

Raltegravir plus OBT in Patients with Multidrug-Resistant HIV  
**005 Trial**

# Raltegravir plus OBT in Patients with Multidrug-Resistant HIV 005: Study Design

## Study Design: 005

- **Background:** Randomized, double-blind, dose-ranging, placebo-controlled phase 2 trial to evaluate raltegravir compared to placebo, with optimized background therapy (OBT), in patients with multidrug-resistant HIV.
- **Inclusion Criteria (n = 179)**
  - Age  $\geq 18$  years
  - Antiretroviral-experienced with resistance to at least 1 NNRTI, 1 NRTI, and 1 PI
  - CD4 count  $>50$  cells/mm<sup>3</sup>
  - HIV RNA  $>5,000$  copies/mL
  - Non-pregnant, no HCV coinfection
- **Treatment Arms (All Received OBT)**
  - Raltegravir 200 mg, 400 mg, or 600 mg BID
  - Placebo

**Raltegravir 200 mg BID  
+ OBT**  
(n = 44)

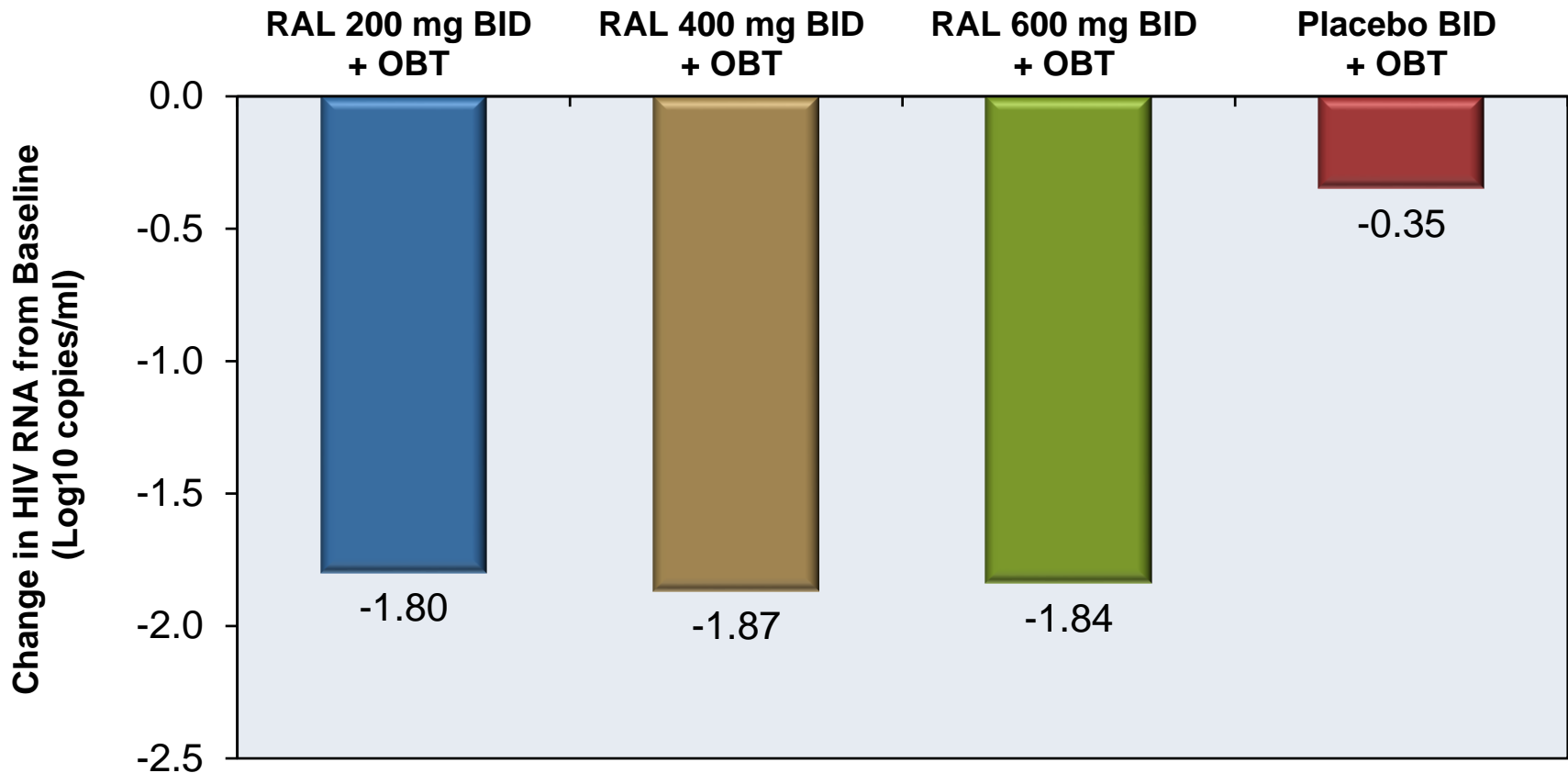
**Raltegravir 400 mg BID  
+ OBT**  
(n = 45)

**Raltegravir 600 mg BID  
+ OBT**  
(n=45)

**Placebo  
+ OBT**  
(n=45)

# Raltegravir plus OBT in Patients with Multidrug-Resistant HIV 005: Results

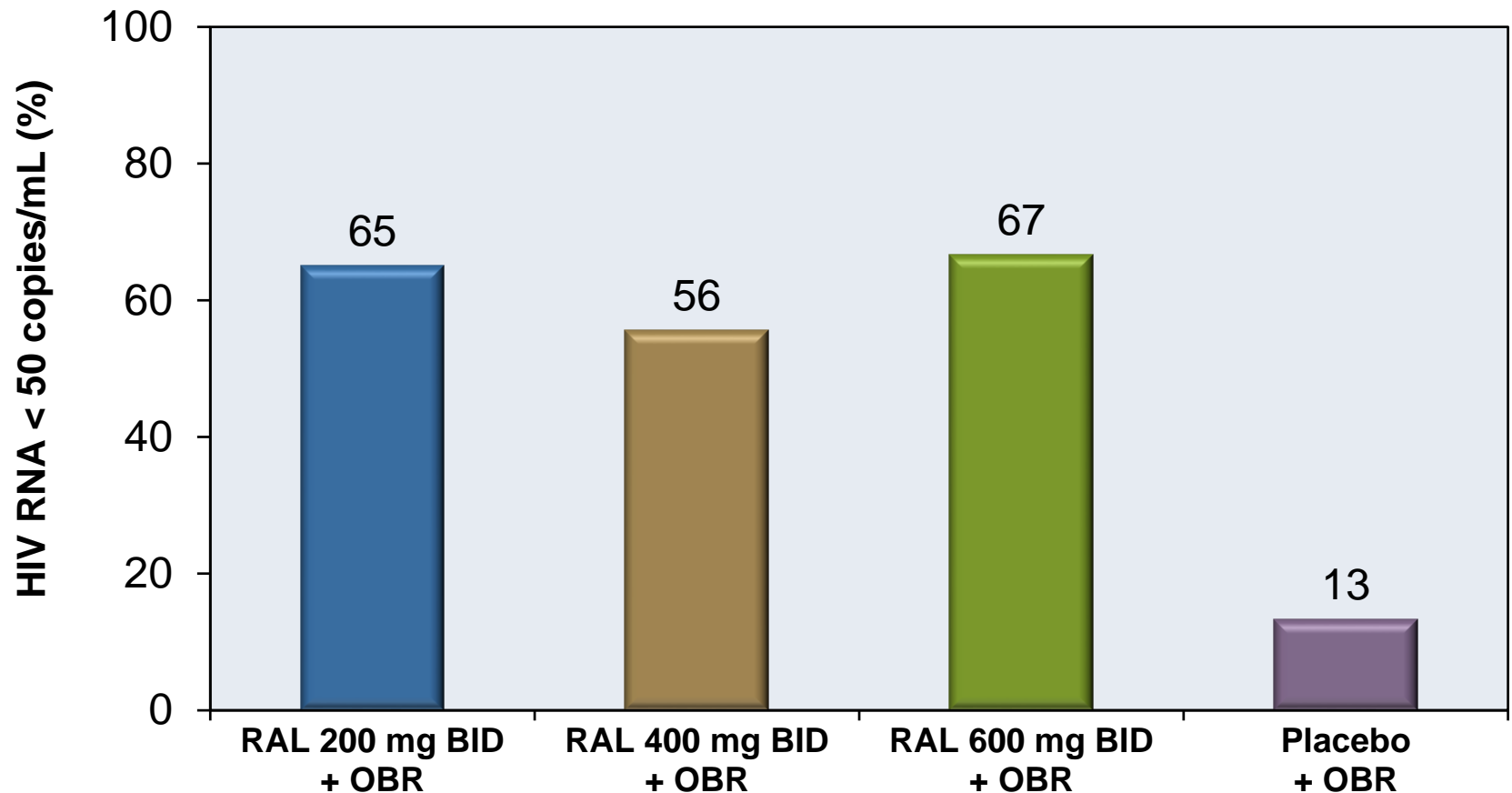
Week 24: Change from Baseline Viral Load



Source: Grinsztejn B, et al. Lancet. 2007;369:1261-9.

# Raltegravir plus OBT in Patients with Multidrug-Resistant HIV 005: Results

Week 24: Virologic Response



Source: Grinsztejn B, et al. Lancet. 2007;369:1261-9.

# Raltegravir plus OBT in Patients with Multidrug-Resistant HIV 005: Conclusions

**Interpretation:** “In patients with few remaining treatment options, raltegravir at all doses studied provided better viral suppression than placebo when added to an optimised background regimen. The safety profile of raltegravir is comparable with that of placebo at all doses studied.”

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