

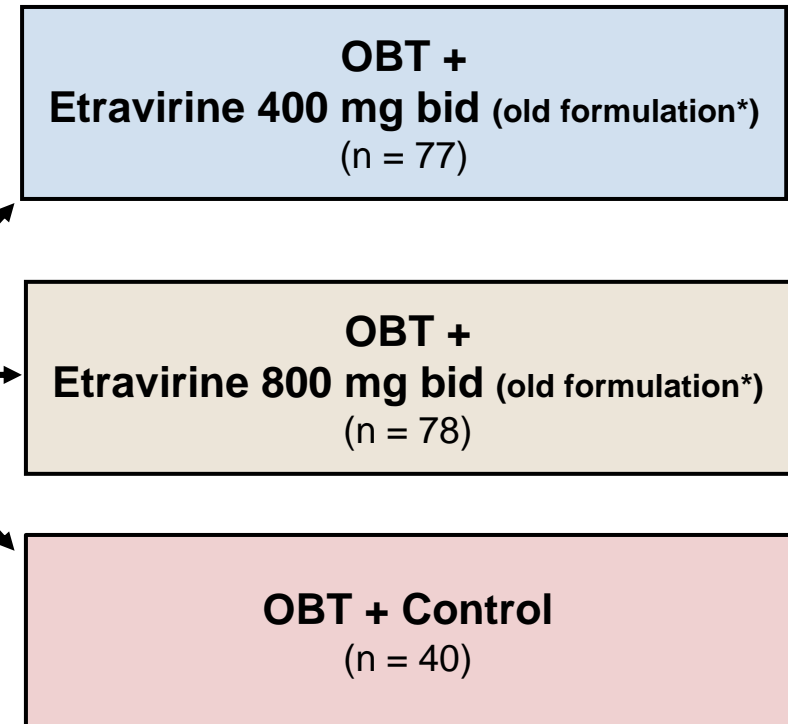
Etravirine in Treatment-Experienced Patients
Study TMC125-C223

Etravirine (formerly TMC125) in Patients with Highly Resistant HIV

Study TMC125-C223: Study Design

Study Design: TMC125-C223

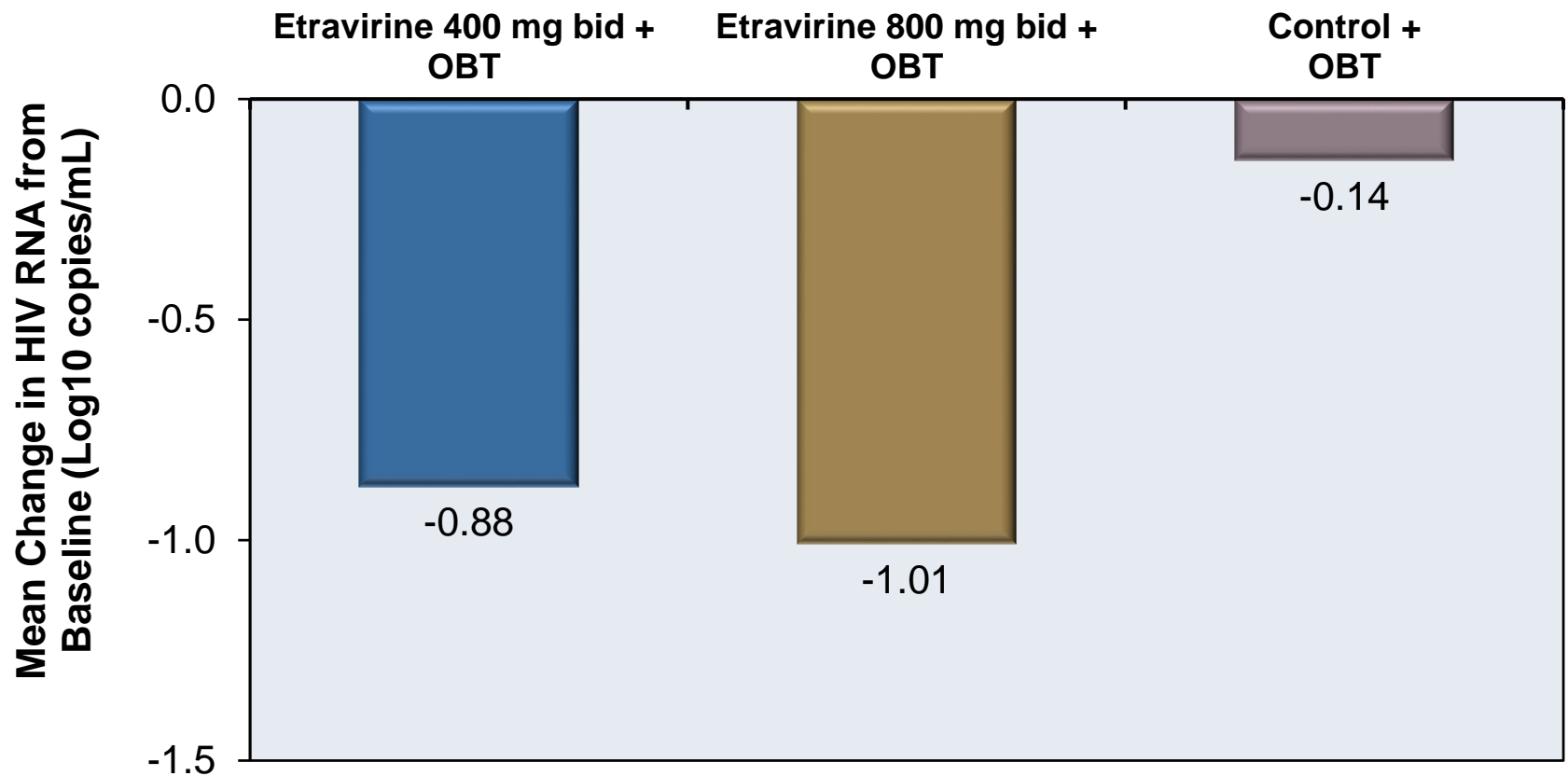
- **Background:** Randomized, controlled, partially-blind, phase 2b trial evaluating the safety and efficacy of phase 2b formulation of etravirine combined with optimized background therapy (OBT) compared with a standard-of-care regimen
- **Inclusion Criteria (n = 199)**
 - Adults with HIV
 - HIV RNA >1,000 copies/mL
 - ≥3 NNRTI resistance mutations
- **Treatment Arms**
 - OBT + *Etravirine 400 mg bid
 - OBT + *Etravirine 800 mg bid
 - OBT + *Control (included at least 3 ARVs: NRTIs, PIs, and/or Enfuvirtide)



*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

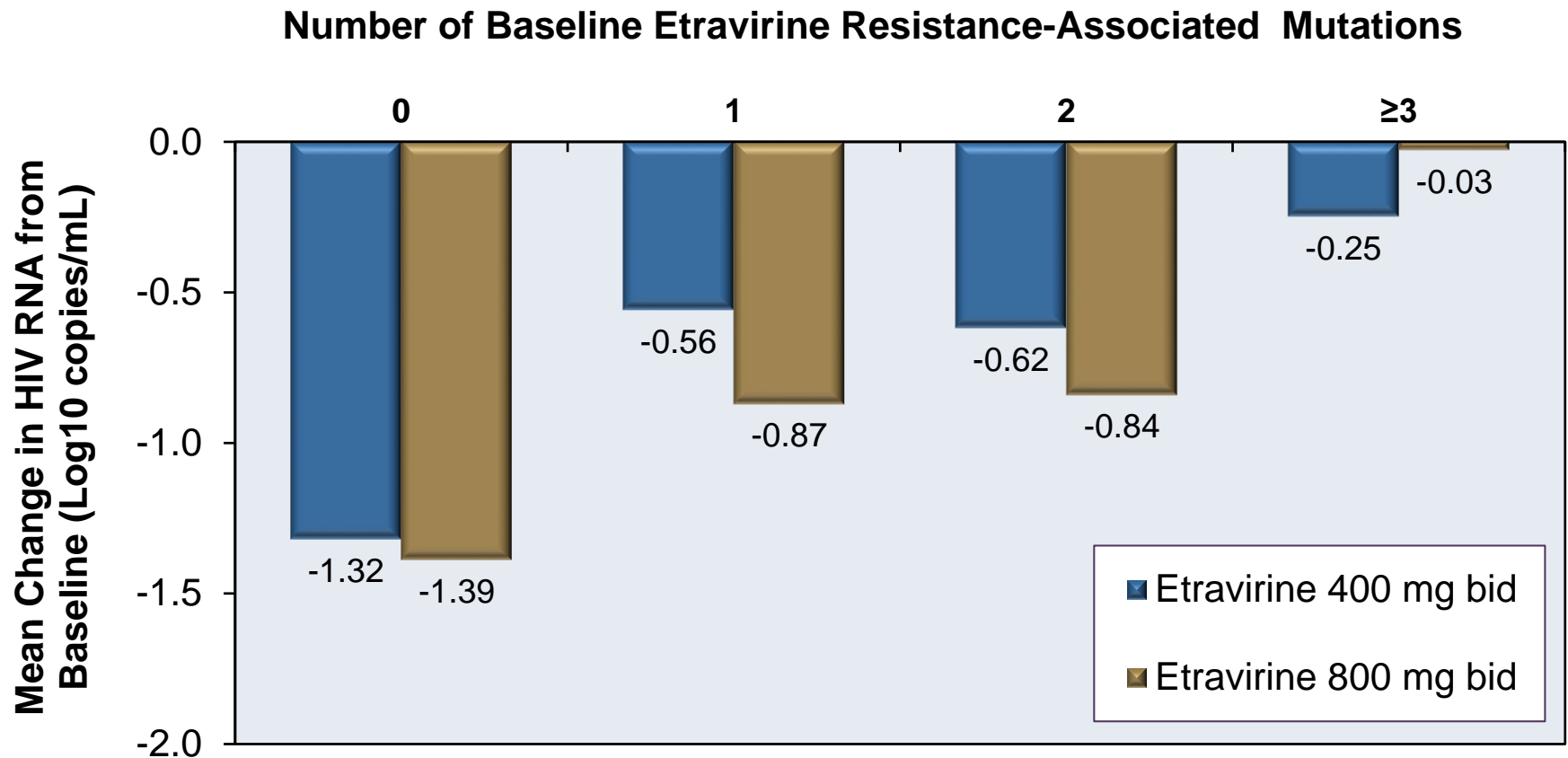
Week 48: Change in HIV RNA Level



Source: Cohen CJ, et al. AIDS. 2009;23:423-6.

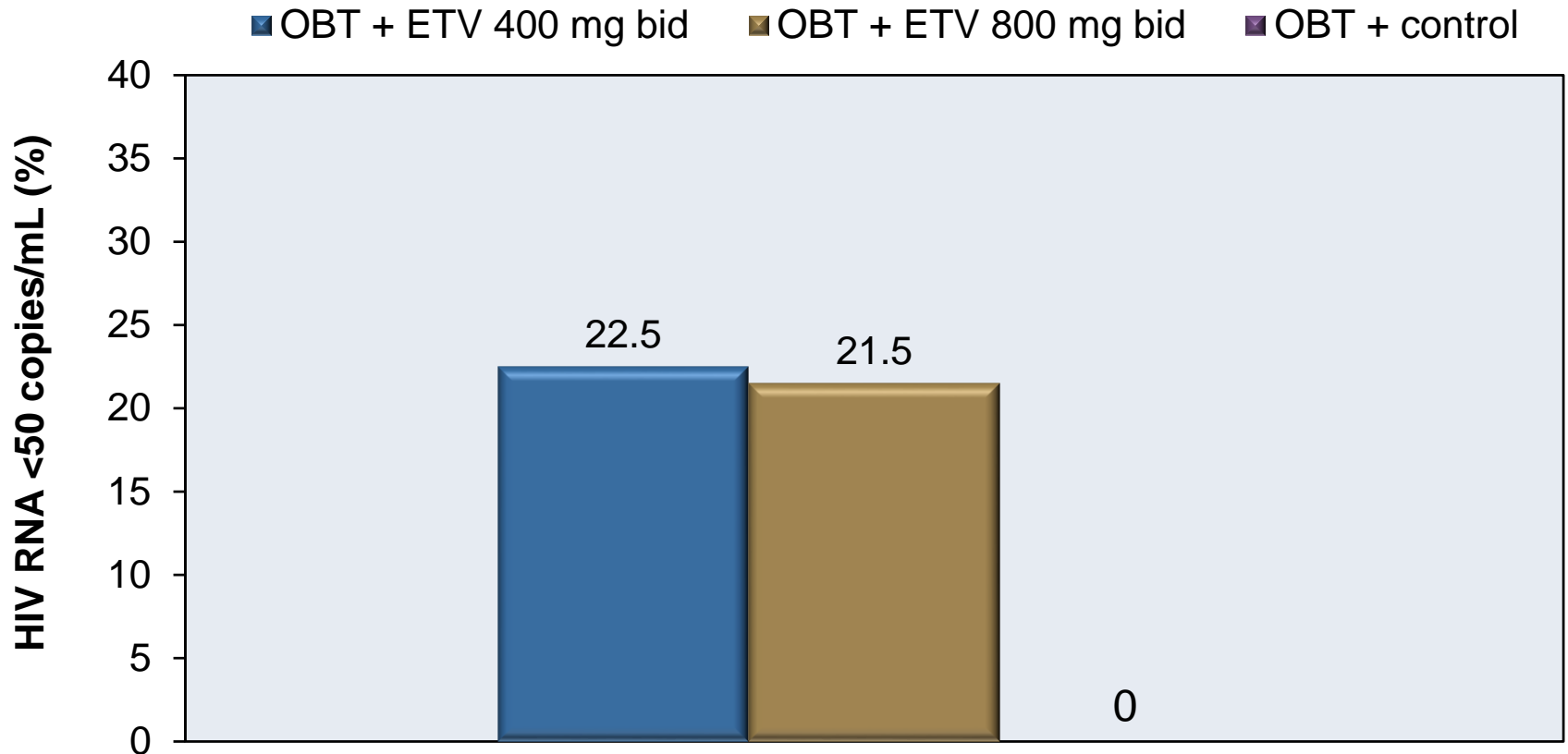
Etravirine (formerly TMC125) in Patients with Highly Resistant HIV Study TMC125-C223: Results

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



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

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



Source: Cohen CJ, et al. AIDS. 2009;23:423-6.

Etravirine (formerly TMC125) in Patients with Highly Resistant HIV Study TMC125-C223: Week 24 Conclusions

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

Acknowledgment

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