**Pitavastatin 4 mg Superior to Pravastatin 40 mg on LDL-C Reduction after 12 and 52 Weeks of Treatment in Patients with HIV Infection and Dyslipidemia with and without Ritonavir-based Therapy**

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**Aim:**
- To determine whether ritonavir use affects the reduction in LDL-C.

**Methods**
- **Statistical Analysis:**
  - Analyses were conducted using the modified intention-to-treat (mITT) population, defined as all randomized subjects who remained on the same dose of study drug at least at the first effectiveness assessment.
  - Confidence intervals (CIs) were calculated for the differences in least-squares (LS) means between treatment groups using analysis of variance models adjusted for site, co-infection, and baseline hepatitis status.
  - Differences in TEAE rates were calculated using Cochran-Mantel-Haenszel analysis.

**Results**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>LDL-C Reduction (Adjusted for Site, Hepatitis B/C, and Ritonavir Use)</th>
<th>Difference in LS Mean % Change</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pitavastatin</td>
<td>4 mg</td>
<td>9.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pravastatin</td>
<td>40 mg</td>
<td>19.3</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Conclusions**

- In the overall study population:
  - Pitavastatin 4 mg demonstrated a superior reduction in LDL-C compared with pravastatin 40 mg in HIV-infected adults with dyslipidemia at Week 12.
  - The reductions in LDL-C at Week 12 and Week 52 were significantly greater for pitavastatin 4 mg vs. pravastatin 40 mg.
  - Ritonavir did not change the primary result of the study, i.e., pitavastatin reduced LDL-C significantly more after pravastatin 40 mg than with or without ritonavir (ANOVA, P < 0.001).
  - Use of ritonavir does not affect the lipoprotein-lowering effect of pitavastatin or pravastatin.

**Table 1: Baseline Demographics/Characteristics (All Randomized Subjects)**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Baseline</th>
<th>12 Weeks</th>
<th>52 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pitavastatin</td>
<td>4 mg</td>
<td>9.8</td>
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<td>Pravastatin</td>
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</tbody>
</table>

**Table 2: LDL-C Measurements (mITT Population)**

- **Primary Endpoint:**
  - Superiority of pitavastatin 4 mg vs. pravastatin 40 mg based on an adjusted mean % change in fasting serum LDL-C from Baseline to Week 12.

**Figure 1:** Primary Study Results: LDL-C: Mean Percent Change from Baseline to Week 12 and Week 52

- **Figure 2:** Week 12: Mean Percent Change from Baseline in LDL-C
- **Figure 3:** Week 52: Pitavastatin vs. Pravastatin in LDL-C Reduction (Adjusted for Site, Hepatitis C/B, and Ritonavir Use)

**Figure 4:** Week 52: Pitavastatin vs. Pravastatin in LDL-C Reduction (Adjusted for Site, Hepatitis B/C, and Ritonavir Use)

**Figure 5:** Changes in LDL-C from Baseline to Week 52 in LDL-C:

- **Figure 6:** Week 52: Mean Percent Change from Baseline in LDL-C

**Table 3: Selected Safety Parameters (52-week data)**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number of Subjects (%)</th>
<th>Total Discontinuations due to TEAEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pitavastatin</td>
<td>4 mg</td>
<td>0</td>
</tr>
<tr>
<td>Pravastatin</td>
<td>40 mg</td>
<td>0</td>
</tr>
</tbody>
</table>

**Table 1:**
- **Race, n (%):**
  - White: 96 (76.2)
  - African-American: 92 (73.0)
  - Other: 14 (11.1)

**Table 2:**
- **Endpoints:**
  - **Primary:** Superiority of pitavastatin 4 mg vs. pravastatin 40 mg based on an adjusted mean % change in fasting serum LDL-C from Baseline to Week 12.
  - **Exploratory:**
    - The effect of pitavastatin 4 mg and pravastatin 40 mg on LDL-C according to concurrent ritonavir use (either ongoing or with a start or end date after the first dose of study drug).

**Figure 3:** Week 12: Pitavastatin vs. Pravastatin in LDL-C Reduction (Adjusted for Site, Hepatitis C/B, and Ritonavir Use)

**Figure 4:** Week 52: Pitavastatin vs. Pravastatin in LDL-C Reduction (Adjusted for Site, Hepatitis B/C, and Ritonavir Use)

**Figure 5:** Changes in LDL-C from Baseline to Week 52 in LDL-C:

- **Week 12:**
  - Pitavastatin: 9.8
  - Pravastatin: 19.3
- **Week 52:**
  - Pitavastatin: 9.8
  - Pravastatin: 19.3