Elvitegravir-Cobicistat-TDF-FTC versus Efavirenz-TDF-FTC

Study 102
Elvitegravir-Cobicistat-TDF-FTC versus Efavirenz-TDF-FTC

Study 102: Design

Study Design: Study 102

- **Background**: Randomized, double-blind, phase 3 trial comparing elvitegravir-cobicistat-tenofovir DF-emtricitabine with efavirenz-tenofovir DF-emtricitabine

- **Inclusion Criteria (n = 700)**
  - Antiretroviral-naïve patients
  - Age ≥ 18
  - HIV RNA ≥ 5,000 copies/mL
  - No AIDS conditions in previous 30 days

- **Treatment Arms**
  - Elvitegravir-Cobicistat-TDF-FTC
  - Efavirenz-TDF-FTC

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Study 102: Result

Week 48 Virologic Response: Snapshot Analysis (ITT, Missing=Failure)

### Treatment Emergent Adverse Events in ≥ 10% of Subjects in Either Group

<table>
<thead>
<tr>
<th>Event</th>
<th>EVG-COBI-TDF-FTC (n = 348)</th>
<th>EFV-TDF-FTC (n = 352)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>23%</td>
<td>19%</td>
</tr>
<tr>
<td>Nausea*</td>
<td>21%</td>
<td>14%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>11%</td>
<td>13%</td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>14%</td>
<td>11%</td>
</tr>
<tr>
<td>Dizziness^</td>
<td>7%</td>
<td>24%</td>
</tr>
<tr>
<td>Headache</td>
<td>14%</td>
<td>10%</td>
</tr>
<tr>
<td>Abnormal Dreams^</td>
<td>15%</td>
<td>27%</td>
</tr>
<tr>
<td>Insomnia^</td>
<td>9%</td>
<td>14%</td>
</tr>
<tr>
<td>Depression</td>
<td>9%</td>
<td>11%</td>
</tr>
<tr>
<td>Rash#</td>
<td>6%</td>
<td>12%</td>
</tr>
</tbody>
</table>

* *p < 0.016; ^p < 0.001; &p < 0.031; #p = 0.009

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Study 102: Conclusions

**Interpretation:** This study met the primary endpoint of non-inferiority of elvitegravir/cobicistat/emtricitabine/tenofovir (EVG/COBI/TDF/FTC) to efavirenz/emtricitabine/tenofovir (EFV/TDF/FTC) and demonstrates the robust antiviral efficacy of the only integrase inhibitor-based single tablet regimen for initial HIV treatment, irrespective of viral load.

Acknowledgment

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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.