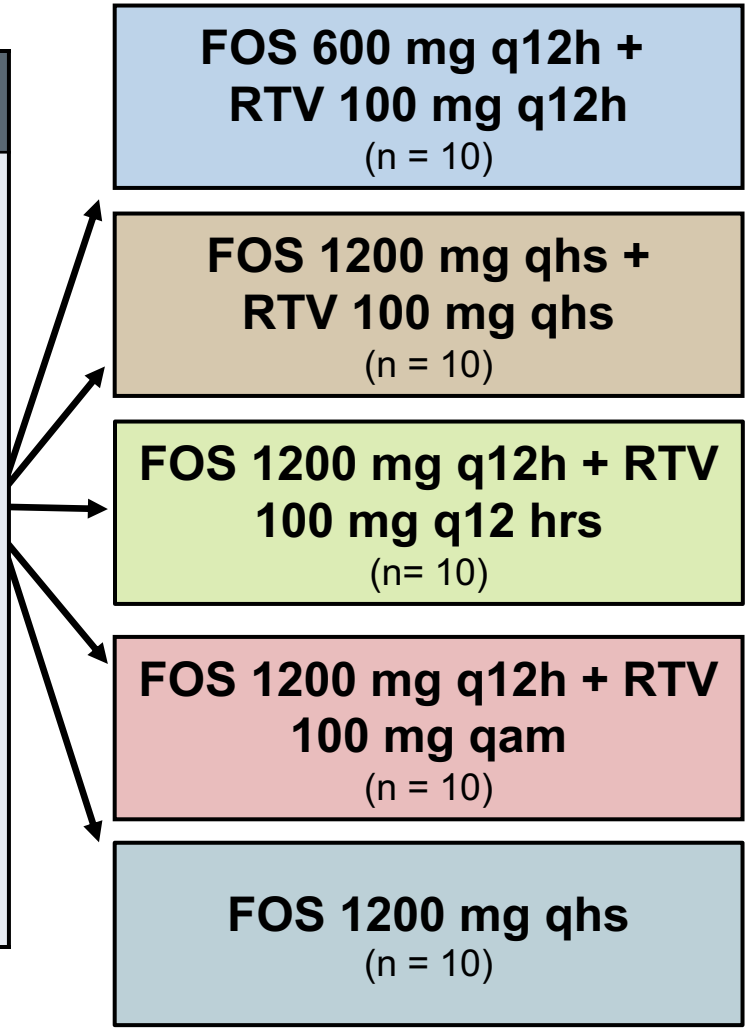
# Fostemsavir (BMS-663068) Dose-Ranging Study

# AI438-006 Study

# Fostemsavir (BMS-663068) Dose-Ranging Study AI438-011: Results

## GS-US-141-1219: Study Design

- **Background**: Randomized, open-label, multiple-dose, parallel phase IIa study
- **Inclusion Criteria (n = 50)**
  - Adults with subtype B HIV-1
  - Treatment-naïve or experienced,
  - If treatment experienced, off ART ≥8 weeks
  - HIV RNA >5,000 copies/mL
  - CD4 count ≥200 cells/$mm^3$
  - Not pregnant; no hepatitis B or C
  - No prior exposure to an HIV attachment inhibitor
- **Treatment Arms**
  - 8 days of fostemsavir (BMS-663068) +/- ritonavir
  - Participants randomized to various dosing arms




Source: Nettles RE, et al. Ray N, et al. J Infect Dis. 2012;206:1002-11.

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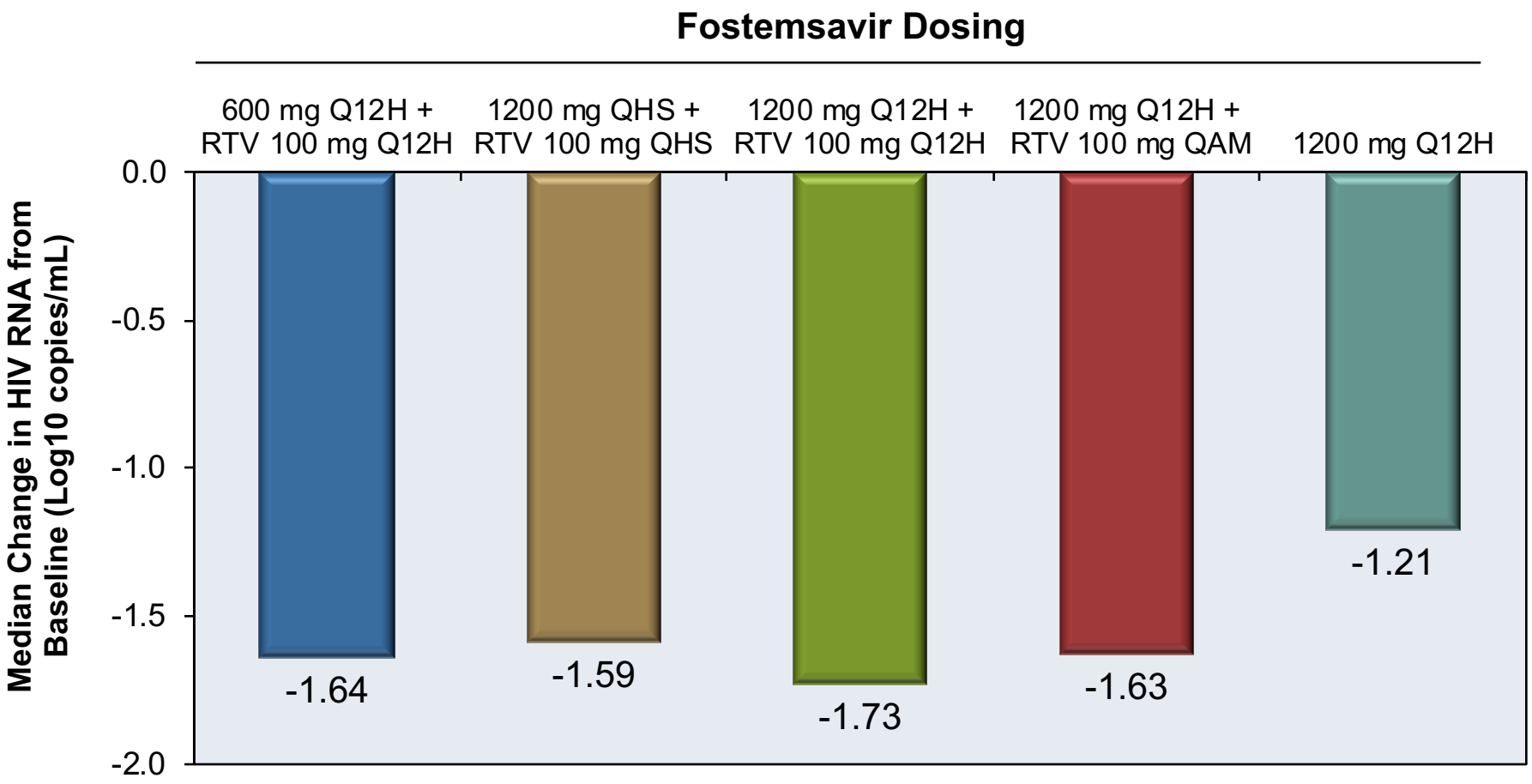
## Baseline to Day 8: Change in Baseline HIV RNA Level




Source: Nettles RE, et al. Ray N, et al. J Infect Dis. 2012;206:1002-11.

# Fostemsavir (BMS-663068) Dose-Ranging Study AI438-011: Conclusions

**Interpretation**: "Administration of BMS-663068 for 8 days with or without ritonavir resulted in substantial declines in plasma HIV-1 RNA levels and was generally well tolerated. Longer-term clinical trials of BMS-663068 as part of combination antiretroviral therapy are warranted."

**Source: Nettles RE, et al. Ray N, et al. J Infect Dis. 2012;206:1002-11.**

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