Etravirine in Treatment Experienced
DUET-2 (TMC125-C216)
Study Design: DUET-2

- **Background**: Randomized, controlled, double-blind, placebo-controlled phase 3 trial evaluating the long-term efficacy, tolerability, and safety of etravirine in treatment-experienced adults with HIV.

- **Inclusion Criteria (n = 591)**
  - Age ≥18 years
  - On stable ARV regimen for ≥8 weeks
  - HIV RNA >5000 copies/mL
  - ≥3 primary PI mutations
  - ≥1 NNRTI resistance-associated mutation

- **Treatment Arms**
  - Etravirine 200 mg BID + OBT*
  - Placebo + OBT*

*OBT = NRTIs, Darunavir/r, +/- Enfuvirtide

Etravirine in Treatment Experienced
DUET-2: Results

Week 24: Virologic Response (ITT-TLOVR*)

![Bar chart showing virologic response at Week 24]

*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response.

Etravirine in Treatment Experienced DUET-2: Results

Week 24: Virologic Response (ITT-TLOVR*)

HIV RNA <50 copies/mL (%)

<table>
<thead>
<tr>
<th>Number of Active Background Antiretrovirals</th>
<th>Etravirine + OBT</th>
<th>Placebo + OBT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>44</td>
<td>7</td>
</tr>
<tr>
<td>1</td>
<td>58/94</td>
<td>62</td>
</tr>
<tr>
<td>2</td>
<td>67/82</td>
<td>70</td>
</tr>
<tr>
<td>≥3</td>
<td>39/49</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>37/51</td>
<td>73</td>
</tr>
</tbody>
</table>

*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response.

Etravirine in Treatment Experienced DUET-2: Results

Week 24: Virologic Response (ITT-TLOVR*) in Patients Re-using or Not Using Enfuvirtide

![Graph showing HIV RNA levels and number of NNRTI resistance associated mutations](image)

*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response.

Interpretation: “In treatment-experienced patients, treatment with TMC125 (etravirine) led to better virological suppression at week 24 than did placebo. The safety and tolerability profile of TMC125 (etravirine) was generally comparable with placebo.”
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