Lopinavir-RTV + Lamivudine vs. Lopinavir-RTV + 2NRTIs
GARDEL Trial
Lopinavir-RTV + Lamivudine versus Lopinavir-RTV + 2NRTIs

GARDEL: Study Design

**Study Design: GARDEL**

- **Background**: Randomized, phase 3, open-label, non-inferiority trial comparing the efficacy of dual therapy with lopinavir-ritonavir plus lamivudine versus standard lopinavir-ritonavir plus 2NRTIs in treatment-naïve patients with HIV infection.

- **Inclusion Criteria (n = 426)**
  - Age ≥18
  - Antiretroviral-naïve
  - HIV RNA ≥1000 copies/mL

- **Treatment Arms**
  - LPV/r (400/100 mg) BID + 3TC 150 mg BID
  - LPV/r (400/100 mg) BID + (3TC or FTC) + 1 NRTI

**Dual Therapy**
LPV-RTV + 3TC
(n=217)

**Triple Therapy**
LPV-RTV + 2 NRTIs
(n = 209)

GARDEL = Global AntiRetroviral Design Encompassing Lopinavir/r and Lamivudine vs LPV/r based standard therapy

Lopinavir-RTV + Lamivudine versus Lopinavir-RTV + 2NRTIs

GARDEL: Results

Week 48: Virologic Response (ITT, exposed, snapshot)

# Lopinavir-RTV + Lamivudine versus Lopinavir-RTV + 2NRTIs

## GARDEL: Results

<table>
<thead>
<tr>
<th>Clinical Adverse Events and Laboratory Abnormalities</th>
<th>LPV-RTV + 3TC (n = 212)</th>
<th>LPV-RTV + 2NRTIs (n = 202)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of grade 2-3 AEs (possibly or probably drug related)</td>
<td>30%</td>
<td>44%</td>
</tr>
<tr>
<td>Total number of patients with grade 2-3 AEs (possibly or probably drug related)</td>
<td>20%</td>
<td>24%</td>
</tr>
<tr>
<td>Serious AEs (possibly or probably drug related)</td>
<td>&lt;1%</td>
<td>0%</td>
</tr>
<tr>
<td>Safety events leading to discontinuation</td>
<td>1%</td>
<td>5%</td>
</tr>
</tbody>
</table>

Interpretation: “Dual therapy with lopinavir and ritonavir plus lamivudine regimen warrants further clinical research and consideration as a potential therapeutic option for antiretroviral-therapy-naive patients.”
Acknowledgment

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