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

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Baseline to Day 8: Change in Baseline HIV RNA Level

<table>
<thead>
<tr>
<th>Fostemsavir Dosing</th>
<th>Median Change in HIV RNA from Baseline (Log10 copies/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>600 mg Q12H + RTV 100 mg Q12H</td>
<td>-1.64</td>
</tr>
<tr>
<td>1200 mg QHS + RTV 100 mg QHS</td>
<td>-1.59</td>
</tr>
<tr>
<td>1200 mg Q12H + RTV 100 mg Q12H</td>
<td>-1.73</td>
</tr>
<tr>
<td>1200 mg Q12H + RTV 100 mg QAM</td>
<td>-1.63</td>
</tr>
<tr>
<td>1200 mg Q12H</td>
<td>-1.21</td>
</tr>
</tbody>
</table>

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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