Elvitegravir-Cobicistat-TAF-FTC in Hepatitis B Coinfection

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

**Study Design: Study 1249**

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

- **Inclusion Criteria (n = 72)**
  - HIV-infected adults with chronic HBV
  - HIV RNA < 50 copies/mL for ≥ 6 months
  - Stable ART regimen for ≥ 4 months
  - CD4 ≥ 200 cells/mm$^3$
  - CrCl ≥ 50 mL/min, ALT ≤ 10x ULN
  - No: cirrhosis, HCC, HCV, hepatitis D

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

**Study Week:**

- 0
- 24
- 48

**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

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

ALT Measurement at Weeks 24 and 48

Changes in General Proteinuria at Weeks 24 and 48

<table>
<thead>
<tr>
<th></th>
<th>Week 24</th>
<th>Week 48</th>
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<tbody>
<tr>
<td>Proteinuria (UPCR)</td>
<td>-10</td>
<td>-13</td>
</tr>
<tr>
<td>Albuminuria (UACR)</td>
<td>-4</td>
<td>-15</td>
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Elvitegravir-Cobicistat-TAF-FTC in HIV/HBV Coinfection Study 1249: Result

Changes in Tubular Proteinuria at Weeks 24 and 48

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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