Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen

SPIRIT STUDY
Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen

Spirit: Design

Study Design: SPIRIT STUDY

- **Background**: Open label, randomized phase 3b trial evaluating switching from ritonavir-boosted PI plus 2 NRTIs to single-tablet regimen of rilpivirine-tenofovir DF-emtricitabine once daily

- **Inclusion Criteria** (n = 476)
  - Age ≥ 18
  - HIV RNA < 50 copies/mL for ≥ 6 months
  - On PI/r ≥ 6 months
  - No known resistance to study drugs

- **Treatment Arms**
  - Rilpivirine-tenofovir DF-emtricitabine
  - Ritonavir-boosted PI + 2 NRTIs x 24 weeks, then rilpivirine-tenofovir DF-emtricitabine

Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen

Spirit: Result

Week 24 Virologic Response (Intent-to-Treat Analysis)

<table>
<thead>
<tr>
<th></th>
<th>RPV-FTC-TDF</th>
<th>PI/r + 2NRTIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>94/317</td>
<td>90/159</td>
</tr>
<tr>
<td>≤ 100,000 copies/mL</td>
<td>95/163</td>
<td>89/93</td>
</tr>
<tr>
<td>&gt; 100,000 copies/mL</td>
<td>95/131</td>
<td>92/52</td>
</tr>
</tbody>
</table>

Baseline HIV RNA Level

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Spirit: Result

Virologic Failure (HIV RNA ≥50 copies/mL) at Weeks 24 and 48

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Spirit: Result

Week 24: Change in Plasma Lipids from Baseline

<table>
<thead>
<tr>
<th></th>
<th>RPV-FTC-TDF</th>
<th>PI/r + 2NRTIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol</td>
<td>-25</td>
<td>0</td>
</tr>
<tr>
<td>LDL</td>
<td>-16</td>
<td>3</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>-53</td>
<td>1</td>
</tr>
<tr>
<td>HDL</td>
<td>-6</td>
<td></td>
</tr>
</tbody>
</table>

Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen

Spirit: Result

Week 48: Change in Plasma Lipids from Baseline

<table>
<thead>
<tr>
<th></th>
<th>Mean change from baseline (mg/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol</td>
<td>Immediate switch: -24, Delayed switch: -24</td>
</tr>
<tr>
<td>LDL</td>
<td>Immediate switch: -16, Delayed switch: -16</td>
</tr>
<tr>
<td>HDL</td>
<td>Immediate switch: -14, Delayed switch: -64</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>Immediate switch: -80, Delayed switch: -80</td>
</tr>
</tbody>
</table>

Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen

Spirit: Result

Week 48 Virologic Outcomes in Patients with Resistance Mutations*

*Pre-existing NRTI or NNRTI resistance mutations by baseline proviral DNA or historical RNA genotype

Conclusion: “Switching to the STR RPV/FTC/TDF from an RTV-boosted protease inhibitor regimen in virologically suppressed, HIV-1-infected participants maintained virologic suppression with a low risk of virologic failure, while improving total cholesterol, LDL, and triglycerides.”
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Spirit: Patient-Reported Outcomes

Occurrence of HIV-Related Symptoms (%)

- Weight loss
- Sex problems
- Muscle pain
- Bloating
- Headache
- Skin Problems
- Anxiety
- Sadness
- Diarrhea
- Nausea
- Memory Loss
- Fever
- Fatigue

**Conclusions**: “These data suggest that switching to the STR RPV/FTC/TDF from a PI-based multi-pill regimen is associated with greater patient-reported treatment satisfaction and improved tolerability in HIV-1-infected, virologically suppressed individuals.”
Acknowledgment

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