Dolutegravir vs. Efavirenz in Antiretroviral Naive

SPRING-1 Study
Dolutegravir versus Efavirenz in ARV-Naïve
SPRING-1: Study Design

**Study Design: SPRING-1**

- **Background**: Dose-ranging, partially-blinded phase 2b trial in antiretroviral-naïve subjects to select a dolutegravir dose for phase 3 trials.

- **Inclusion Criteria (n = 205)**
  - Age ≥18
  - Antiretroviral-naïve
  - CD4 >200 cells/mm³
  - HIV RNA >1,000 copies/mL
  - No NNRTI mutations

- **Treatment Arms**
  - Dolutegravir: 2, 10, or 50 mg daily + 2 NRTIs*
  - Efavirenz: 600 mg daily + 2 NRTIs*

*2 NRTIs = Tenofovir DF-Emtricitabine or Abacavir-Lamivudine

Dolutegravir versus Efavirenz in ARV-Naïve SPRING-1: Results

Week 48 Virologic Response (TLOVR)

Dolutegravir versus Efavirenz in ARV-Naïve SPRING-1: Results

Week 16, 24, and 48 Virologic Response (TLOVR)

### Dolutegravir versus Efavirenz in ARV-Naive SPRING-1: Adverse Events

<table>
<thead>
<tr>
<th>Adverse Effect</th>
<th>DTG 10 mg</th>
<th>DTG 25 mg</th>
<th>DTG 50 mg</th>
<th>DTG Subtotal</th>
<th>EFV 600 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious Adverse Events</td>
<td>3 (6%)</td>
<td>1 (2%)</td>
<td>4 (8%)</td>
<td>8 (5%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>7 (13%)</td>
<td>6 (12%)</td>
<td>6 (12%)</td>
<td>19 (12%)</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4 (8%)</td>
<td>3 (6%)</td>
<td>5 (10%)</td>
<td>12 (8%)</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2 (4%)</td>
<td>0</td>
<td>3 (6%)</td>
<td>5 (3%)</td>
<td>9 (18%)</td>
</tr>
<tr>
<td>Headache</td>
<td>2 (4%)</td>
<td>4 (8%)</td>
<td>4 (8%)</td>
<td>10 (6%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>1 (2%)</td>
<td>3 (6%)</td>
<td>1 (2%)</td>
<td>5 (3%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>0</td>
<td>0</td>
<td>3 (6%)</td>
<td>3 (2%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Abnormal Dreams</td>
<td>1 (2%)</td>
<td>0</td>
<td>0</td>
<td>1 (&lt;1%)</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Rash</td>
<td>2 (4%)</td>
<td>0</td>
<td>0</td>
<td>2 (1%)</td>
<td>4 (8%)</td>
</tr>
</tbody>
</table>

Interpretation: “Dolutegravir was effective when given once daily without a pharmacokinetic booster and was well tolerated at all assessed doses. Our findings support the assessment of once daily 50 mg dolutegravir in phase 3 trials.”
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