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/mm³
  - 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

- **Dosing Arms**
  - FOS 600 mg q12h + RTV 100 mg q12h (n = 10)
  - FOS 1200 mg qhs + RTV 100 mg qhs (n = 10)
  - FOS 1200 mg q12h + RTV 100 mg q12 hrs (n = 10)
  - FOS 1200 mg q12h + RTV 100 mg qam (n = 10)
  - FOS 1200 mg qhs (n = 10)

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Baseline to Day 8: Change in Baseline HIV RNA Level

Median Change in HIV RNA from Baseline (Log10 copies/mL)

- 600 mg Q12H + RTV 100 mg Q12H: -1.64
- 1200 mg QHS + RTV 100 mg QHS: -1.59
- 1200 mg Q12H + RTV 100 mg Q12H: -1.73
- 1200 mg Q12H + RTV 100 mg QAM: -1.63
- 1200 mg Q12H: -1.21

**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.”

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