EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC

Study 104 and Study 111
Study Design: 104/111

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

- **Inclusion Criteria (n = 1733)**
  - Antiretroviral-naïve adults
  - Age ≥18 years
  - HIV RNA ≥1000 copies/mL
  - Any CD4 count allowed
  - No AIDS conditions in prior 30 days

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

---

**EVG-COBI-TAF-FTC**
*(Genvoya)*
(n = 866)

**EVG-COBI-TDF-FTC**
*(Stribild)*
(n = 867)

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
Study 104/111: Result

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

Study 104/111: Adverse Effects

Week 48: Change in Serum Creatinine from Baseline

Mean Change in Serum Creatinine (mg/dL)

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
Study 104/111: Adverse Effects

Week 48: Changes in Quantitative Proteinuria

Week 48: Changes in Spine and Hip Bone Mineral Density

# Study 104/111: Adverse Effects

## Week 48: Changes in Lipid Parameters

<table>
<thead>
<tr>
<th>Median Change from Baseline to Week 48</th>
<th>EVG/COBI/TAF/FTC (n = 866)</th>
<th>EVG/COBI/TDF/FTC (n = 867)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cholesterol</td>
<td>+29</td>
<td>+14</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LDL</td>
<td>+14</td>
<td>+5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>HDL</td>
<td>+8</td>
<td>+4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>+19</td>
<td>+8</td>
<td>0.027</td>
</tr>
<tr>
<td>Total cholesterol:HDL ratio</td>
<td>+0.1</td>
<td>+0.1</td>
<td>0.84</td>
</tr>
</tbody>
</table>

**Interpretation**: “Through 48 weeks, more than 90% of patients given E/C/F/tenofovir alafenamide or E/C/F/tenofovir disoproxil fumarate had virological success. Renal and bone effects were significantly reduced in patients given E/C/F/tenofovir alafenamide. Although these studies do not have the power to assess clinical safety events such as renal failure and fractures, our data suggest that E/C/F/tenofovir alafenamide will have a favourable long-term renal and bone safety profile.”

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.*