DOR-TDF-3TC vs. EFV-TDF-FTC as Initial Therapy

DRIVE AHEAD
DOR-TDF-3TC vs. EFV-TDF-FTC as Initial Therapy

DRIVE AHEAD: Design

**DRIVE AHEAD: Study Design**

- **Background**: Randomized, double-blind, active-controlled, phase 3 study evaluating the efficacy and safety of doravirine-tenofovir DF-lamivudine versus efavirenz-tenofovir DF-emtricitabine for treatment-naïve individuals.

- **Inclusion Criteria**
  - Age ≥18
  - Antiretroviral-naïve
  - HIV RNA ≥1,000 copies/mL
  - No resistance to any study drug
  - Chronic HBV or HCV allowed

- **Regimens**
  - Doravirine-TDF-3TC (100/300/300 mg)
  - Efavirenz-TDF-FTC (600/300/200 mg)

DOR-TDF-3TC vs. EFV-TDF-FTC as Initial Therapy

DRIVE AHEAD: Results

Week 48 Virologic Response (Observed Failure)

DOR-TDF-3TC vs. EFV-TDF-FTC as Initial Therapy

DRIVE AHEAD: Results

Week 48 Virologic Response (FDA Snapshot: All missing data= Failure)

Response (%)

HIV RNA ≤50 copies/mL

Doravirine-Tenofovir DF-Lamivudine: 84.3%

Efavirenz-Tenofovir DF-Emtricitabine: 80.8%

HIV RNA >50 copies/mL

Doravirine-Tenofovir DF-Lamivudine: 10.7%

Efavirenz-Tenofovir DF-Emtricitabine: 10.2%

## DOR-TDF-3TC vs. EFV-TDF-FTC as Initial Therapy
### DRIVE AHEAD: Results

<table>
<thead>
<tr>
<th>Treatment Emergent Adverse Events in DRIVE AHEAD Through Week 48</th>
<th>DOR/TDF/3TC (n = 364)</th>
<th>EFV/TDF/FTC (n = 364)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug-related AE’s, %</td>
<td>31</td>
<td>63</td>
</tr>
<tr>
<td>Discontinued due to drug-related AE, %</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Headache, %</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>Diarrhea, %</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>Nausea, %</td>
<td>8</td>
<td>11</td>
</tr>
<tr>
<td>Vomiting, %</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Abnormal Dreams, %</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>Rash, %</td>
<td>5</td>
<td>12</td>
</tr>
</tbody>
</table>

DOR-TDF-3TC vs. EFV-TDF-FTC as Initial Therapy
DRIVE AHEAD: Results

Proportion with Pre-Defined Neuropsychiatric Side Effects at Week 48

DOR-TDF-3TC vs. EFV-TDF-FTC as Initial Therapy
DRIVE AHEAD: Results

Change in Baseline Fasting Lipids at Week 48

<table>
<thead>
<tr>
<th>Lipid</th>
<th>Doravirine-Tenofovir DF-Lamivudine</th>
<th>Efavirenz-Tenofovir DF-Emtricitabine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholesterol</td>
<td>21.8</td>
<td>22.0</td>
</tr>
<tr>
<td>LDL Cholesterol</td>
<td>8.7</td>
<td>8.5</td>
</tr>
<tr>
<td>HDL Cholesterol</td>
<td>1.9</td>
<td>12.4</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>-12.4</td>
<td></td>
</tr>
</tbody>
</table>

Change from Baseline, mg/dL

Conclusions: “In HIV-1 treatment-naive adults, doravirine/lamivudine/tenofovir DF demonstrated non-inferior efficacy to efavirenz/emtricitabine/tenofovir DF at week 48 and was well tolerated, with significantly fewer neuropsychiatric events and minimal changes in LDL-C and non-HDL-C compared with efavirenz/emtricitabine/tenofovir DF.”
Acknowledgment

The National HIV Curriculum is a free educational resource from the AIDS Education and Training Center (AETC) Program and is funded by the United States Health Resources and Services Administration. The project is led by the University of Washington.

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.