Switch RPV-TDF-FTC from NVP-Based Regimen

**Near-Rwanda Trial**
Switch to RPV-TDF-FTC from NVP-Based Regimen Near-Rwanda: Study Design

• **Background:** Randomized, open-label, single-center, noninferiority study conducted in Rwanda to evaluate a switch from a nevirapine (NVP)-based regimen to a single tablet regimen of rilpivirine-tenofovir DF-emtricitabine (RPV-TDF-FTC)

• **Inclusion Criteria (n = 150 enrolled)**
  - Rwandan adults with HIV-1 infection
  - HIV RNA <50 copies/mL within 12 months of screening
  - HIV RNA <50 copies/mL at screening visit
  - On NVP + lamivudine + 2nd NRTI ≥12 months
  - No prior virologic failure
  - No prior ART change except NRTI substitution
  - eGFR >60 mL/min and Hemoglobin >8 g/dL
  - No active TB or pregnancy

• **Treatment Arms (2:1 randomization)**
  - Continue NVP + 2 NRTIs
  - Switch to RPV-FTC-TDF

**Switch Arm**
RPV-TDF-FTC
(n = 99)

**Continuation Arm**
NVP + 2 NRTI’s
(n = 51)

Switch to RPV-TDF-FTC from NVP-Based Regimen Near-Rwanda: Results

24 Week Virologic Response (FDA Snapshot Analysis)

![Graph showing virologic response endpoints with percentages](chart)

- **HIV RNA <200 copies/mL:**
  - Rilpivirine-Tenofovir DF-Emtricitabine: 93% (92/99) vs. 92% (47/51) for Nevirapine + 2 NRTI's

- **HIV RNA <50 copies/mL:**
  - Rilpivirine-Tenofovir DF-Emtricitabine: 89% (89/99) vs. 84% (43/51) for Nevirapine + 2 NRTI's

Switch to RPV-TDF-FTC from NVP-Based Regimen Near-Rwanda: Results

Week 24: Change in Plasma Lipids from Baseline

<table>
<thead>
<tr>
<th>Lipid</th>
<th>Mean change from baseline (mg/dL)</th>
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<tbody>
<tr>
<td>Total Cholesterol</td>
<td>-16.6</td>
</tr>
<tr>
<td>LDL</td>
<td>-2.8</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>-9.2</td>
</tr>
<tr>
<td>HDL</td>
<td>-12.0</td>
</tr>
</tbody>
</table>

Conclusions: “A switch from nevirapine-based ART to rilpivirine-emtricitabine-tenofovir disoproxil fumarate had similar virologic efficacy to continued nevirapine-based antiretroviral therapy after 24 weeks with few adverse events.”
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