Switch from PI-Based Regimen to EVG-COBI-TDF-FTC

Study 115 (STRATEGY-PI)
Switch from PI-Based Regimen to EVG-COBI-TDF-FTC

STRATEGY-PI: Design

Study Design: STRATEGY-PI

- **Background**: Open-label, randomized study, Phase 3b trial comparing switch to elvitegravir-cobicistat-tenofovir DF-emtricitabine versus continuation of baseline regimen of ritonavir + PI + tenofovir DF-emtricitabine

- **Inclusion Criteria (n = 433)**
  - HIV RNA <50 copies/mL on ART for ≥6 months
  - Baseline regimen of RTV + PI + TDF-FTC
  - No prior virologic failure
  - No resistance to TDF or FTC
  - CrCl ≥70 mL/min

- **Treatment Arms**
  - EVG-COBI-TDF-FTC (Switch group)
  - Remain on RTV + PI + TDF-FTC (No switch group)

*NOTE*: 3 participants from switch group, and 1 participant from no-switch group, were excluded from study after screening for protocol violations.

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STRATEGY-PI: Result

Week 48: Virologic Response (Modified Intent-to-Treat Analysis)

<table>
<thead>
<tr>
<th></th>
<th>EVG-COBI-TDF-FTC (Switch)</th>
<th>RTV + PI + TDF-FTC (No switch)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV RNA &lt; 50 copies/mL</td>
<td>94/272</td>
<td>87/121</td>
</tr>
<tr>
<td>No Virologic Data</td>
<td>6/16290</td>
<td>12/16139</td>
</tr>
</tbody>
</table>

**Interpretation:** “Coformulated elvitegravir, cobicistat, emtricitabine, and tenofovir might be a useful regimen simplification option for virologically suppressed adults with HIV taking a multitablet ritonavir-boosted protease inhibitor regimen.”
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