Switch from Efavirenz + ZDV-3TC to Efavirenz + TDF-FTC

SWEET Trial
Switch to Efavirenz + TDF-FTC

SWEET: Design

Study Design: SWEET Study

- **Background**: Randomized, controlled, open label phase 3 trial evaluating a simplification strategy for patients suppressed on efavirenz-based ART by switching from twice-daily zidovudine-lamivudine to once-daily tenofovir DF-emtricitabine in adults with HIV

- **Inclusion Criteria (n = 234)**
  - Age ≥18 years
  - On EFV + ZDV-3TC for >6 months
  - No resistance to study drugs
  - HIV RNA <400 copies/mL for ≥3 months and HIV RNA <50 copies/mL on 2 occasions

- **Treatment Arms**
  - Efavirenz + TDF-FTC
  - Efavirenz + ZDV-3TC

Switch to Efavirenz + TDF-FTC
SWEET: Result

Week 48 Virologic Response (ITT Analysis, M=F)

Switch to Efavirenz + TDF-FTC

SWEET: Result

Week 48: Patients with Change in Absolute Hemoglobin from Baseline

Switch to Efavirenz + TDF-FTC
SWEET: Result

Week 24: Change in Limb Fat from Baseline

Switch to Efavirenz + TDF-FTC
SWEET: Result

Week 24: Change in Plasma Lipids from Baseline

<table>
<thead>
<tr>
<th></th>
<th>EFV + TDF-FTC (switch arm)</th>
<th>EFV + ZDV-3TC (maintain arm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol</td>
<td>-0.39</td>
<td>-0.06</td>
</tr>
<tr>
<td>HDL</td>
<td>-0.03</td>
<td>-0.02</td>
</tr>
<tr>
<td>LDL</td>
<td>-0.10</td>
<td>-0.09</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>0.05</td>
<td>-0.24</td>
</tr>
</tbody>
</table>

Switch to Efavirenz + TDF-FTC
SWEET: Result

Week 24: Change in Plasma Lipids, by Baseline Cholesterol (Treated Analysis)

- Median Change from Baseline (mmol/L)
  - < 5.2 mmol/L (desirable): -0.30
  - 5.2-6.3 mmol/L (borderline): -0.35
  - ≥6.3 mmol/L (high): -1.04

Baseline Cholesterol Category (NCEP)

Switch to Efavirenz + TDF-FTC
SWEET: Result

Week 48: Change in Plasma Lipids from Baseline

<table>
<thead>
<tr>
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<th>EFV + ZDV-3TC (maintain arm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Cholesterol</strong></td>
<td>-0.22</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>HDL</strong></td>
<td>-0.06</td>
<td>0.01</td>
</tr>
<tr>
<td><strong>LDL</strong></td>
<td>-0.08</td>
<td>-0.14</td>
</tr>
<tr>
<td><strong>Triglycerides</strong></td>
<td>-0.17</td>
<td>0.04</td>
</tr>
</tbody>
</table>

**Interpretation**: “Switching from zidovudine/lamivudine to tenofovir disoproxil fumarate/emtricitabine in persons on efavirenz therapy maintains virological control, establishes a once-daily regimen, results in improvements in hemoglobin and key lipid parameters, and preserves and restores limb fat relative to continuation of zidovudine/lamivudine.”

Acknowledgment

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