EFV + ABC-3TC versus EFV + TDF-FTC
ASSERT Trial
Efavirenz + ABC-3TC versus Efavirenz + TDF-FTC

ASSERT: Study Design

**Study Design: ASSERT Study**

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

- **Inclusion Criteria** (n = 385)
  - Antiretroviral-naïve adults
  - Age ≥18 years
  - 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

**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

![Bar chart showing bone density loss at hip and spine for EFV + ABC-3TC and EFV + TDF-FTC groups.]

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