Etravirine in Treatment-Experienced Patients

Study TMC125-C223
Etravirine (formerly TMC125) in Patients with Highly Resistant HIV
Study TMC125-C223: Study Design

Study Design: TMC125-C223

• **Background**: Randomized, controlled, partially-blind, phase 2b trial evaluating the safety and efficacy of phase 2b formulation of etravirine combined with optimized background therapy (OBT) compared with a standard-of-care regimen.

• **Inclusion Criteria** (n = 199)
  - Adults with HIV
  - HIV RNA >1,000 copies/mL
  - ≥3 NNRTI resistance mutations

• **Treatment Arms**
  - OBT + *Etravirine 400 mg bid
  - OBT + *Etravirine 800 mg bid
  - OBT + *Control (included at least 3 ARVs: NRTIs, PIs, and/or Enfuvirtide)

*Old formulation of etravirine 800 mg equivalent to 200 mg of FDA-approved formulation of etravirine

Etravirine (formerly TMC125) in Patients with Highly Resistant HIV Study TMC125-C223: Results

Week 48: Change in HIV RNA Level

Etravirine (formerly TMC125) in Patients with Highly Resistant HIV
Study TMC125-C223: Results

Week 48: Change in HIV RNA, by Baseline Etravirine Mutations

Number of Baseline Etravirine Resistance-Associated Mutations

<table>
<thead>
<tr>
<th>Number of Mutations</th>
<th>Etravirine 400 mg bid</th>
<th>Etravirine 800 mg bid</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>-1.32</td>
<td>-1.39</td>
</tr>
<tr>
<td>1</td>
<td>-0.56</td>
<td>-0.87</td>
</tr>
<tr>
<td>2</td>
<td>-0.62</td>
<td>-0.84</td>
</tr>
<tr>
<td>≥3</td>
<td>-0.25</td>
<td>-0.03</td>
</tr>
</tbody>
</table>

Mean Change in HIV RNA from Baseline (Log10 copies/mL)

Etravirine (formerly TMC125) in Patients with Highly Resistant HIV
Study TMC125-C223: Results

Week 48: Virologic Response (Intent-to-Treat Analysis)

Conclusion: “Etravirine demonstrated higher efficacy than control, irrespective of the number of detectable nonnucleoside reverse transcriptase inhibitor resistance-associated mutations.”
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