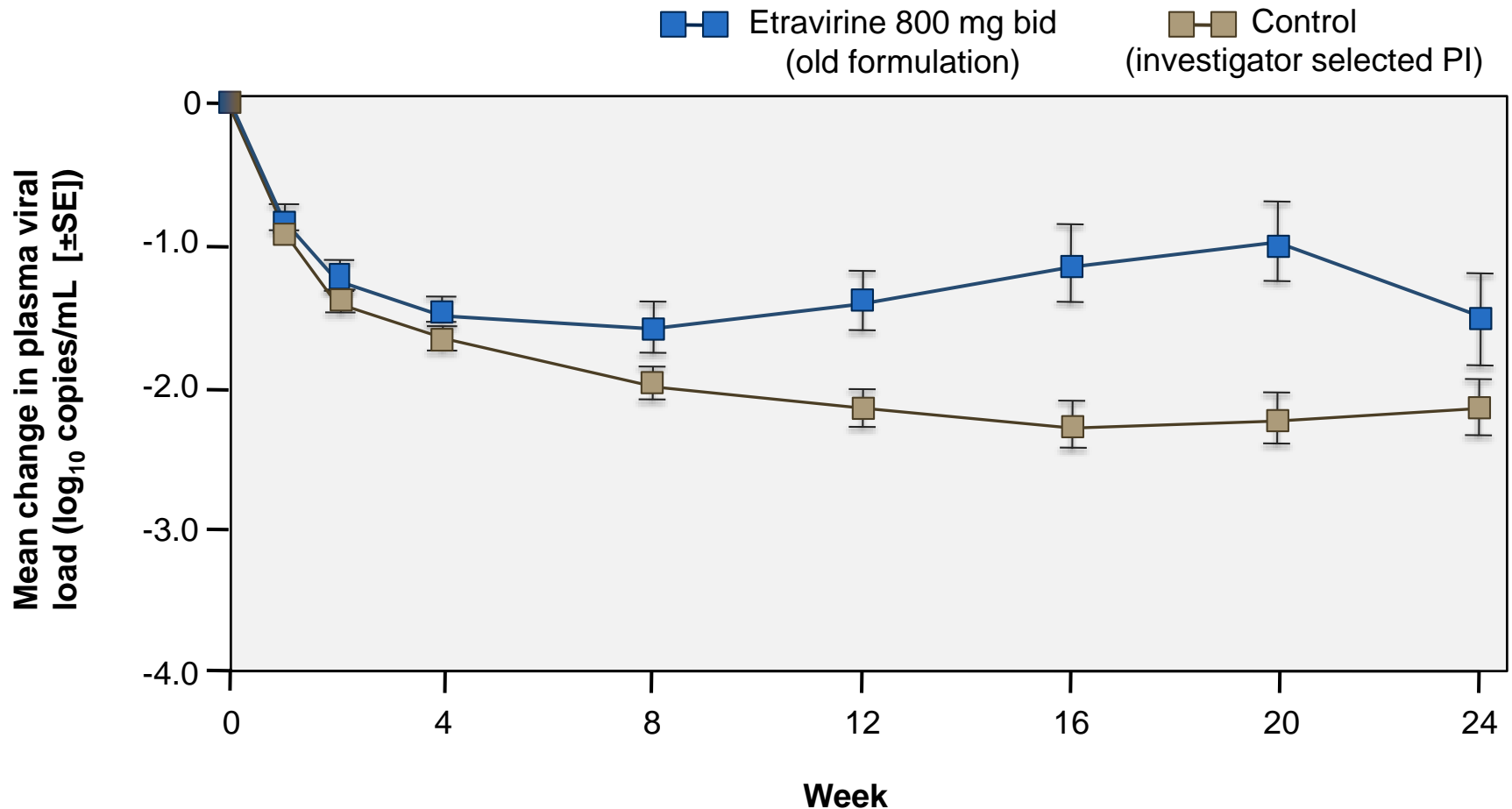
TMC125-C223: Results

Weeks 12 and 24: Change in HIV RNA



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

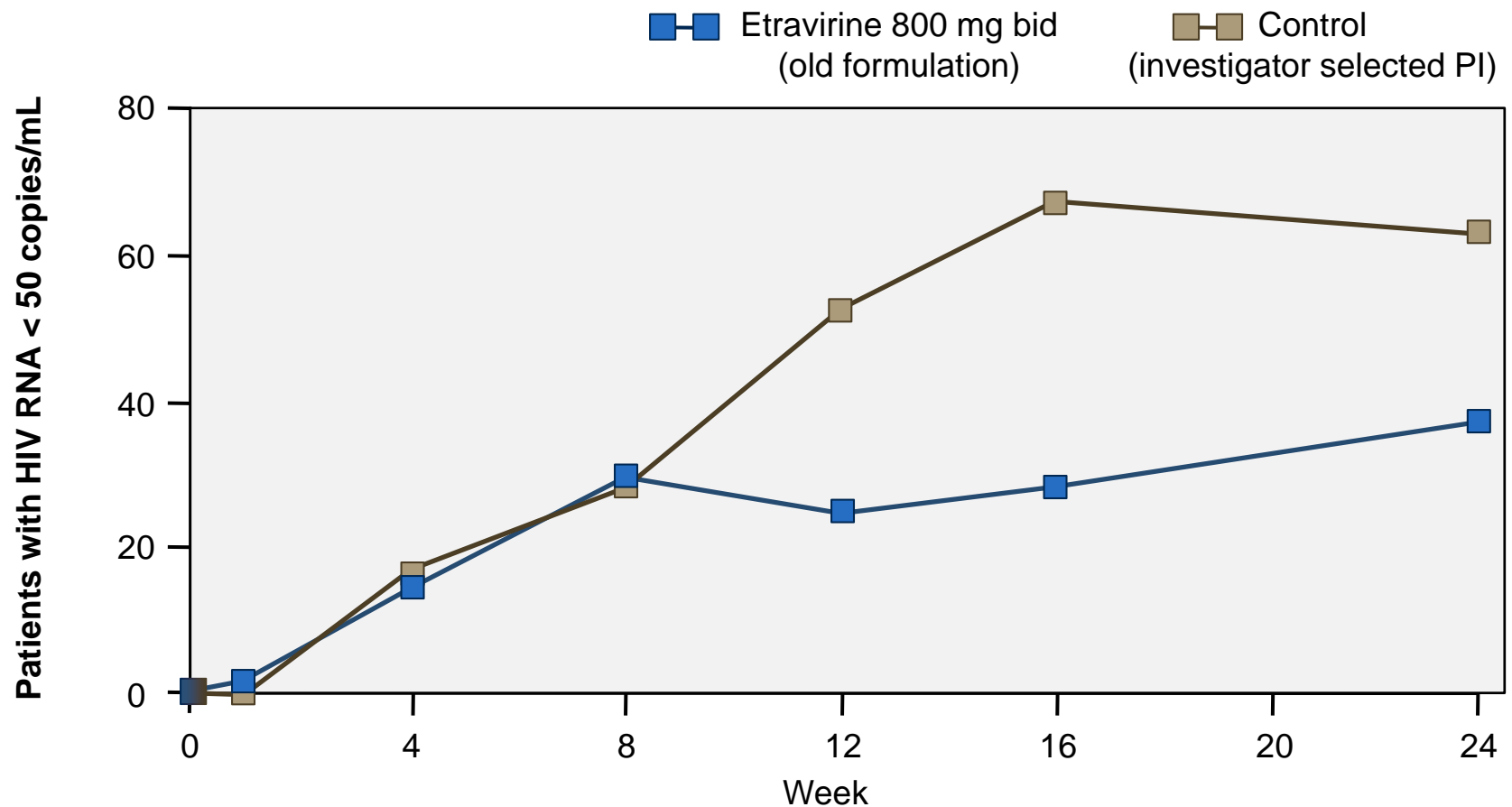
Week 24: Mean Change of HIV RNA From Baseline (observed data)



Source: Ruxrungtham K, et al. HIV Med. 2008;9:883-96.

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

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



Source: Ruxrungtham K, et al. HIV Med. 2008;9:883-96.

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

Conclusions: “In a PI-naïve 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 naïve 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.”

Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling \$800,000 with 0% financed with non-governmental sources. This project is led by the University of Washington's Infectious Diseases Education and Assessment (IDEA) Program.

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