Durability of virologic response to etravirine is not affected by time to reach virologic response

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Introduction

Etravirine (ETR; TMC125), a next-generation NNRTI provided durable and statistically superior efficacy versus placebo over 48 weeks in treatment-experienced patients in the DUET trials. This pooled DUET analysis investigates whether time to reach virologic response impacts durability of response.

Methods

The primary endpoint was the percentage of patients with viral load <50 copies/mL (time-to-loss of virologic response [TLOVR] analysis). The intent-to-treat (ITT) population included all patients; the as-treated population excluded patients who discontinued for non-virologic reasons.

Results

Five hundred and ninety-nine and 604 patients received ETR and placebo, respectively. Baseline characteristics were comparable between treatment groups with regards to median baseline viral load (4.8 log10, copies/mL), CD4 count (99 vs 109 cells/mm3), overall enfuvirtide (ENF) use (45.4% vs 46.7%), darunavir (DRV) and NRTI sensitivity, and median number of sensitive antiretrovirals (ARVs) at baseline. At Weeks 12, 24 and 48, virologic response (viral load <50 copies/mL) in ETR-treated patients was 47%, 61% and 61%, respectively. The number of responders at Week 48 on the first timepoint on which virologic response was seen is presented below.

Baseline demographics and background ARVs

<table>
<thead>
<tr>
<th>Parameter</th>
<th>ETR (n=599)</th>
<th>Placebo (n=604)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>50% Male</td>
<td>50% Male</td>
</tr>
<tr>
<td>Race</td>
<td>48% White</td>
<td>48% White</td>
</tr>
<tr>
<td>Region</td>
<td>47% Europe</td>
<td>48% Europe</td>
</tr>
<tr>
<td>First virologic response (by time to first virologic response)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First virologic response</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>First virologic response &gt; 12 weeks</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>First virologic response &gt; 24 weeks</td>
<td>50%</td>
<td>50%</td>
</tr>
</tbody>
</table>

Conclusion

Durable, high virologic response rates were observed up to Week 48 in ETR-treated patients. Virologic response at Week 12 does not fully predict response at Week 48; full suppression of HIV RNA by Week 48 can occur in patients who have not yet suppressed viral load at Week 12.

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DUET-1


DUET-2


References