Dolutegravir in Patients with Integrase-Resistant HIV

VIKING-3
Dolutegravir in Patients with Integrase Inhibitor Resistance

VIKING-3: Study Design

**Day 1**

- Functional Monotherapy Phase
  - **Dolutegravir: 50 mg BID**

**Day 7**

- Continuation Phase
  - **Dolutegravir: 50 mg BID + OBR**

**Week 24**

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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

Dolutegravir in Patients with Integrase Inhibitor Resistance

VIKING-3: Results

24 Week Virologic Response, by Baseline HIV RNA Level

<table>
<thead>
<tr>
<th>Baseline HIV RNA Level (copies/mL)</th>
<th>126/183</th>
<th>60/70</th>
<th>52/72</th>
<th>16/41</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>69</td>
<td>86</td>
<td>72</td>
<td>39</td>
</tr>
</tbody>
</table>

Dolutegravir in Patients with Integrase Inhibitor Resistance

VIKING-3: Results

24 Week Virologic Response, by Baseline Genotype

<table>
<thead>
<tr>
<th>Baseline Genotype</th>
<th>HIV RNA &lt;50 copies/mL (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>69</td>
</tr>
<tr>
<td>No Q148 Mutation*</td>
<td>79</td>
</tr>
<tr>
<td>Q148 + 1 Mutation^</td>
<td>58</td>
</tr>
<tr>
<td>Q148 + ≥2 Mutations^</td>
<td>24</td>
</tr>
</tbody>
</table>

*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.

Dolutegravir in Patients with Integrase Inhibitor Resistance

VIKING-3: Results

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.”
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