Dolutegravir + Boosted-Darunavir as Maintenance Therapy
DUALIS
Switch to Boosted DRV + DTG vs Continue Boosted DRV + 2 NRTI’s

DUALIS: Background

**Study Design: DUALIS**

- **Background:**
  - Randomized, open label, multicenter phase 3 non-inferiority trial comparing a switch to boosted darunavir + dolutegravir to continued boosted darunavir + 2 NRTIs

- **Enrollment Criteria:**
  - Age ≥18 years
  - HIV RNA <50 copies/mL for >6 months
  - Taking boosted darunavir + 2 NRTI’s
  - One HIV RNA level >200 copies/mL within past 6 months allowed, as long as subsequently returned to <50 copies/mL
  - Estimated GFR >50 mL/min
  - No active hepatitis B, AIDS-defining condition, or severe hepatis impairment

**Switch Regimen**

Boosted darunavir + dolutegravir
(n = 131)

**Maintain Regimen**

Boosted darunavir + 2 NRTIs
(n = 132)

Primary endpoint: virologic response at 48 weeks by FDA snapshot

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DUALIS: Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Boosted DRV + DTG (n = 131)</th>
<th>Boosted DRV + 2 NRTIs (n = 132)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, median (IQR)</td>
<td>47 (39-55)</td>
<td>48 (40-53)</td>
</tr>
<tr>
<td>Male sex, n (%)</td>
<td>115 (88)</td>
<td>122 (92)</td>
</tr>
<tr>
<td>White, n (%)</td>
<td>118 (90)</td>
<td>118 (89)</td>
</tr>
<tr>
<td>MSM, n (%)</td>
<td>90 (69)</td>
<td>92 (70)</td>
</tr>
<tr>
<td>eGFR, median (IQR), mL/min</td>
<td>92 (70-104)</td>
<td>92 (81-106)</td>
</tr>
<tr>
<td>Baseline CD4, median (IQR)</td>
<td>609 (401-818)</td>
<td>585 (453-823)</td>
</tr>
<tr>
<td>NRTIs at baseline, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tenofovir-DF-emtricitabine</td>
<td>110 (84)</td>
<td>94 (71)</td>
</tr>
<tr>
<td>Tenofovir-alafenamide-emtricitabine</td>
<td>11 (8)</td>
<td>13 (10)</td>
</tr>
<tr>
<td>Abacavir-lamivudine</td>
<td>9 (7)</td>
<td>23 (17)</td>
</tr>
</tbody>
</table>

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DUALIS: Results

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

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DUALIS: Results

Week 48 Changes in Serum Lipid Parameters

Conclusions: “Switching to dolutegravir plus boosted darunavir was noninferior to continuing 2 nucleoside reverse transcriptase inhibitors plus boosted darunavir in subjects already treated with 2 nucleoside reverse transcriptase inhibitors plus boosted darunavir.”

The National HIV Curriculum is an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $800,000 with 0% financed with non-governmental sources. This project is led by the University of Washington’s Infectious Diseases Education and Assessment (IDEA) Program.

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