Elvitegravir-Cobicistat-TAF-FTC in Adolescents

Study 106
Elvitegravir-Cobicistat-TAF-FTC in Treatment Naïve Adolescents
Study 106: Design

**Study Design: Study 106**

- **Background**: Open-label, single arm phase 2/3 trial evaluating safety and efficacy of once-daily elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine in treatment-naïve adolescents with HIV

- **Inclusion Criteria** (n = 50)
  - Treatment-naïve adolescents with HIV
  - Adolescents aged 12-18 yrs, ≥ 35kg
  - HIV RNA ≥1000 copies/mL
  - CD4 count ≥100 cells/mm³
  - GFR ≥90 mL/min
  - No resistance to EVG, FTC, or TDF

- **Treatment Arms**
  - EVG-COBI-TAF-FTC

Elvitegravir-Cobicistat-TAF-FTC in Treatment Naïve Adolescents
Study 106: Result

Week 48 Virologic Response

Elvitegravir-Cobicistat-TAF-FTC in Treatment Naïve Adolescents
Study 106: Result

Week 48: Changes in Quantitative Proteinuria

![Graph showing changes in proteinuria levels for different parameters.]

- **Proteinuria (UPCR):** Median change from baseline of -27.0%
- **RBP/Cr:** Median change from baseline of -21.6%
- **β2M/Cr:** Median change from baseline of -29.4%

RBP:Cr = retinol binding protein:creatinine ratio; β2M:Cr = beta-2 microalbumin:creatinine ratio

Elvitegravir-Cobicistat-TAF-FTC in Treatment Naïve Adolescents
Study 106: Result

Week 48: Changes in Spine and Total Body Bone Mineral Density

### Treatment Emergent Adverse Events in > 5% of Subjects

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>EVG-COBI-TAF-FTC (n = 50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>20%</td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td>12%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>10%</td>
</tr>
<tr>
<td>Upper Abdominal Pain</td>
<td>6%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>6%</td>
</tr>
<tr>
<td>Somnolence</td>
<td>6%</td>
</tr>
</tbody>
</table>

Interpretation: “The elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide regimen was well tolerated and achieved component plasma pharmacokinetic exposures similar to those in adults. Although non-comparative with a small sample size, these data support the use of this regimen in HIV-infected adolescents and its timely assessment in younger children.”

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