Dolutegravir + Lamivudine as Maintenance Dual Therapy

LAMIDOL
Dolutegravir plus Lamivudine as Maintenance Dual Therapy
LAMIDOL: Design

Study Design: LAMIDOL

• **Background**: Non-comparative, open-label, single-arm, multicenter trial to evaluate the efficacy and tolerance of once daily dolutegravir plus lamivudine as maintenance dual therapy

• **Inclusion Criteria**:  
  - Age ≥18 years  
  - Nadir CD4 count >200 cells/mm³  
  - HIV RNA <50 copies/mL for ≥2 years  
  - Wild-type baseline genotype  
  - First-line 3-drug ART:  
    - 2 NRTI’s + NNRTI, boosted PI, or INSTI  
  - Prior modifications for intolerance or simplification allowed  
  - No HBV co-infection

• **Regimen (Once daily)**  
  - Dolutegravir 50 mg + Lamivudine 300 mg

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LAMIDOL: Baseline Characteristics

<table>
<thead>
<tr>
<th>Participants who Entered Phase 2</th>
<th>N = 104</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (median)</td>
<td>45 years</td>
</tr>
<tr>
<td>Male</td>
<td>89 (85.6%)</td>
</tr>
<tr>
<td>MSM</td>
<td>73 (70.2%)</td>
</tr>
<tr>
<td>Duration since HIV diagnosis (median)</td>
<td>6.3 years</td>
</tr>
<tr>
<td>Time on current ART (median)</td>
<td>4.0 years</td>
</tr>
<tr>
<td>Nadir CD4 count (median)</td>
<td>399 cells/mm³</td>
</tr>
<tr>
<td>Current CD4 count (median)</td>
<td>743 cells/mm³</td>
</tr>
<tr>
<td>Baseline NNRTI</td>
<td>58 (55.8%)</td>
</tr>
<tr>
<td>Baseline PI</td>
<td>24 (23.1%)</td>
</tr>
<tr>
<td>Baseline INSTI</td>
<td>22 (21.2%)</td>
</tr>
</tbody>
</table>

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LAMIDOL: Results

Week 48 Virologic Response (by FDA Snapshot Analysis)

*Other 3 participants:
- 1 with low-level viremia (resuppressed with 3-drug antiretroviral therapy),
- 1 treatment modification decided by investigator, and
- 1 lost to follow-up

**Conclusion**: “Dolutegravir plus lamivudine is a promising maintenance therapy in HIV-1-infected patients with controlled virological suppression.”

Acknowledgment

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