DRV-COBI-TAF-FTC versus DRV-COBI plus TDF-FTC

GS-299-0102
0102: Study Design

- **Background:** Randomized, double-blind, placebo controlled, phase 2 study evaluating the efficacy and safety of a single tablet regimen of DRV/COBI/FTC/TAF compared with DRV + COBI + TDF-FTC for treatment-naïve individuals.

- **Inclusion Criteria (n=153)**
  - Age > 18
  - Antiretroviral-naïve
  - CD4 count > 50 cells/mm³
  - HIV RNA ≥ 5,000 copies/mL
  - eGFR ≥ 70 mL/min
  - Genotypic sensitivity to DRV, TDF, FTC
  - No hepatitis B or C
  - Not pregnant
  - No AIDS-defining condition within 30 days

DRV-COBI-TAF-FTC versus DRV-COBI plus TDF-FTC
GS-299-0102: Results

Week 24 and 48: Virologic Response by FDA Snapshot Analysis, ITT

DRV-COBI-TAF-FTC versus DRV-COBI plus TDF-FTC
GS-299-0102: Results

Week 48: Change in Urinary Markers of Tubular Dysfunction

- **RBP/Cr =** retinol binding protein-to-creatinine ratio
- **β-2 microglobulin/Cr =** β-2 microglobulin-to-creatinine ratio

Week 48: Change in Bone Mineral Density

**DRV-COBI-TAF-FTC versus DRV-COBI plus TDF-FTC
GS-299-0102: Results**

<table>
<thead>
<tr>
<th>Measure</th>
<th>DRV/COBI/FTC/TAF TAF group (n = 103)</th>
<th>DRV/COBI + TDF-FTC TDF group (n = 50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cholesterol, mg/dL</td>
<td>40</td>
<td>5</td>
</tr>
<tr>
<td>LDL, mg/dL</td>
<td>26</td>
<td>4</td>
</tr>
<tr>
<td>HDL, mg/dL</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>TC:HDL</td>
<td>0.0</td>
<td>-0.2</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>29</td>
<td>-5</td>
</tr>
<tr>
<td>Serum glucose, mg/dL</td>
<td>5</td>
<td>2</td>
</tr>
</tbody>
</table>

Conclusions: “The tenofovir alafenamide arm had significantly improved renal and bone safety parameters: less proteinuria and less change in hip and spine BMD, consistent with results from a similarly designed study of the elvitegravir-cobicistat-emtricitabine-tenofovir alafenamide single table regimen. This darunavir-cobicistat-emtricitabine-tenofovir alafenamide single tablet regimen offers a promising option for initial HIV treatment, with the high barrier to resistance of darunavir, and the potential for improved long-term renal and bone safety with tenofovir alafenamide.”

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.*