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)

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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)

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

Week 48: Changes in Markers of Proximal Tubulopathy

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Study GS-366-1216: Results

Week 48: Change in Plasma Lipids from Baseline

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

**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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