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

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 patients with HIV infection

• **Inclusion Criteria (n = 591)**
  - 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-2: Results

Week 24: Virologic Response (ITT-TLOVR*)

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

Etravirine in Treatment Experienced DUET-2: Results

Week 24: Virologic Response (ITT-TLOVR*)

![Bar chart showing viremia at Week 24 for Etravirine + OBT and Placebo + OBT stratified by number of active background antiretrovirals.]

<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>19/43</td>
<td>3/45</td>
</tr>
<tr>
<td>1</td>
<td>58/94</td>
<td>62</td>
</tr>
<tr>
<td>2</td>
<td>40116</td>
<td>45/64</td>
</tr>
<tr>
<td>≥3</td>
<td>82/82</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>82/116</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

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

Etravirine in Treatment Experenced
DUET-2: Conclusions

**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.”

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

<table>
<thead>
<tr>
<th>Study Design: DUET-1 and DUET-2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Background:</strong> 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</td>
</tr>
<tr>
<td><strong>Inclusion Criteria (n = 1203)</strong></td>
</tr>
<tr>
<td>- Age ≥18</td>
</tr>
<tr>
<td>- On stable ARV regimen for ≥8 weeks</td>
</tr>
<tr>
<td>- HIV RNA &gt;5000 copies/mL</td>
</tr>
<tr>
<td>- ≥3 primary PI mutations and ≥1 NNRTI resistance-associated mutation</td>
</tr>
<tr>
<td><strong>Treatment Arms</strong></td>
</tr>
<tr>
<td>- Etravirine 200 mg BID + OBT*</td>
</tr>
<tr>
<td>- Placebo + OBT*</td>
</tr>
</tbody>
</table>

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

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

Week 48: Virologic Response (ITT-TLOVR*)

![Graph showing virologic response at Week 48.]

- **Etravirine + OBT**: 61/365 = 16.86%
- **Placebo + OBT**: 40/242 = 16.52%

*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.”

The National HIV Curriculum is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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.