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

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/mm$^3$
  - HIV RNA $\geq$ 5,000 copies/mL
  - eGFR $\geq$ 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

**Change from Baseline (%)**

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

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

Week 48: Change in Bone Mineral Density

Change from Baseline (%)

- Hip
  - DRV-COBI-TAF-FTC: -0.84
  - DRV-COBI + TDF-FTC: -3.82

- Lumbar spine
  - DRV-COBI-TAF-FTC: -1.57
  - DRV-COBI + TDF-FTC: -3.62

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

### 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>
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<td>3</td>
</tr>
<tr>
<td>TC:HDL</td>
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<td>-0.2</td>
</tr>
<tr>
<td>Triglycerides</td>
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<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.”
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.