Maraviroc in Patients with Multiclass Drug Resistance

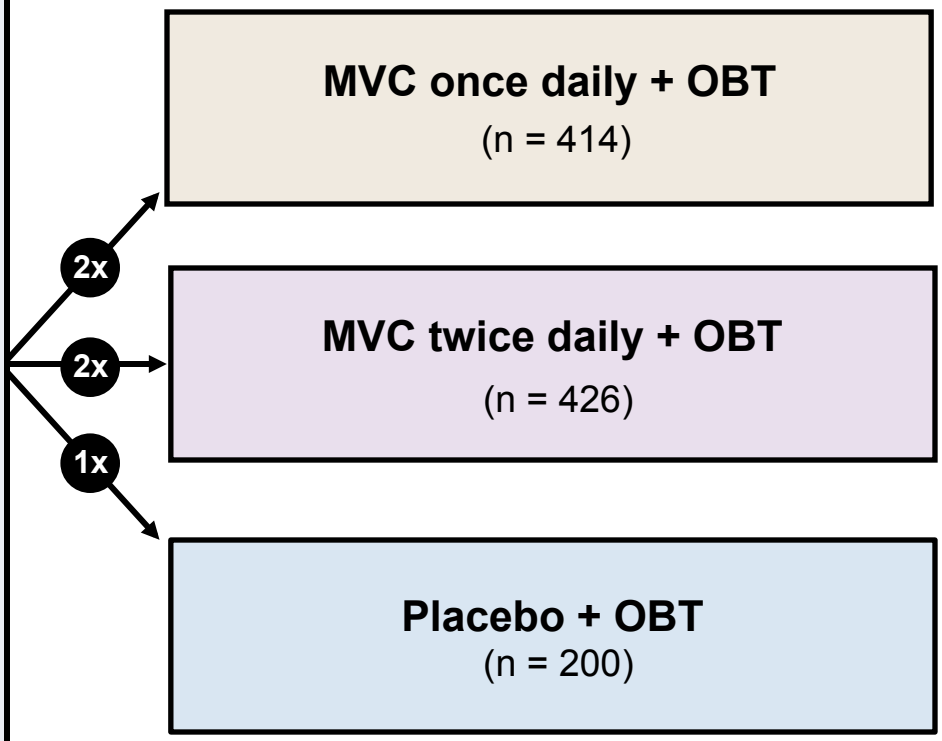
MOTIVATE 1 and 2 Trials

Maraviroc in Patients with Multiclass Drug Resistance
MOTIVATE 1 and 2: Study Design

MOTIVATE = **M**araviroc versus **O**ptimized **T**herapy **i**n **V**iremic **A**ntiretroviral **T**reatment-**E**xperienced Patients

Study Design: MOTIVATE 1 and 2

- **Background**: Parallel, randomized, double-blind, placebo-controlled, phase 3 trials to evaluate safety and efficacy of maraviroc in treatment-experienced patients
- **Inclusion Criteria (n = 1049)**
  - Age ≥ 16
  - Resistance to ≥ 3 ARV classes
  - R-5 tropic virus
  - On stable ARV regimen or no regimen for ≥ 4 weeks with HIV RNA ≥ 5000 copies/ml
- **Treatment Arms**
  - Maraviroc* once daily + OBT**
  - Maraviroc* twice daily + OBT**
  - Placebo + OBT**



*MVC dose 300mg daily or BID with PI-containing regimens, 150mg daily or BID with all other regimens
**OBT= Optimized Background Therapy (investigator-selected, 3-6 agents).

Source: Gulick RM, et al. N Engl J Med. 2008;359:1429-41.

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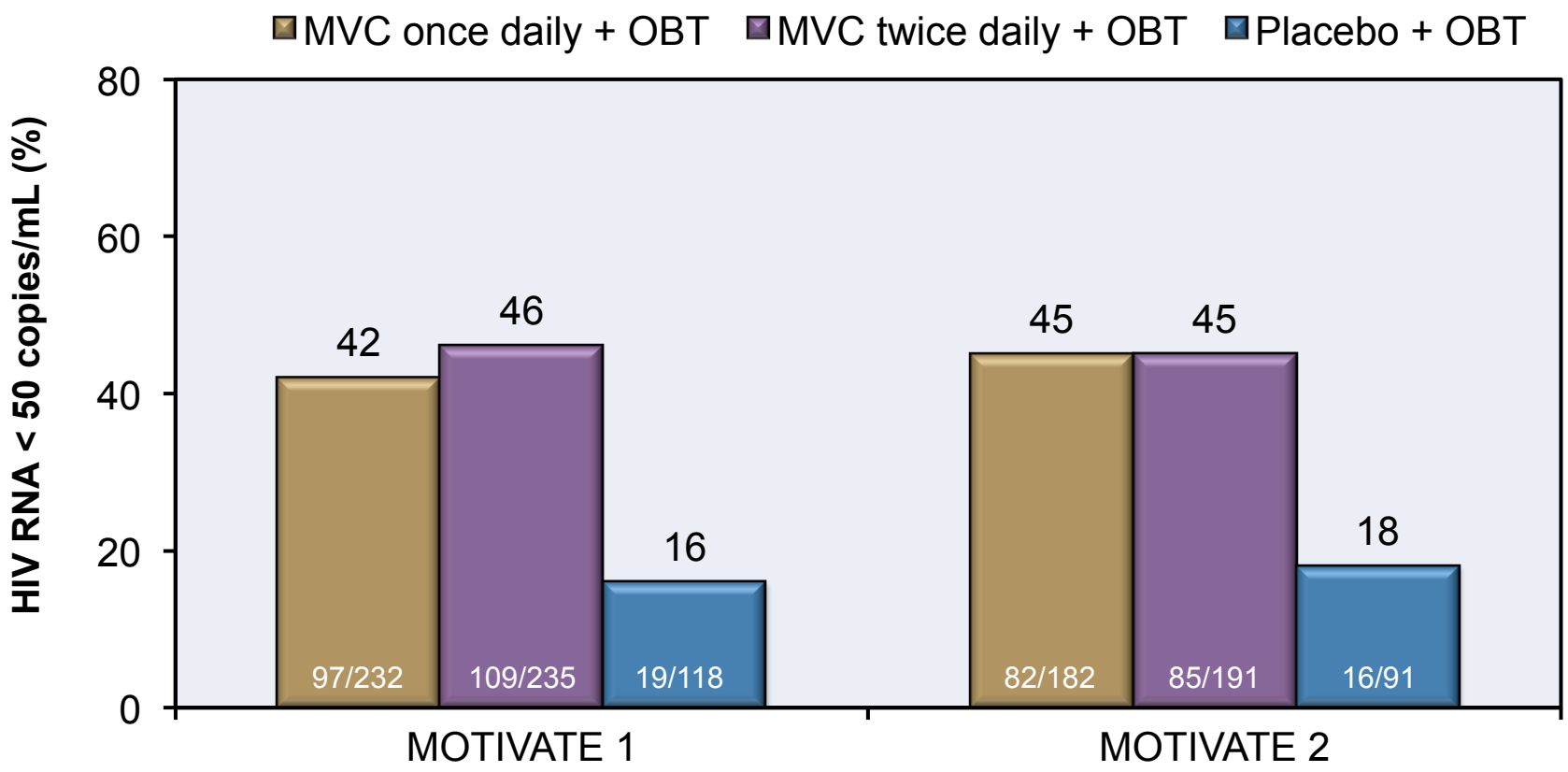
MOTIVATE 1 and 2: Results

Week 48: Virologic Response (ITT, missing=nonresponse)



Source: Gulick RM, et al. N Engl J Med. 2008;359:1429-41.

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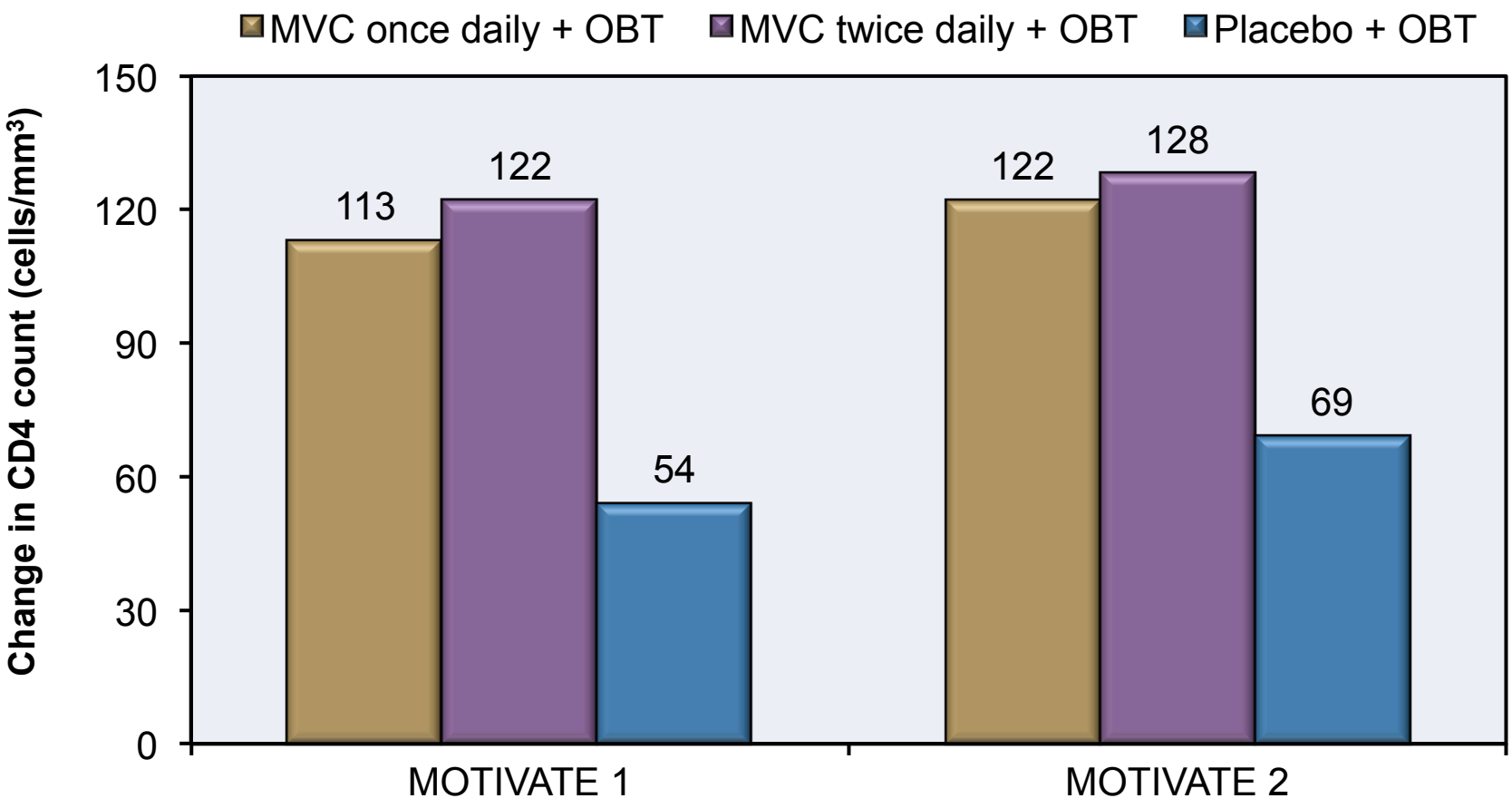
MOTIVATE 1 and 2: Results

Week 48: Change in CD4 Cell Count from Baseline



Source: Gulick RM, et al. N Engl J Med. 2008;359:1429-41.

Maraviroc in Patients with Multiclass Drug Resistance
MOTIVATE 1 and 2: Result

Grade 2-4 Adverse Events (all causes) Occurring in ≥ 5% of Patients
(MOTIVATE 1 and MOTIVATE 2 Study Populations Combined)

	Maraviroc once daily + OBT (n = 414)	Maraviroc twice daily + OBT (n = 426)	Placebo (n = 219)
Diarrhea	43 (10%)	32 (8%)	20 (10%)
Fatigue	13 (3%)	21 (4%)	13 (6%)
Fever	9 (2%)	24 (6%)	9 (4%)
Headache	22 (5%)	9 (2%)	12 (6%)
Nausea	25 (6%)	25 (6%)	15 (7%)
Upper respiratory infection	16 (4%)	20 (5%)	3 (1%)
Death	6 (1%)	9 (2%)	2 (1%)

Source: Gulick RM, et al. N Engl J Med. 2008;359:1429-41.

Maraviroc in Patients with Multiclass Drug Resistance
MOTIVATE 1 and 2: Conclusions

Conclusions: "Maraviroc, as compared with placebo, resulted in significantly greater suppression of HIV-1 and greater increases in CD4 cell counts at 48 weeks in previously treated patients with R5 HIV-1 who were receiving OBT."

Source: Gulick RM, et al. N Engl J Med. 2008;359:1429-41.

Acknowledgment

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National HIV Curriculum

AETC AIDS Education & Training Center Program
National Coordinating Resource Center