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

GS-264-0111
Switch from **EFV-TDF-FTC** to **RPV-TDF-FTC**

**GS-264-0111: Study Design**

### Study Design: GS-264-0111 Study

**Background**: Open-label, phase 2b study evaluating the efficacy and safety of switching from EFV-TDF-FTC to RPV-TDF-FTC in virologically suppressed patients with HIV-1.

**Inclusion Criteria (n = 49)**
- Age ≥ 18 years
- On EFV-TDF-FTC for ≥ 3 months
- Experiencing efavirenz intolerance
- HIV RNA < 50 copies/mL for ≥ 8 weeks
- No resistance to study drugs
- No proton pump inhibitor use
- CrCl ≥ 50 mL/min

**Switch Arm**
- Rilpivirine-tenofovir DF-emtricitabine

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

GS-264-0111: Result

Virologic Outcomes at Weeks 12, 24, and 48

![Virologic Outcomes Chart]

**HIV RNA < 50 copies/mL (%)**

- **12 Weeks**: 100/49 = 100%
- **24 Weeks**: 100/49 = 100%
- **48 Weeks**: 94/49 = 94%

**Week Following Switch to RPV-TDF-FTC**

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

GS-264-0111: Result

**Week 24: Change in Plasma Lipids from Baseline**

<table>
<thead>
<tr>
<th>Lipid</th>
<th>Change from baseline median (mg/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol</td>
<td>-17</td>
</tr>
<tr>
<td>LDL</td>
<td>-8</td>
</tr>
<tr>
<td>HDL</td>
<td>-2</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>-26</td>
</tr>
</tbody>
</table>

**Lipid Changes in Patients Switched to RPV-TDF-FTC**

**Conclusions:** “Switching from EFV/FTC/TDF to RPV/FTC/TDF was a safe, efficacious option for virologically suppressed HIV-infected patients with efavirenz intolerance wishing to remain on an single tablet regimen.”

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