Background: EFV is a 1st in class integrase strand-transfer inhibitor. Metabolic abnormalities have been reported with most antiretroviral therapies, and reports, which were compared between EFV-based and RAL-based regimens over 48 weeks of treatment.

Methods: The present manuscript is a double-blind study of EFV, 600 mg qHS, and RAL 400 mg b.i.d., with TDF/ FTC (440/100 mg). Groups were compared for metabolic parameters, including fasting lipid and glucose abnormalities according to Daids criteria (Any Grade ≥110 mg/dL for cholesterol, HDL-cholesterol, and triglyceride concentrations were assessed).

Overall Efficacy and Safety Results

1. RAL provided potent and statistically non-inferior viral suppression compared to EFV.
2. Key inclusion criteria:
   - Viral susceptibility to EFV, TDF, and FTC
   - HIV RNA level >5000 copies/mL

Results: 26/281 on RAL and 42/282 on EFV had fasting serum glc of any grade (p<0.001). Investigator-reported lipodystrophy was considered possibly related to study therapy.

Conclusions: Investigator-reported lipodystrophy were common in EFV but not in RAL. Relatively low prevalence of investigator-reported lipodystrophy was considered possibly related to study therapy.

Mean Change from Baseline in Metabolic Parameters

- Overall efficacy and safety results
- Mean % change from baseline are based on the measurements of the pts who were measured at baseline and the time point be followed at Wk 48
- Investigator-reported lipodystrophy were common in EFV but not in RAL. Relatively low prevalence of investigator-reported lipodystrophy was considered possibly related to study therapy.

Investigator-reported Lipodystrophy

- Investigator-reported lipodystrophy were common in EFV but not in RAL. Relatively low prevalence of investigator-reported lipodystrophy was considered possibly related to study therapy.
- There were no patients in the EFV treatment group that reported clinical adverse events (mild to moderate)

**Table:**

<table>
<thead>
<tr>
<th>Stratum</th>
<th>n (%)</th>
<th>Mean % Change from Baseline</th>
<th>95% CI</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Clade B</td>
<td>35</td>
<td>-5.0 (4 to 6)</td>
<td>-15 to -0.1</td>
<td>0.046</td>
</tr>
<tr>
<td>European/Africa</td>
<td>33 (61.1)</td>
<td>-30 (5 to 55)</td>
<td>-50 to -10</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Multiracial</td>
<td>27 (57.4)</td>
<td>-21 (10, 32)</td>
<td>-30 to -11</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Native American</td>
<td>1 (2)</td>
<td>-40 (26 to 54)</td>
<td>-50 to -26</td>
<td>0.001</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (0.3)</td>
<td>-10 (100 to 110)</td>
<td>-100 to 0</td>
<td>0.125</td>
</tr>
<tr>
<td>Female</td>
<td>123 (44)</td>
<td>-16 (6, 26)</td>
<td>-24 to -8</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Figure:**

- Parameters at Week 48
- Overall efficacy and safety results
- Mean % change from baseline are based on the measurements of the pts who were measured at baseline and the time point be followed at Wk 48
- Investigator-reported lipodystrophy were common in EFV but not in RAL. Relatively low prevalence of investigator-reported lipodystrophy was considered possibly related to study therapy.

**Conclusion:**

- Investigator-reported lipodystrophy were common in EFV but not in RAL. Relatively low prevalence of investigator-reported lipodystrophy was considered possibly related to study therapy.
- There were no patients in the EFV treatment group that reported clinical adverse events (mild to moderate)