EFV + ABC-3TC versus EFV + TDF-FTC
ASSERT Trial
### Study Design: ASSERT Study

**Background**: Randomized, open label phase 3 study comparing tenofovir DF-emtricitabine plus efavirenz with zidovudine-lamivudine plus efavirenz

**Inclusion Criteria (n = 385)**
- Antiretroviral-naïve patients
- Age ≥ 18
- HIV RNA ≥ 1,000 copies/mL
- HLA-B*5701 negative
- CrCl ≥ 50 mL/min
- No AIDS conditions or HBV infection

**Treatment Arms**
- Efavirenz + abacavir-lamivudine
- Efavirenz + tenofovir DF-emtricitabine

---

**Efavirenz + ABC-3TC versus Efavirenz + TDF-FTC**

**ASSERT: Result**

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

<table>
<thead>
<tr>
<th>Baseline HIV RNA Level</th>
<th>EFV + ABC-3TC</th>
<th>EFV + TDF-FTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>59/192</td>
<td>71/193</td>
</tr>
<tr>
<td>&lt; 100,000 copies/mL</td>
<td>64/95</td>
<td>75/83</td>
</tr>
<tr>
<td>≥ 100,000 copies/mL</td>
<td>55/97</td>
<td>68/110</td>
</tr>
</tbody>
</table>

Efavirenz + ABC-3TC versus Efavirenz + TDF-FTC

ASSERT: Renal Biomarkers

Week 48: Changes in Markers of Renal Tubular Function

**Interpretation**: “The study showed no difference in estimated glomerular filtration rate between the arms, however, increases in markers of tubular dysfunction were observed in the tenofovir/emtricitabine arm, the long-term consequence of which is unclear. A significant difference in efficacy favoring tenofovir/emtricitabine was observed.”
Efavirenz + ABC-3TC versus Efavirenz + TDF-FTC

ASSERT: Bone Effects

Week 48: Changes in Spine and Hip Bone Mineral Density from Baseline

Efavirenz + ABC-3TC versus Efavirenz + TDF-FTC

ASSERT: Bone Effects

Week 48: Proportion of Subjects with Decrease in BMD from Baseline

Acknowledgment

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.