Fostemsavir in Treatment-Experienced Patients
AI438-011 Study
Fostemsavir in Treatment-Experienced Patients AI438-011: 24 Week Results

Study Design

- Randomized, international, active controlled, phase 2b study comparing different doses of fostemsavir in treatment experienced with ART failure
- HIV RNA ≥1,000 copies/ml
- CD4 ≥50 cells/mm³
- HIV susceptible to:
  - Raltegravir
  - Tenofovir
  - Temsavir

<table>
<thead>
<tr>
<th>Dose</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fostemsavir 400 mg BID + Raltegravir + Tenofovir DF</td>
<td>n = 50</td>
</tr>
<tr>
<td>Fostemsavir 800 mg BID + Raltegravir + Tenofovir DF</td>
<td>n = 49</td>
</tr>
<tr>
<td>Fostemsavir 600 mg QD + Raltegravir + Tenofovir DF</td>
<td>n = 51</td>
</tr>
<tr>
<td>Fostemsavir 1200 mg QD + Raltegravir + Tenofovir DF</td>
<td>n = 51</td>
</tr>
<tr>
<td>Atazanavir + RTV 300/100 mg qd + Raltegravir + Tenofovir DF</td>
<td>n = 51</td>
</tr>
</tbody>
</table>

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AI438-011: 24 Week 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.”

Fostemsavir in Treatment-Experienced Patients

AI438-011 Study: Week 48 Results
Fostemsavir in Treatment-Experienced Patients AI438-011: 48 Week Results

Proportion with HIV RNA <50 copies/mL at 48 weeks (FDA snapshot analysis)

Interpretation: “Through week 48, fostemsavir continued to be well tolerated and showed similar efficacy to ATV/r. These results support the ongoing Phase III trial in heavily treatment-experienced adults with limited therapeutic options (≤2 classes of active antiretrovirals remaining).”

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