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

**Phase 1**
- 8 weeks

**Phase 2**
- 40 weeks

*Phase 1: third agent switched to dolutegravir

**Phase 2: 2NRTIs switched to lamivudine

### Participants who Entered Phase 2

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</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/mm&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>Current CD4 count (median)</td>
<td>743 cells/mm&lt;sup&gt;3&lt;/sup&gt;</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>

**Source:** Joly V et al. Abstract 458. CROI 2017. Seattle, WA.
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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: “Switching to dolutegravir + lamivudine combination maintained virologic suppression at week 40, was safe and well tolerated in this population of selected patients without previous virological failure. Longer follow-up and comparative trials are needed to evaluate more precisely the role of this attractive maintenance strategy in HIV care.”
The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

*The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.*