Switch to RPV-TAF-FTC from EFV-TDF-FTC

Study GS-366-1160
Switch to RPV-TAF-FTC from EFV-TDF-FTC
Study GS-366-1160: Design

Study Design: Study GS-366-1160

- **Background**: Phase 3b, multinational, randomized, double-blind, placebo controlled, non-inferiority trial investigating the tolerability of switching to the single tablet regimen rilpivirine-tenofovir alafenamide-emtricitabine (RPV-TAF-FTC)

- **Inclusion Criteria (n = 881 randomized)**
  - HIV-1-infected adults
  - HIV RNA <50 copies/mL for ≥6 months on EFV-TDF-FTC
  - Creatinine clearance at least 50 mL/min
  - No resistance to EFV, RPV, TDF, or FTC

- **Treatment Arms**
  - Switch to RPV-TAF-FTC (Switch group)
  - Remain on EFV-TDF-FTC (No switch group)

*NOTE*: of 881 participants randomized, 6 were never treated (875 individuals treated)

Switch to RPV-TAF-FTC from EFV-TDF-FTC
Study GS-366-1160: Results

Week 48 Virologic Response (FDA Snapshot Analysis)

Switch to RPV-TAF-FTC from EFV-TDF-FTC
Study GS-366-1160: Results

Week 48: Changes in Bone Mineral Density (BMD)

Mean Change in BMD (%)

- **Hip:**
  - **RPV-TAF-FTC (Switch):** 1.65
  - **EFV-TDF-FTC (No Switch):** -0.05

- **Spine:**
  - **RPV-TAF-FTC (Switch):** 1.28
  - **EFV-TDF-FTC (No Switch):** -0.13

Switch to RPV-TAF-FTC from EFV-TDF-FTC Study GS-366-1160: Results

Week 48: Changes in Markers of Proximal Tubulopathy

- Proteinuria (UPCR): -30, Switch: -2, No Switch: -30
- Albuminuria (APCR): -14, Switch: -14, No Switch: -14
- Retinol binding protein: Switch: 12, No Switch: 29
- β2 microglobulin: Switch: -28, No Switch: -41

Switch to RPV-TAF-FTC from EFV-TDF-FTC

Study GS-366-1160: Results

Week 48: Change in Plasma Lipids from Baseline

<table>
<thead>
<tr>
<th>Parameter</th>
<th>RPV-TAF-FTC (Switch)</th>
<th>EFV-TDF-FTC (No Switch)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol</td>
<td>-9</td>
<td>-3</td>
</tr>
<tr>
<td>LDL</td>
<td>-3</td>
<td>-3</td>
</tr>
<tr>
<td>HDL</td>
<td>-2</td>
<td>-1</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>-4</td>
<td>-2</td>
</tr>
</tbody>
</table>

**Interpretation:** “Switching to rilpivirine, emtricitabine, and tenofovir alafenamide from efavirenz, emtricitabine, and tenofovir disoproxil fumarate was non-inferior in maintaining viral suppression and was well tolerated at 48 weeks. These findings support guidelines recommending tenofovir alafenamide-based regimens, including coformulation with rilpivirine and emtricitabine, as initial and ongoing treatment for HIV-1 infection.”

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