Elvitegravir-Cobicistat-TAF-FTC in Hepatitis B Coinfection

Study 1249
**Elvitegravir-Cobicistat-TAF-FTC in HIV/HBV Coinfection Study 1249: Design**

- **Background**: Open-label, single-arm, phase 3b trial evaluating switching to once-daily elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine in adults with HIV and HBV

- **Inclusion Criteria** (n = 72)
  - Adults with HIV and chronic HBV
  - HIV RNA <50 copies/mL for ≥6 months
  - Stable ART regimen for ≥4 months
  - CD4 ≥200 cells/mm³
  - CrCl ≥50 mL/min, ALT ≤10x ULN
  - No cirrhosis, HCC, HCV, hepatitis D

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

**Study Week:**

<table>
<thead>
<tr>
<th>Study Week</th>
<th>0</th>
<th>24</th>
<th>48</th>
</tr>
</thead>
</table>

**Baseline ART** (n = 72) → **EVG-COBI-TAF-FTC** (n = 72)

Elvitegravir-Cobicistat-TAF-FTC in HIV/HBV Coinfection Study 1249: Result

HIV Efficacy at Weeks 24 and 48

Elvitegravir-Cobicistat-TAF-FTC in HIV/HBV Coinfection Study 1249: Result

HBV Efficacy at Weeks 24 and 48, Missing = Failure

HBV DNA <29 IU/mL

Week 24: 86%
Week 48: 92%

HBV DNA ≥29 IU/mL

Week 24: 10%
Week 48: 3%

Data Missing

Week 24: 4%
Week 48: 6%

Elvitegravir-Cobicistat-TAF-FTC in HIV/HBV Coinfection Study 1249: Subgroup Analysis Result

ALT Measurement at Weeks 24 and 48

![Graph showing participants with normal ALT (as %) at weeks 24 and 48 for baseline ALT >ULN and baseline ALT normal conditions.]

Elvitegravir-Cobicistat-TAF-FTC in HIV/HBV Coinfection
Study 1249: Result

Changes in General Proteinuria at Weeks 24 and 48 from Baseline

Elvitegravir-Cobicistat-TAF-FTC in HIV/HBV Coinfection Study 1249: Result

Changes in Tubular Proteinuria at Weeks 24 and 48 from Baseline

**Median Change in Tubular Proteinuria (%)**

<table>
<thead>
<tr>
<th></th>
<th>Week 24</th>
<th>Week 48</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBP:Cr</td>
<td>-22</td>
<td>-6</td>
</tr>
<tr>
<td>β2M:Cr</td>
<td>-36</td>
<td>-22</td>
</tr>
</tbody>
</table>


RBP:Cr = retinol binding protein:creatinine ratio; β2M:Cr = beta-2 microalbumin:creatinine ratio
**Interpretation:** “In this first study in HIV/HBV-coinfected participants with suppressed HIV infection, E/C/F/TAF was effective against HIV and HBV, well tolerated, and demonstrated improvements in renal and bone safety consistent with the clinical profile of TAF. These data support the use of E/C/F/TAF in treating HIV/HBV coinfections.”

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