Dolutegravir + Lamivudine as Initial Dual Therapy

PADDLE
Dolutegravir plus Lamivudine as Initial Dual Therapy

PADDLE: Design

**Study Design: PADDLE**

- **Background**: Pilot, phase 4, single-arm, open-label trial conducted in Argentina to evaluate the efficacy and tolerance of once daily dolutegravir plus lamivudine as initial dual therapy.

- **Inclusion Criteria** (n = 20)
  - Age ≥18 years
  - Antiretroviral therapy naive
  - Nadir CD4 count >200 cells/mm³
  - HIV RNA >5,000 and ≤100,000 copies/mL
  - Wild-type baseline genotype
  - No HBV co-infection

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

*Cohort 1*

Dolutegravir + Lamivudine (n = 10)

*Cohort 2*

Dolutegravir + Lamivudine (n = 10)

4 patients enrolled with HIV RNA >100,000 copies/mL

Cohort 2 patients enrolled following confirmation that 8/10 patients had >1 log decrease in HIV RNA at week 8

# Dolutegravir plus Lamivudine as Initial Dual Therapy

## PADDLE: Baseline Characteristics

<table>
<thead>
<tr>
<th>Demographic and Baseline Characteristics</th>
<th>Dolutegravir + Lamivudine (n = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), median</td>
<td>34 years</td>
</tr>
<tr>
<td>Male</td>
<td>19 (95%)</td>
</tr>
<tr>
<td>Mode of Transmission</td>
<td></td>
</tr>
<tr>
<td>MSM</td>
<td>15 (75%)</td>
</tr>
<tr>
<td>Heterosexual</td>
<td>5 (25%)</td>
</tr>
<tr>
<td>HIV RNA (copies/mL), median</td>
<td>24,128</td>
</tr>
<tr>
<td>CD4 count (cells/mm³), median</td>
<td>507</td>
</tr>
</tbody>
</table>

Week 48 Virologic Response (by FDA Snapshot Analysis)

*Other 2 participants:
- 1 committed suicide during study
- 1 developed virologic failure with HIV RNA = 99 copies/mL at week 36 and 246 copies/mL at week 39; patient had HIV RNA <50 copies/mL at week 48 (baseline HIV RNA = 106,320 copies/mL)

Conclusions: “This novel dual regimen of dolutegravir and lamivudine warrants further clinical research and consideration as a potential therapeutic option for ARV-therapy-naive patients.”
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