

Etravirine in Treatment Experienced  
**DUET-1 (TMC125-C206)**

# Etravirine in Treatment Experienced DUET-1: Study Design

## Study Design: DUET-1

- **Background:** Randomized, controlled, double-blind, placebo-controlled phase 3 trial evaluating the long-term efficacy, tolerability, and safety of etravirine in treatment-experienced adults with HIV
- **Inclusion Criteria (n = 612)**
  - Age  $\geq 18$  years
  - On stable ARV regimen for  $\geq 8$  weeks
  - HIV RNA  $> 5000$  copies/mL
  - $\geq 3$  primary PI mutations
  - $\geq 1$  NNRTI resistance-associated mutation
- **Treatment Arms**
  - Etravirine 200 mg BID + OBT\*
  - Placebo + OBT\*

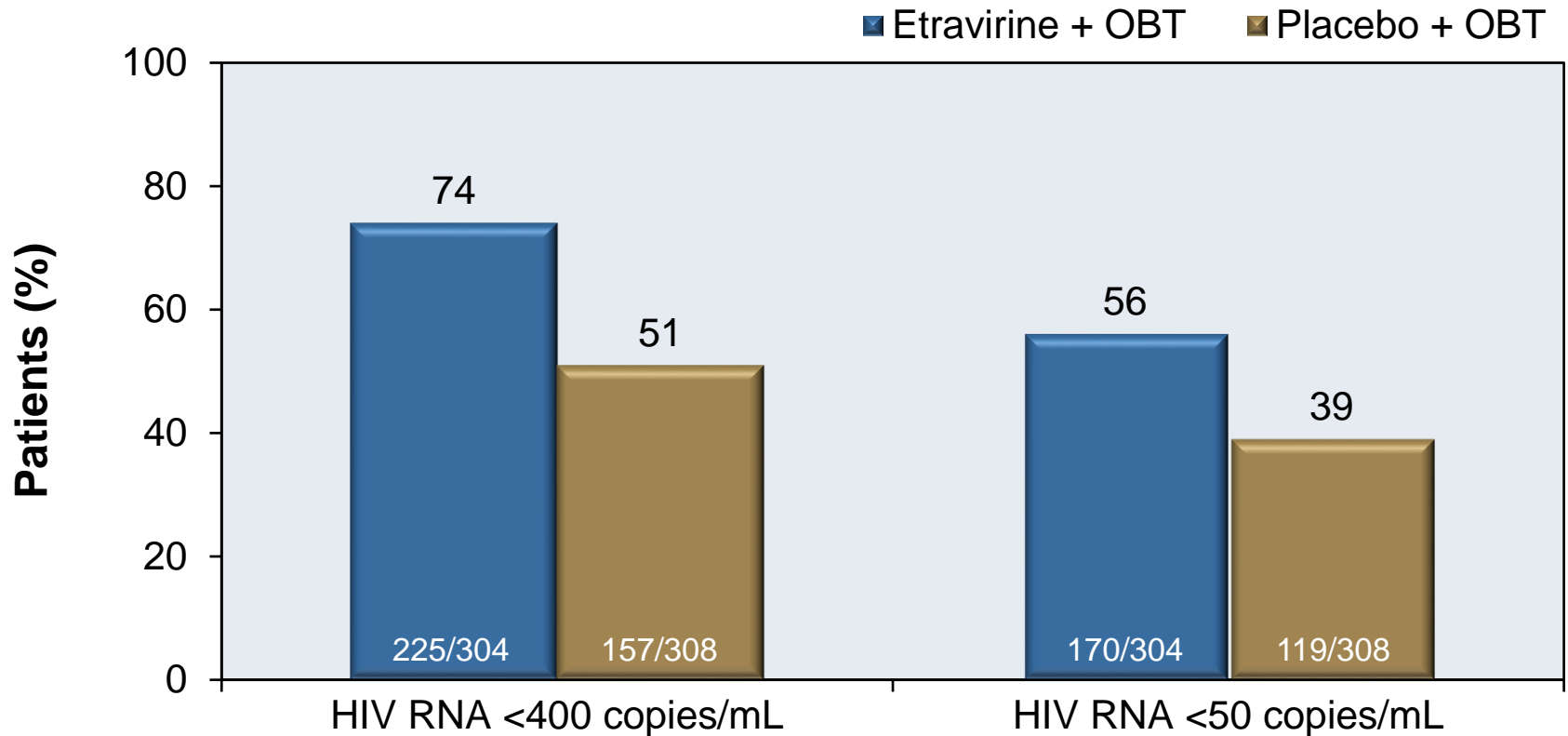
**Etravirine 200 mg BID + OBT**  
(n = 304)

**Placebo + OBT**  
(n = 308)

\*OBT = NRTIs, Darunavir/r, +/- Enfuvirtide

# Etravirine in Treatment Experienced DUET-1: Results

Week 24: Virologic Response (ITT-TLOVR\*)

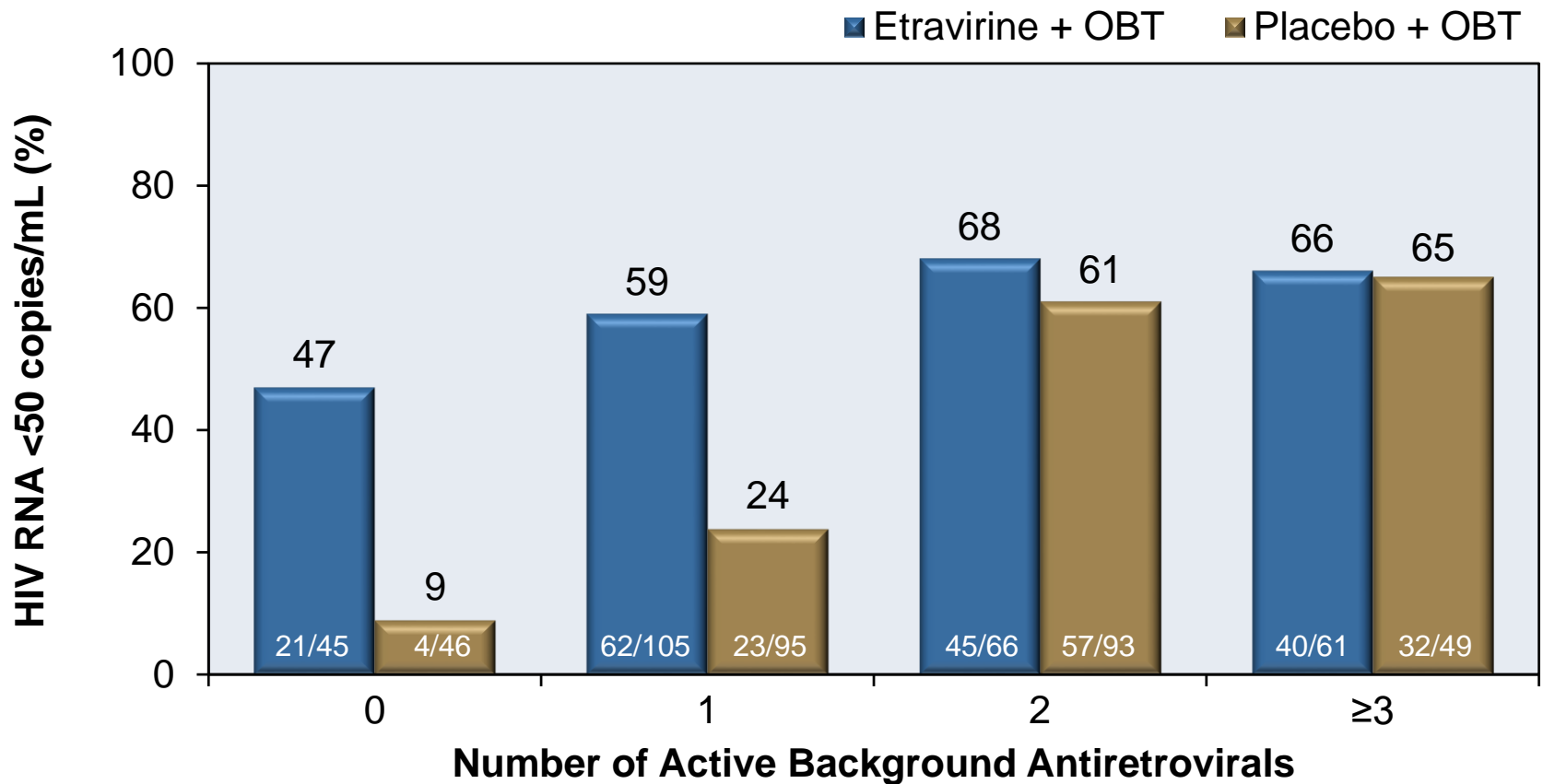


\*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response.

Source: Madrugá JV, et al. *Lancet*. 2007;370:29-38.

# Etravirine in Treatment Experienced DUET-2: Results

Week 24: Virologic Response (ITT-TLOVR\*)

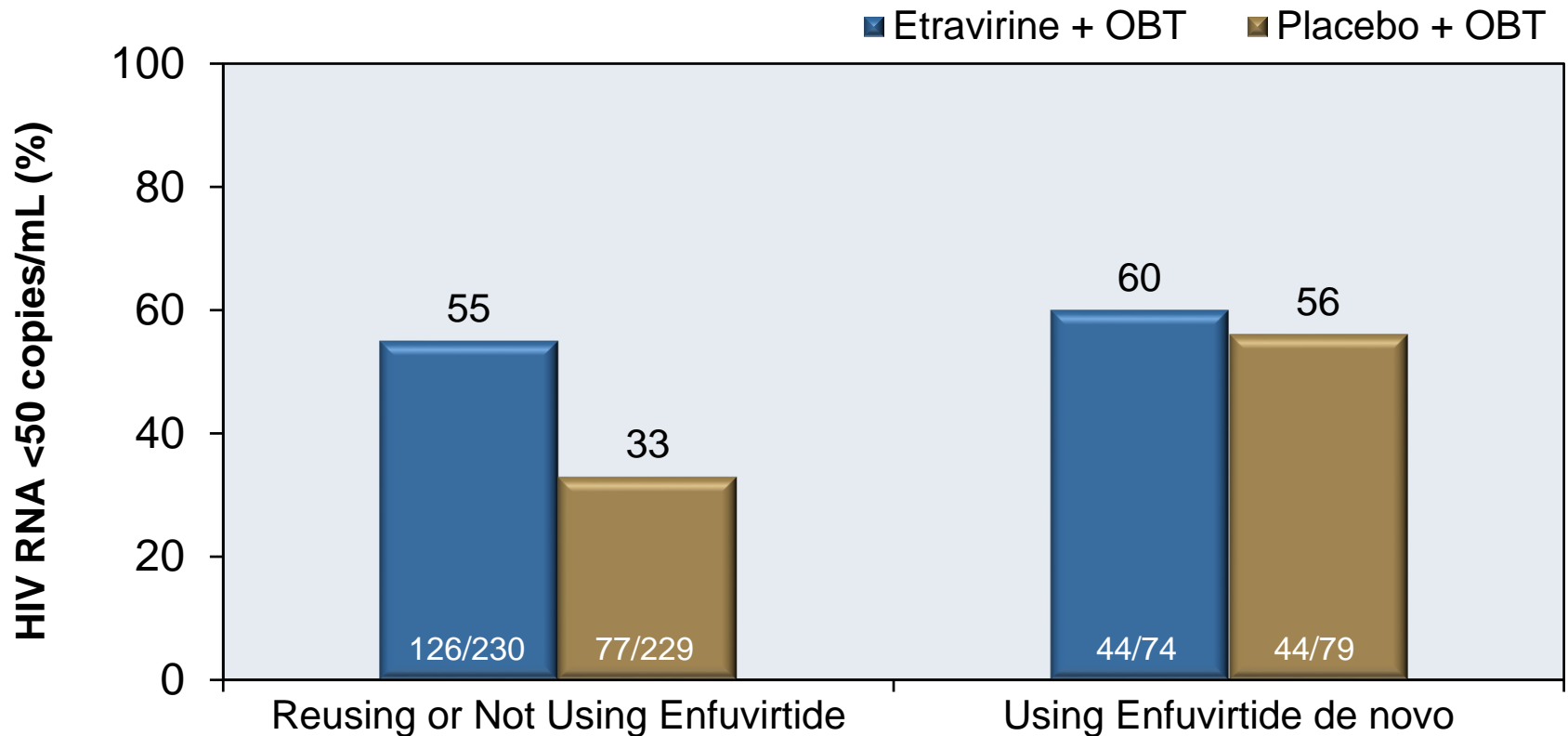


\*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response.

Source: Lazzarin A, et al. Lancet. 2007;370:39-48.

# Etravirine in Treatment Experienced DUET-1: Results

Week 24: Virologic Response (ITT-TLOVR\*)

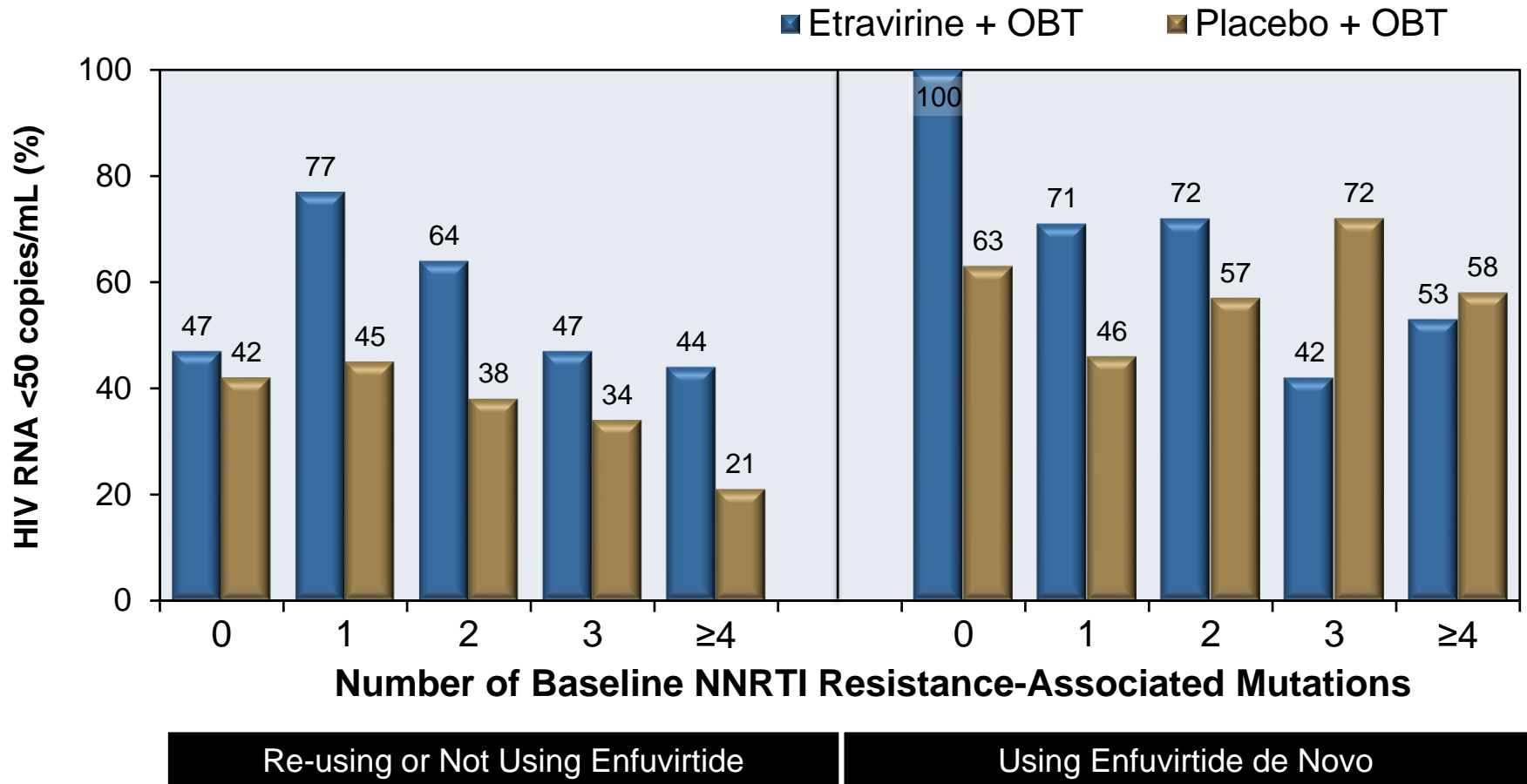


\*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response.

Source: Madruga JV, et al. Lancet. 2007;370:29-38.

# Etravirine in Treatment Experienced DUET-1: Results

Week 24: Virologic Response (ITT-TLOVR\*)



Source: Madruga JV, et al. Lancet. 2007;370:29-38.

# Etravirine in Treatment Experienced DUET-1: Conclusions

**Interpretation:** “In treatment-experienced patients with NNRTI resistance, treatment with TMC125 (etravirine) achieved better virological suppression at week 24 than did placebo. The safety and tolerability profile of TMC125 (etravirine) was generally comparable with placebo.”

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