Etravirine in Treatment Experienced

DUET-1 (TMC125-C206)
Etravirine in Treatment Experienced
DUET-1: Study Design

Study Design: DUET-1

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

- **Inclusion Criteria (n = 612)**
  - Age ≥18
  - 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-1: Results

Week 24: Virologic Response (ITT-TLOVR*)

Week 24: Virologic Response (ITT-TLOVR*)

![Chart showing virologic response results for Etravirine + OBT and Placebo + OBT at Week 24. The chart displays the percentage of patients with HIV RNA <400 copies/mL and HIV RNA <50 copies/mL.]

- Etravirine + OBT: 74/225 (32.9%) for HIV RNA <400 copies/mL and 56/170 (32.9%) for HIV RNA <50 copies/mL.
- Placebo + OBT: 51/157 (32.3%) for HIV RNA <400 copies/mL and 39/119 (32.8%) for HIV RNA <50 copies/mL.

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

Etravirine in Treatment Experienced DUET-2: Results

Week 24: Virologic Response (ITT-TLOVR*)

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

Week 24: Virologic Response (ITT-TLOVR*)

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

Etravirine in Treatment Experienced DUET-1: Results

Week 24: Virologic Response (ITT-TLOVR*)

HIV RNA <50 copies/mL (%)

<table>
<thead>
<tr>
<th>Number of Baseline NNRTI Resistance-Associated Mutations</th>
<th>Etravirine + OBT</th>
<th>Placebo + OBT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>47</td>
<td>42</td>
</tr>
<tr>
<td>1</td>
<td>45</td>
<td>45</td>
</tr>
<tr>
<td>2</td>
<td>64</td>
<td>38</td>
</tr>
<tr>
<td>3</td>
<td>47</td>
<td>34</td>
</tr>
<tr>
<td>≥4</td>
<td>44</td>
<td>21</td>
</tr>
</tbody>
</table>

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

Etravirine in Treatment Experienced

DUET-1 and DUET-2 (Pooled Analysis)
Etravirine in Treatment Experienced
DUET-1 and DUET-2 Pooled Analysis: Study Design

Study Design: DUET-1 and DUET-2

• **Background**: Pooled analysis of 2 randomized, controlled, double-blind, placebo-controlled phase 3 trial evaluating the long-term efficacy, tolerability, and safety of etravirine in treatment-experienced patients with HIV infection

• **Inclusion Criteria (n = 1203)**
  - Age ≥18
  - On stable ARV regimen for ≥8 weeks
  - HIV RNA >5000 copies/mL
  - ≥3 primary PI mutations and ≥1NNRTI resistance-associated mutation

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

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

Etravirine in Treatment Experienced DUET-1 and DUET-2 Pooled Analysis: Results

Week 48: Virologic Response (ITT-TLOVR*)


*ITT-TLOVR = Intention to Treat-Time to Loss of Virologic Response.
Etravirine in Treatment Experienced DUET-1 and DUET-2 Pooled Analysis: Results

Week 48: Virologic Response (ITT-TLOVR*), by Number of Active ARVs

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

Etravirine in Treatment Experienced DUET-1 and DUET-2: Pooled Analysis

Week 48: Virologic Response in Etravirine Group, by Weighted Genotypic Score

**Conclusion**: “At 48 weeks, treatment-experienced patients receiving etravirine plus background regimen had statistically superior and durable virologic responses (viral load less than 50 copies/ml) than those receiving placebo plus background regimen, with comparable tolerability and no new safety signals reported since week 24.”
Acknowledgment

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*The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.*