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

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

**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

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $800,000 with 0% financed with non-governmental sources. This project is led by the University of Washington’s Infectious Diseases Education and Assessment (IDEA) Program.

*The content in this presentation are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government.*