Dolutegravir in Patients with Integrase-Resistant HIV

VIKING-3
Dolutegravir in Patients with Integrase Inhibitor Resistance

VIKING-3: Study Design

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 7</th>
<th>Week 24</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Functional Monotherapy Phase</strong></td>
<td><strong>Continuation Phase</strong></td>
<td></td>
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<tr>
<td><strong>Dolutegravir: 50 mg BID</strong></td>
<td><strong>Dolutegravir: 50 mg BID + OBR</strong></td>
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**Study Design: VIKING-3**

- **Background**: Single arm, open-label, phase 3 trial to determine the efficacy of twice daily dolutegravir in patients with integrase resistance

- **Inclusion Criteria (n=183)**
  - Age ≥ 18
  - Antiretroviral experienced, resistance to raltegravir and/or elvitegravir
  - Resistance to 2 classes of ARVs (in addition to integrase resistance)
  - HIV RNA ≥ 500 copies/mL
  - At least one fully active drug for optimized background regimen
  - Dolutegravir naïve

- **Treatment arm**: Dolutegravir 50 mg twice daily, with OBR added on day 7

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VIKING-3: Results

24 Week Virologic Response, by Baseline HIV RNA Level

<table>
<thead>
<tr>
<th>Baseline HIV RNA Level (copies/mL)</th>
<th>0-50 copies/mL (%)</th>
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<tbody>
<tr>
<td>Overall</td>
<td>69/183</td>
</tr>
<tr>
<td>≤10,000</td>
<td>86/70</td>
</tr>
<tr>
<td>&gt;10,000 to ≤100,000</td>
<td>72/72</td>
</tr>
<tr>
<td>&gt;100,000</td>
<td>39/41</td>
</tr>
</tbody>
</table>

Dolutegravir in Patients with Integrase Inhibitor Resistance

VIKING-3: Results

24 Week Virologic Response, by Baseline Genotype


*Included primary INI-resistance mutations N155H, Y143C/H/R, T66A or E92Q or only historical evidence of resistance

^Secondary mutations from G140A/C/S, E138A/K/T or L74I.
24 Week Virologic Response, by Baseline Phenotype

Conclusions: “Dolutegravir 50 mg BID-based therapy was effective in this highly treatment-experienced population with integrase inhibitor-resistant virus.”

Acknowledgment

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