Switching to TAF from TDF, each with RPV and FTC

Study GS-366-1216
Switch from TDF to TAF, each with RPV and FTC
Study GS-366-1216: Design

Study Design: Study GS-366-1160

- **Background**: Phase 3b, multinational, randomized, double-blind, placebo controlled, non-inferiority trial to investigate safety, and tolerability of switching to the single tablet regimen rilpivirine-tenofovir alafenamide-emtricitabine (RPV-TAF-FTC)
- **Inclusion Criteria** (n = 632 randomized)
  - HIV-1-infected adults
  - HIV RNA <50 copies/mL ≥6 months on RPV-TDF-FTC
  - Creatinine clearance at least 50 mL/min
  - No resistance to RPV, TDF, or FTC
- **Treatment Arms**
  - Switch to RPV-TAF-FTC (Switch group)
  - Remain on RPV-TDF-FTC (No switch group)

*NOTE*: of 632 participants randomized, 2 were never treated (630 individuals treated)

Switch to TAF from TDF, each with RPV and FTC
Study GS-366-1216: Design

Week 48 Virologic Response (FDA Snapshot Analysis)

Switch to TAF from TDF, each with RPV and FTC
Study GS-366-1216: Results

Week 48: Changes in Bone Mineral Density (BMD)

Mean Change in BMD (%)

- Hip
  - RPV-TAF-FTC (Switch): 1.04
  - RPV-TDF-FTC (No Switch): -0.25

- Spine
  - RPV-TAF-FTC (Switch): 1.61
  - RPV-TDF-FTC (No Switch): 0.08

Switch to TAF from TDF, each with RPV and FTC
Study GS-366-1216: Results

Week 48: Changes in Markers of Proximal Tubulopathy

**Median Change from Baseline (%)**

- **Proteinuria (UPCR)**: -19
- **Albuminuria (APCR)**: -8
- **Retinol binding protein**: -18
- **β2 microglobulin**: -29

**Source:** Orkin C et al. Lancet HIV. 2017;4:e195-e204.
Switch to TAF from TDF, each with RPV and FTC
Study GS-366-1216: Results

Week 48: Change in Plasma Lipids from Baseline

<table>
<thead>
<tr>
<th></th>
<th>RPV-TAF-FTC (Switch)</th>
<th>RPV-TDF-FTC (No Switch)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol</td>
<td>16</td>
<td>-2</td>
</tr>
<tr>
<td>LDL</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>HDL</td>
<td>2</td>
<td>-1</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>5</td>
<td>-6</td>
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</table>

Interpretation: “Switching to rilpivirine, emtricitabine, and tenofovir alafenamide was non-inferior to continuing rilpivirine, emtricitabine, tenofovir disoproxil fumarate 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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