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

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

- **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 years
  - HIV RNA ≥5,000 copies/mL
  - Any CD4 count
- **Treatment Arms**
  - Elvitegravir-Cobicistat-TDF-FTC
  - Atazanavir + RTV + TDF-FTC

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

Week 48 Virologic Response

DeJesus E, et al. 19th IAC. 2012; Abstract TUPE43.
## Treatment Emergent Adverse Events in ≥ 10% of Subjects in Either Group

<table>
<thead>
<tr>
<th>Event</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.”
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