Tenofovir AF vs Tenofovir DF in HBeAg-Positive Study 110
Tenofovir AF vs Tenofovir DF for HBeAg-Positive Study 110: Design

• **Background**
  - Randomized double-blind placebo-controlled non-inferiority trial of tenofovir alafenamide (TAF) versus tenofovir disoproxil fumarate (TDF) in HBeAg-positive chronic hepatitis B patients

• **Subjects**
  - N = 1473 with chronic hepatitis B eAg-positive infection
  - HBV DNA level >20,000 IU/mL
  - ALT >60 IU/L in men, >38 IU/L in women; <10 x ULN for both

• **Regimens**
  - Tenofovir AF 25 mg once daily with matching placebo
  - Tenofovir DF 300 mg once daily with matching placebo

• **Study End-Point**
  - HBV DNA level <29 IU/mL at week 48

Tenofovir AF vs Tenofovir DF for HBeAg-Positive Study 110: Design

Study Participants
- HBeAg-positive
- HBV DNA level >20,000 IU/mL
- ALT >60 IU/L for men
- ALT >38 IU/L for women
- CrCl>50 ml/min

Tenofovir alafenamide: 25 mg/day (n = 581)

Tenofovir DF: 300 mg/day (n = 292)

# Tenofovir AF vs Tenofovir DF for HBeAg-Positive

**Study 110: Baseline Characteristics**

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Tenofovir AF (n = 581)</th>
<th>Tenofovir DF (n = 292)</th>
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<tbody>
<tr>
<td>Age, mean (±SD), years</td>
<td>38 (11)</td>
<td>38 (12)</td>
</tr>
<tr>
<td>Male, no. (%)</td>
<td>371 (64)</td>
<td>189 (65)</td>
</tr>
<tr>
<td>Race, no. (%)</td>
<td></td>
<td></td>
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<tr>
<td>Asian</td>
<td>482 (83)</td>
<td>232 (79)</td>
</tr>
<tr>
<td>White</td>
<td>96 (17)</td>
<td>53 (18)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (1)</td>
<td>7 (2)</td>
</tr>
<tr>
<td>ALT &gt; ULN by central lab, no. (%)</td>
<td>537 (98)</td>
<td>288 (99)</td>
</tr>
<tr>
<td>HBV DNA, log$_{10}$ IU/mL (±SD)</td>
<td>7.6 (1.3)</td>
<td>7.6 (1.4)</td>
</tr>
<tr>
<td>FibroTest score, mean (±SD)</td>
<td>0.34 (0.23)</td>
<td>0.32 (0.22)</td>
</tr>
<tr>
<td>Cirrhosis, no. (%)</td>
<td>41 (7)</td>
<td>24 (8)</td>
</tr>
<tr>
<td>Serum creatinine, mean (±SD)</td>
<td>0.81 (0.17)</td>
<td>0.82 (0.16)</td>
</tr>
</tbody>
</table>

Tenofovir AF vs Tenofovir DF for HBeAg-Positive Study 110: Results at Week 48

*Using normal ranges of ≤30 U/L for men and ≤19 U/L for women

Tenofovir AF vs Tenofovir DF for HBeAg-Positive Study 110: Adverse Effects

Week 48 Changes in Bone Mineral Density (BMD)

Tenofovir AF vs Tenofovir DF for HBeAg-Positive Study 110: Conclusion

**Interpretation**: “In patients with HBeAg-positive HBV infection, tenofovir alafenamide was non-inferior to tenofovir disoproxil fumarate, and had improved bone and renal effects. Longer term follow-up is needed to better understand the clinical impact of these changes.”