EVG-COBI-TDF-FTC versus ATV + RTV + TDF-FTC

Study 103
Elvitegravir-Cobicistat-TDF-FTC versus Atazanavir + Ritonavir + TDF-FTC

Study 103: Design

**Study Design: Study 103**

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

- **Inclusion Criteria (n = 708)**
  - Antiretroviral-naïve adults
  - Age ≥18
  - HIV RNA ≥5,000 copies/ml
  - Any CD4 count

- **Treatment Arms**
  - Elvitegravir-Cobicistat-TDF-FTC
  - Atazanavir + RTV + TDF-FTC

**Elvitegravir-Cobicistat-TDF-FTC**
(n = 353)

**Atazanavir + Ritonavir + TDF-FTC**
(n = 355)

Elvitegravir-Cobicistat-TDF-FTC versus Atazanavir + RTV + TDF-FTC
Study 103: Result

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

DeJesus E, et al. 19th IAC. 2012; Abstract TUPE43.
## Elvitegravir-Cobicistat-TDF-FTC versus Atazanavir + RTV + TDF-FTC
### Study 103: Common Adverse Events

<table>
<thead>
<tr>
<th>Treatment Emergent Adverse Events in ≥ 10% of Subjects in Either Group</th>
<th>EVG-COBI-TDF-FTC (n = 353)</th>
<th>ATV + RTV + TDF-FTC (n= 355)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>22%</td>
<td>27%</td>
</tr>
<tr>
<td>Nausea*</td>
<td>20%</td>
<td>19%</td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>15%</td>
<td>16%</td>
</tr>
<tr>
<td>Headache</td>
<td>15%</td>
<td>12%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>14%</td>
<td>13%</td>
</tr>
<tr>
<td>Ocular Icterus*</td>
<td>1%</td>
<td>14%</td>
</tr>
</tbody>
</table>

*p < 0.001

**Interpretation**: This study met the primary endpoint of non-inferiority of elvitegravir/cobicistat/emtricitabine/tenofovir (EVG/COBI/FTC/TDF) to atazanavir plus ritonavir plus emtricitabine/tenofovir (ATV+RTV+FTC/TDF) and demonstrates the robust antiviral efficacy of the only integrase inhibitor-based single tablet regimen for initial HIV treatment.
Acknowledgment

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