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

![Graph showing virologic response](image)

- **24 weeks:**
  - DRV-COBI-TAF-FTC: 75/103
  - DRV-COBI + TDF-FTC: 74/50

- **48 weeks:**
  - DRV-COBI-TAF-FTC: 77/103
  - DRV-COBI + TDF-FTC: 84/50

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

Week 48: Change in Urinary Markers of Tubular Dysfunction

Investigational

**Week 48: Change in Urinary Markers of Tubular Dysfunction**

**Change from Baseline (%)**

- **RBP/Cr**
  - DRV-COBI-TAF-FTC: 9%
  - DRV-COBI + TDF-FTC: 54%

- **β-2 microglobulin/Cr**
  - DRV-COBI-TAF-FTC: -42%
  - DRV-COBI + TDF-FTC: 2.3%

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


**National HIV Curriculum**
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>Median Change in Fasting Metabolic Assessments at Week 48</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DRV/COBI/FTC/TAF</strong></td>
</tr>
<tr>
<td><em>TAF group</em></td>
</tr>
<tr>
<td>(n = 103)</td>
</tr>
<tr>
<td>Total cholesterol, mg/dL</td>
</tr>
<tr>
<td>LDL, mg/dL</td>
</tr>
<tr>
<td>HDL, mg/dL</td>
</tr>
<tr>
<td>TC:HDL</td>
</tr>
<tr>
<td>Triglycerides</td>
</tr>
<tr>
<td>Serum glucose, mg/dL</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.”

Acknowledgment

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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.