EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
GS-292-0104 and GS-292-0111 Study
Study Design: GS-292-0104 & GS-292-0111

**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 patients
- Age ≥18
- 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

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

Week 48: Change in Serum Creatinine from Baseline

Mean Change in Serum Creatinine (mg/dl)

- Tenofovir alafenamide arm
- Tenofovir DF arm

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
GS-292-0104 and GS-292 0111 Study: Adverse Effects

Week 48: Changes in Quantitative Proteinuria

Week 48: Changes in Spine and Hip Bone Mineral Density

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

**GS-292-0104 and GS-292 0111 Study: 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

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