Ibalizumab for Antiretroviral Salvage

TMB-301: Study

Ibalizumab Added to OBR for Adults Failing ART
TMB-301: Study Design

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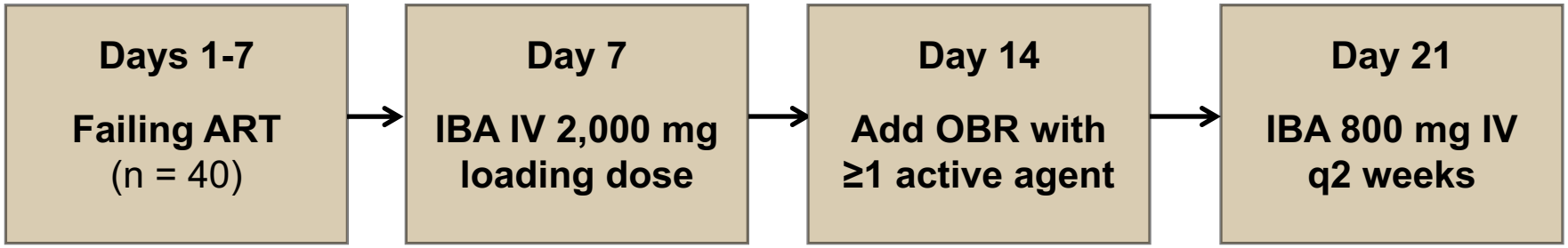
- **Study design:**
  - Single-arm, open label study of ibalizumab (IBA) added to optimized background therapy (OBR) for individuals failing ART
  - Primary endpoint: proportion achieving ≥0.5 $\log_{10}$ decrease in HIV RNA 7 days after initiating IBA therapy (day 14 of study)
  - Secondary endpoints: virologic outcomes, safety, and tolerability at 24 weeks
- **Inclusion Criteria:**
  - Adults with HIV, on ART for ≥6 months, HIV RNA >1,000 copies/mL, and ≥3 class drug resistance (but ≥1 remaining active drug)



Source: Emu B, et al. N Engl J Med. 2018;379:645-54.

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Baseline Characteristics of the 40 Participants in TMB-301	
Characteristic	**N = 40**
Median age (range)—years	53 (23-65)
Male	34 (85%)
Non-white	18 (45%)
Mean duration since HIV diagnosis—years	20±8
Mean CD4 count—cells/mm^3	150±182
Mean HIV RNA—copies/mL)	100,287
Participants with HIV RNA >100,000 copies/mL	7 (18%)

Source: Emu B, et al. N Engl J Med. 2018;379:645-54.

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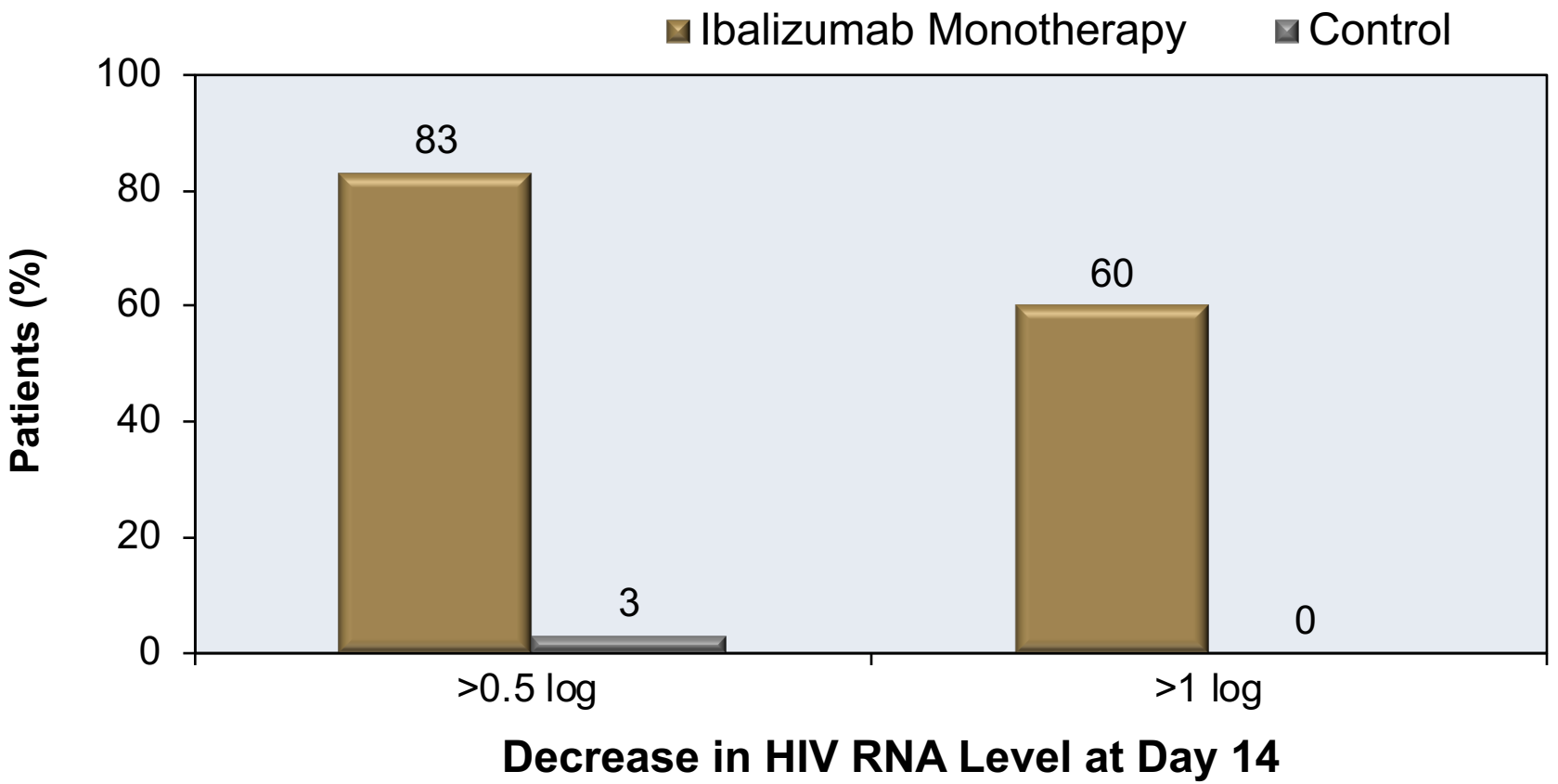
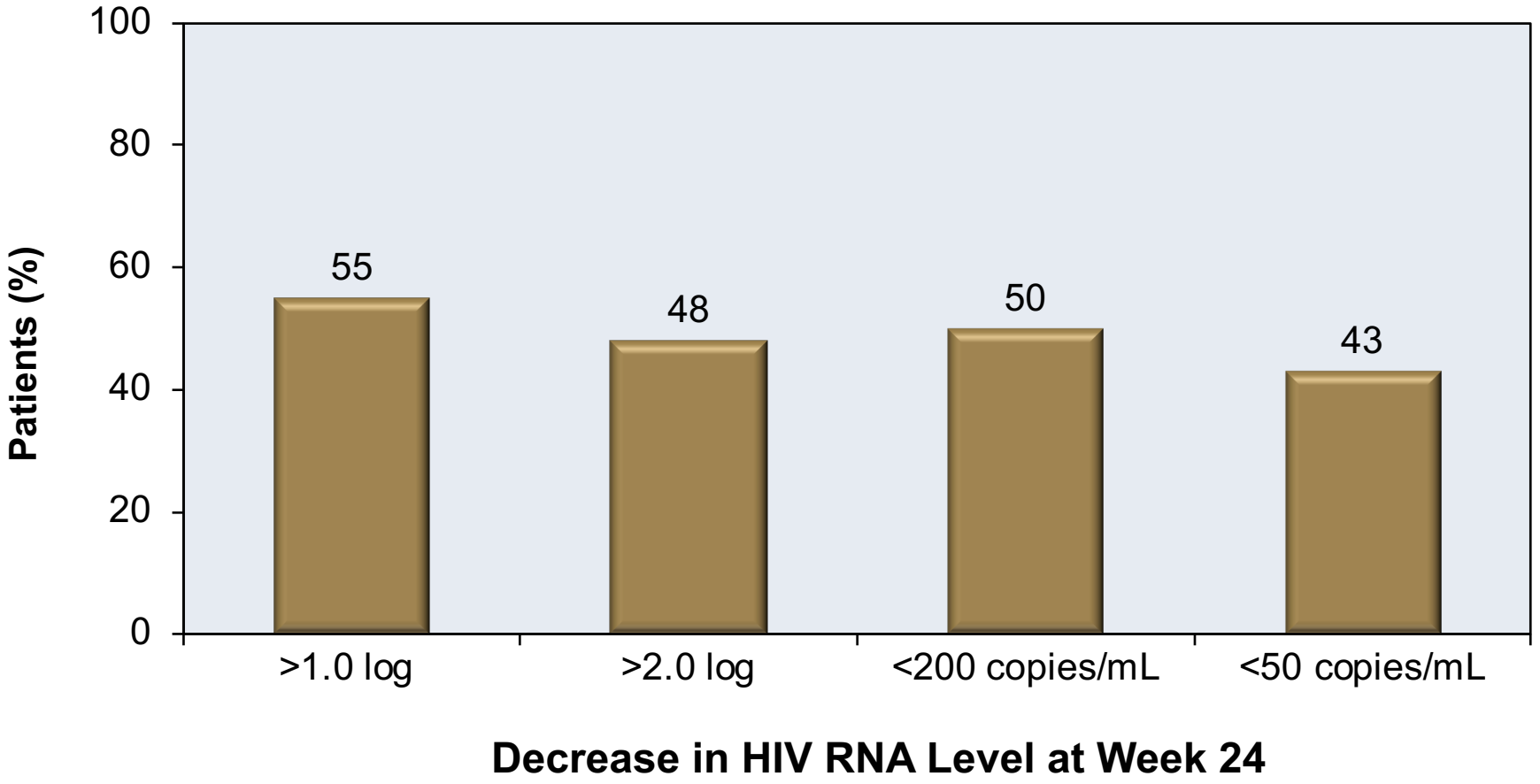
TMB-301: Efficacy at Day 14



IBA Monotherapy = after 7 days of IBA added to failing ART (functional monotherapy)
Control = after 7 days of baseline failing ART

Source: Emu B, et al. N Engl J Med. 2018;379:645-54.

Ibalizumab Added to OBR for Adults Failing ART
TMB-301: Efficacy at Week 24

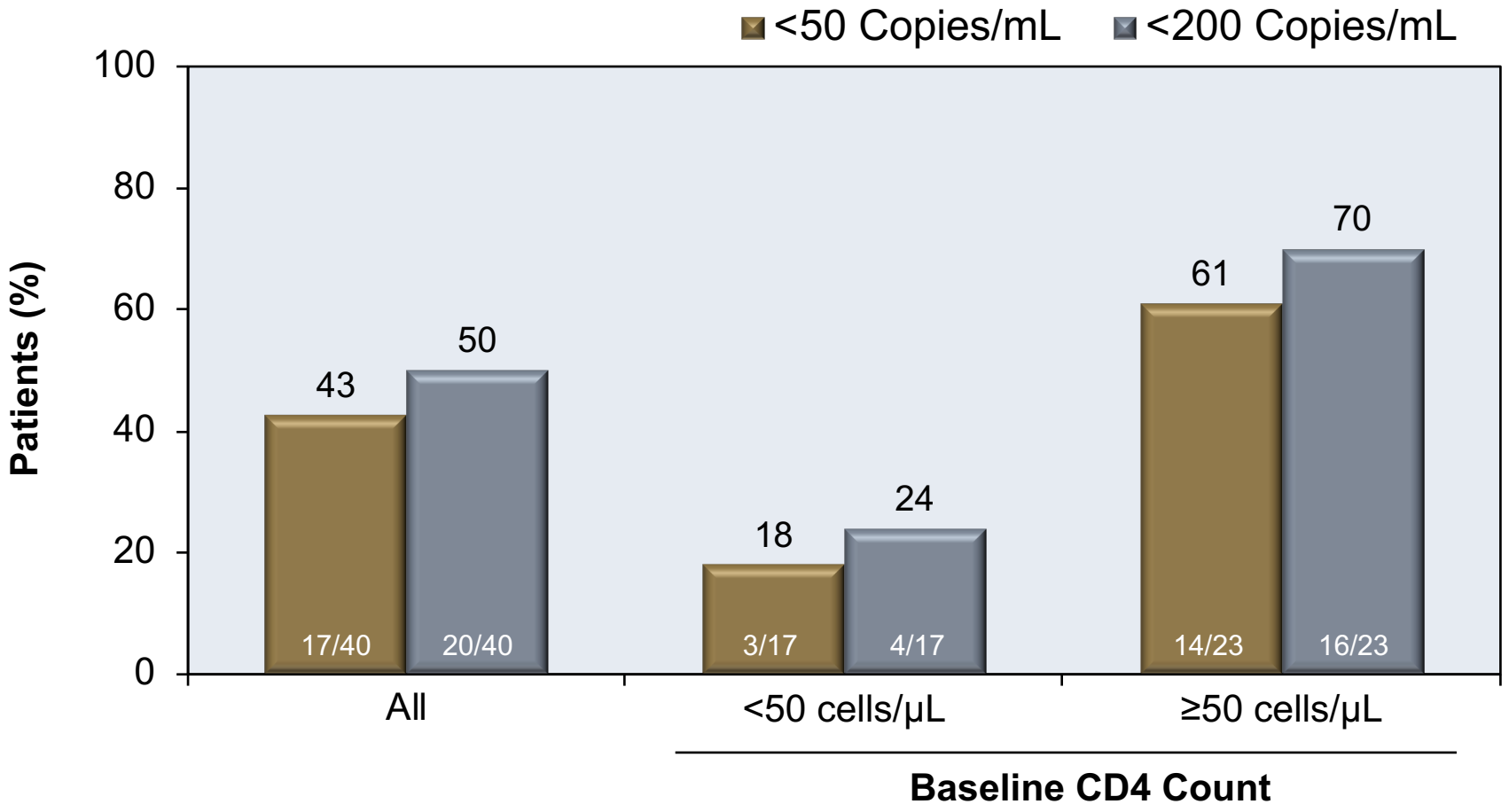


Optimized background regimen (OBR) added at day 14

Source: Emu B, et al. N Engl J Med. 2018;379:645-54.

Ibalizumab Added to OBR for Adults Failing ART
TMB-301: Efficacy at Week 25, by Baseline CD4 Cell Count

Week 25 Virologic Response (Intention-to-Treat Analysis)



Source: Emu B, et al. N Engl J Med. 2018;379:645-54.

Ibalizumab Added to OBR for Adults Failing ART
TMB-301: Efficacy at Week 24

Conclusions: “In patients with multidrug-resistant HIV-1 infection who had advanced disease and limited treatment options, ibalizumab had significant antiviral activity during a 25-week study. Evidence of the emergence of diminished ibalizumab susceptibility was observed in vitro in patients who had virologic failure.”

Source: Emu B, et al. N Engl J Med. 2018;379:645-54.

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