Once-Daily versus Twice-Daily Lopinavir-ritonavir
M02-418 Trial
Once-daily versus twice-daily Lopinavir/r in Treatment-Naïve M02-418: Study Design

**Study Design: M02-418**

- **Background**: Randomized, open-label, phase 3 study to evaluate the efficacy, pharmacokinetics, and tolerability of once-daily versus twice-daily lopinavir and ritonavir in combination with tenofovir and emtricitabine in treatment-naïve patients with HIV infection.

- **Inclusion Criteria** (n = 190)
  - Age ≥18
  - Antiretroviral-naïve
  - HIV RNA ≥1000 copies/mL
  - No CD4 criteria

- **Treatment Arms**
  - Lopinavir-ritonavir 800/200 mg QD + TDF + FTC (n=115)
  - Lopinavir-ritonavir 400/100 mg BID + TDF + FTC (n = 75)

Once-daily versus twice-daily Lopinavir/r in Treatment-Naïve M02-418: Results

Week 48: Virologic Response (ITT, Noncompleter=Failure)

Once-daily versus twice-daily Lopinavir/r in Treatment-Naïve

M02-418: Results

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>LPV/r 800/200mg QD  (n= 115)</th>
<th>LPV/r 400/100mg BID (n=75)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>16%</td>
<td>5%</td>
</tr>
<tr>
<td>Nausea</td>
<td>9%</td>
<td>8%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>AST &gt;5x ULN</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>ALT &gt;5x ULN</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Triglycerides (&gt;750 mg/dL or 8.47 mmol/L)</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Amylase &gt; 2x ULN</td>
<td>7%</td>
<td>5%</td>
</tr>
</tbody>
</table>

Conclusions: “Through 48 weeks, a once-daily regimen of lopinavir/ritonavir + TDF + FTC appears to have similar virologic and immunologic responses in antiretroviral-naive subjects as the same regimen with lopinavir/ritonavir administered twice daily. Both regimens were relatively well tolerated, and no LPV or TDF resistance was observed.”

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