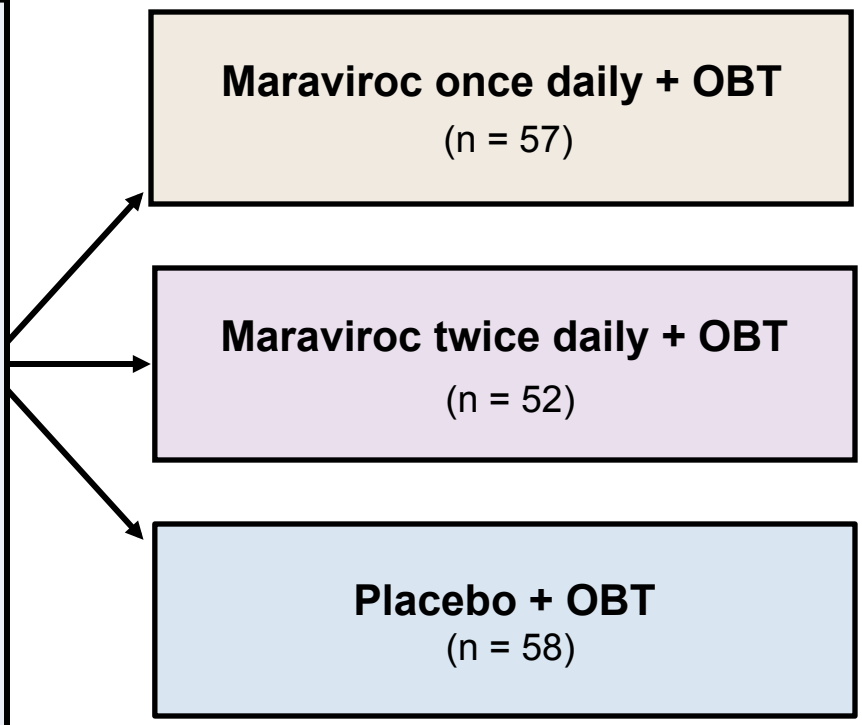
Maraviroc in Treatment-Experienced Patients with non-R5 HIV

A4001029 Trial

Maraviroc in Treatment-Experienced Patients with non-R5 HIV
A4001029: Study Design

Study Design: A4001029

- **Background**: Randomized, double-blind, placebo-controlled, phase 2b trials to evaluate safety and efficacy of maraviroc in treatment-experienced patients infected with non-R5 tropic HIV
- **Inclusion Criteria (n = 190)**
  - Resistance to ≥2 ARV classes, or ≥3 months of treatment ≥3 ARV classes
  - X4, dual, or mixed-tropic HIV
- **Treatment Arms**
  - Maraviroc 300 mg once daily + OBT*
  - Maraviroc 300 mg twice daily + OBT*
  - Placebo + OBT*



*OBT = Optimized Background Therapy (investigator selected, 3-6 agents). MVC dose reduced to 150 mg (daily or BID) in patients taking protease inhibitors (except tipranavir) or delavirdine.

Source: Saag M, et al. J Infect Dis. 2009;199:1638-47.

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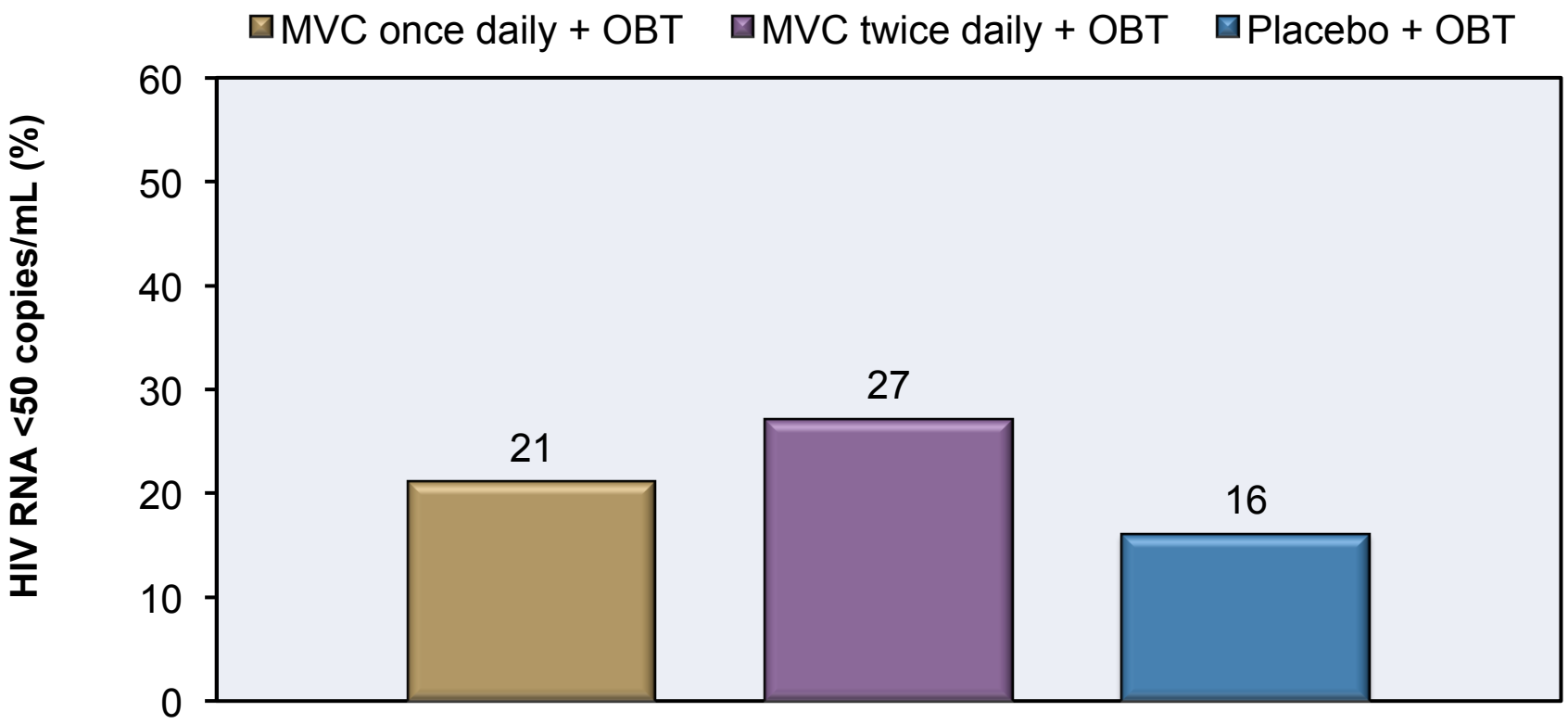
A4001029: Results

Week 24: Virologic Response*



*Values for patients with missing data or who discontinued treatment imputed as 0

Source: Saag M, et al. J Infect Dis. 2009;199:1638-47.

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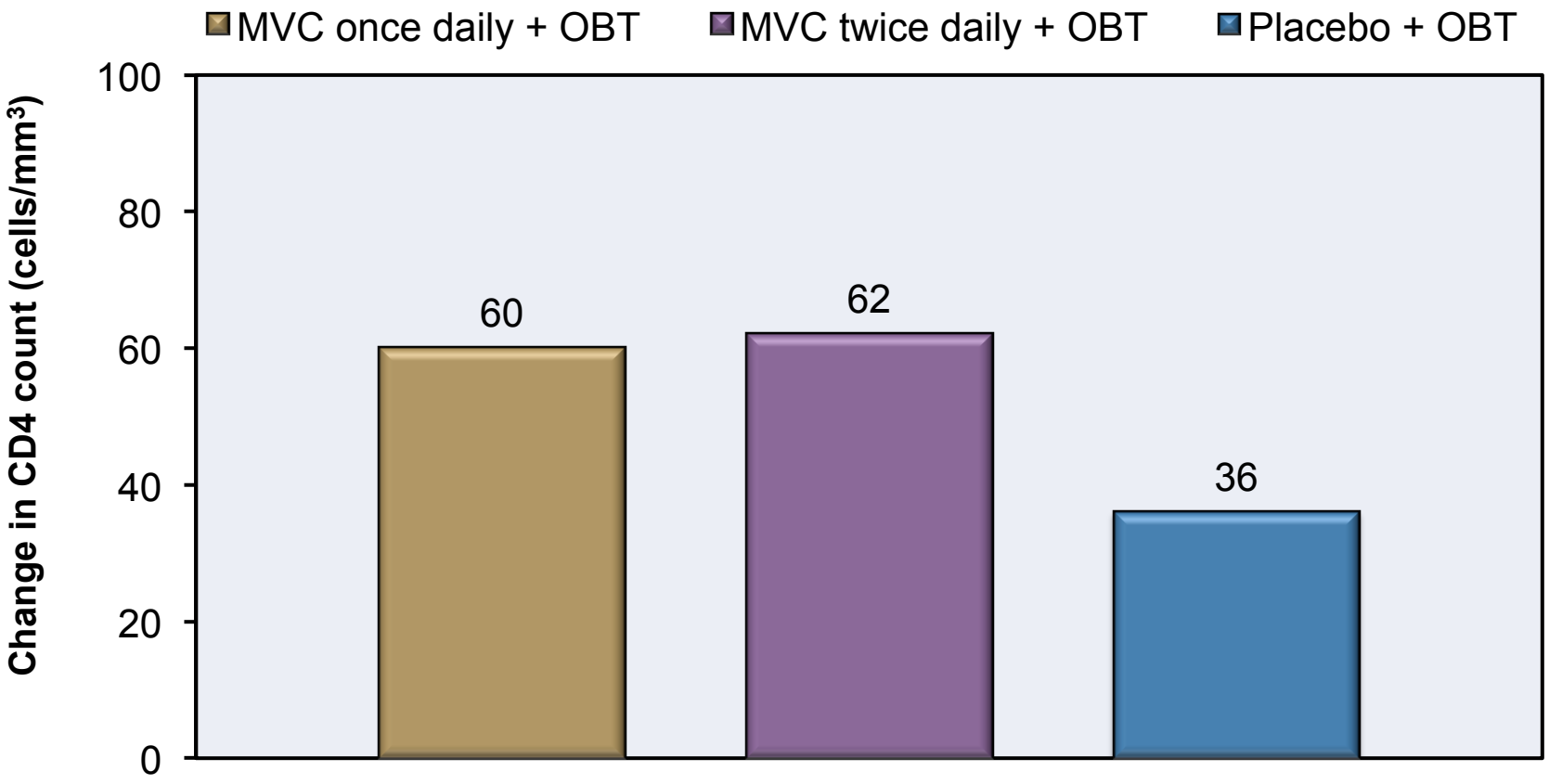
A4001029: Results

Week 24: Change in CD4 Cell Count from Baseline*



*Using last observation carried forward method

Source: Saag M, et al. J Infect Dis. 2009;199:1638-47.

Maraviroc in Treatment-Experienced Patients with non-R5 HIV
A4001029: Conclusions

Conclusions: "In this exploratory study involving extensively treatment-experienced patients with advanced, non-R5 HIV-1 infection, neither superiority nor noninferiority was statistically demonstrated for either maraviroc dosage compared with placebo at 24 weeks of treatment."

Source: Saag M, et al. J Infect Dis. 2009;199:1638-47.

Acknowledgment

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National HIV Curriculum

AETC AIDS Education & Training Center Program
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