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 Schedules**
  - 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

**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.”

Fostemsavir in Treatment-Experienced Patients

AI438-011 Study
Fostemsavir in Treatment-Experienced Patients AI438-011: Results

Study Design
- Randomized, active controlled
- Phase 2b study
- Location: International
- Treatment Experienced
- HIV RNA ≥ 1,000 copies/ml
- CD4 ≥ 50 cells/mm³
- Susceptible to:
  - Raltegravir
  - Tenofovir
  - Temsavir

Fostemsavir in Treatment-Experienced Patients AI438-011: Results

Proportion with HIV RNA <50 copies/mL at 24 weeks (FDA snapshot analysis)

All regimens given in combination with a backbone of raltegravir + tenofovir DF

Interpretation: “In a comparison with ritonavir-boosted atazanavir, efficacy and safety of BMS-663068 up to the week 24 analysis support continued development of BMS-663068, which is being assessed in a phase 3 trial in heavily treatment-experienced individuals.”
Acknowledgment

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*The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.*