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

Investigational

Week 24:
- DRV-COBI-TAF-FTC: 77/103 (75%)
- DRV-COBI + TDF-FTC: 37/50 (74%)

Week 48:
- DRV-COBI-TAF-FTC: 79/103 (77%)
- DRV-COBI + TDF-FTC: 42/50 (84%)

Investigational

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

Week 48: Change in Urinary Markers of Tubular Dysfunction

![Bar chart showing change from baseline in urinary markers of tubular dysfunction.]

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

Week 48: Change in Bone Mineral Density

### Median Change in Fasting Metabolic Assessments at Week 48

<table>
<thead>
<tr>
<th></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 TAF 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/C/F/TAF STR. This D/C/F/TAF STR 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 TAF.”

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.

The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.