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

• **Inclusion Criteria (n = 234)**
- Age ≥ 18
- 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 arm**
Efavirenz + TDF-FTC QD  
(n = 117)

**Maintain arm**
Efavirenz QD + ZDV-3TC BID  
(n = 117)

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

![Bar graph showing mean change in limb fat from baseline for two groups.]

- **EFV + TDF-FTC (switch arm):** 261 g
- **EFV + ZDV-3TC (maintain arm):** -189 g

Switch to Efavirenz + TDF-FTC
SWEET: Result

Week 24: Change in Plasma Lipids from Baseline

Switch to Efavirenz + TDF-FTC

SWEET: Result

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

Median Change from Baseline (mmol/L)

<table>
<thead>
<tr>
<th>Baseline Cholesterol Category (NCEP)</th>
<th>EFV + TDF-FTC (switch arm)</th>
<th>EFV + ZDV-3TC (maintain arm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 5.2 mmol/L (desirable)</td>
<td>-0.30</td>
<td>-0.44</td>
</tr>
<tr>
<td>5.2-6.3 mmol/L (borderline)</td>
<td>-0.35</td>
<td>-0.11</td>
</tr>
<tr>
<td>≥6.3 mmol/L (high)</td>
<td></td>
<td>-1.04</td>
</tr>
</tbody>
</table>

Switch to Efavirenz + TDF-FTC
SWEET: Result

Week 48: Change in Plasma Lipids from Baseline

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

Change in Median Value (mmol/L)

Switch to Efavirenz + TDF-FTC
SWEET: Result

**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.”

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

*The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.*