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 patients
  - 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 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**

### 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

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**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.
The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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