LPV-RTV + 3TC vs. LPV-RTV + 2 NRTIs in Virologically Suppressed OLE Trial
## Study Design: OLE

### Background
Randomized, open-label, non-inferiority, phase 3 trial to compare the dual treatment (lopinavir-ritonavir plus lamivudine) with triple treatment (lopinavir-ritonavir plus two NRTIs) in treatment-experienced persons with suppressed HIV RNA levels.

### Inclusion Criteria (n = 250)
- Age $\geq 18$
- Taking LPV-RTV + (3TC or FTC) + 2nd NRTI for $\geq 2$ months
- HIV RNA $< 50$ copies/mL for $\geq 6$ months
- No genotypic resistance (or history of failure) to LPV, ritonavir, 3TC, or FTC

### Treatment Arms
- **Dual treatment**
  - Lopinavir-ritonavir 400-100 mg BID + 3TC
  - (n = 123)

- **Triple treatment**
  - Lopinavir-ritonavir 400-100 mg BID + 2NRTIs
  - (n = 127)

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LPV-RTV + 3TC versus LPV-RTV + 2 NRTIs in Virologically Suppressed OLE: Results

Week 48: Virologic Response (ITT)

LPV-RTV + 3TC versus LPV-RTV + 2 NRTIs in Virologically Suppressed OLE: Results

Week 48: Responders and Non-responders in ITT Population

<table>
<thead>
<tr>
<th>Summary of Adverse Events</th>
<th>LPV-RTV + 3TC (n = 118)</th>
<th>LPV-RTV + 2 NRTIs (n = 121)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any adverse event</td>
<td>53%</td>
<td>58%</td>
</tr>
<tr>
<td>Grade 3 or 4 adverse event</td>
<td>7%</td>
<td>6%</td>
</tr>
<tr>
<td>Serious adverse event</td>
<td>4%</td>
<td>7%</td>
</tr>
<tr>
<td>Discontinuation due to adverse event</td>
<td>1%</td>
<td>3%</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Interpretation: “Dual treatment with lopinavir-ritonavir plus lamivudine has non-inferior therapeutic efficacy and is similarly tolerated to triple treatment.”
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