Dolutegravir + ABC-3TC versus Efavirenz-TDF-FTC

SINGLE Study
Dolutegravir + ABC-3TC versus Efavirenz-TDF-FTC
SINGLE Study: Design

• **Background:**
  - Randomized, double-blind study, phase 3 trial comparing dolutegravir + abacavir-lamivudine with efavirenz-tenofovir DF-emtricitabine

• **Inclusion Criteria (n = 833)**
  - Antiretroviral-naïve adults
  - Age ≥18 years
  - HIV RNA ≥1,000 copies/mL
  - No active CDC AIDS-defining condition

• **Treatment Arms**
  - Dolutegravir (QD) + Abacavir-Lamivudine
  - Efavirenz-Tenofovir DF-Emtricitabine

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SINGLE Study: Results

Week 48 Virologic Response (Intention-to-Treat Analysis)

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SINGLE Study: Results

Week 48 Virologic Response (Intention-to-Treat Analysis)

Discontinuation of therapy due to adverse events
Dolutegravir + Abacavir-Lamivudine: 2%
Efavirenz-Tenofovir-Emtricitabine: 10%

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SINGLE Study: Results

Mean Change from Baseline in Serum Creatinine Levels

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Conclusions: “Dolutegravir plus abacavir-lamivudine had a better safety profile and was more effective through 48 weeks than the regimen with efavirenz-tenofovir DF-emtricitabine.”

Dolutegravir + ABC-3TC versus Efavirenz-TDF-FTC SINGLE Study: Results

Week 96 and Week 144 Virologic Response (Intention-to-Treat Analysis)

Dolutegravir + ABC-3TC versus Efavirenz-TDF-FTC
SINGLE Study: Results

<table>
<thead>
<tr>
<th>Treatment Emergent Adverse Events (AEs &gt;5%)</th>
<th>DTG-ABC-3TC (n = 414)</th>
<th>EFV-TDF-FTC (n = 419)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Week 96</td>
<td>Week 144</td>
</tr>
<tr>
<td>Any, %</td>
<td>44</td>
<td>+1</td>
</tr>
<tr>
<td>Dizziness, %</td>
<td>7</td>
<td>+0</td>
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<tr>
<td>Abnormal dreams, %</td>
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<td>+0</td>
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<tr>
<td>Nausea, %</td>
<td>11</td>
<td>+0.2</td>
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<tr>
<td>Insomnia, %</td>
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<tr>
<td>Diarrhea, %</td>
<td>6</td>
<td>+0</td>
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<tr>
<td>Fatigue, %</td>
<td>7</td>
<td>+0</td>
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<tr>
<td>Headache, %</td>
<td>6</td>
<td>+0</td>
</tr>
<tr>
<td>Rash, %</td>
<td>&lt;1</td>
<td>+0</td>
</tr>
</tbody>
</table>

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