Switch from Boosted PI to Dolutegravir

NEAT 022
Switching from a Boosted PI to Dolutegravir NEAT 022: Design

<table>
<thead>
<tr>
<th>Study Design</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Background</strong>: Randomized, open-label, multicenter trial in Europe evaluating the impact of switching from a boosted PI to dolutegravir in virologically suppressed persons with older age or elevated cardiovascular risk.</td>
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<tr>
<td><strong>Inclusion Criteria</strong></td>
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<tr>
<td>- Age ≥50 years or Framingham 10-year estimated cardiovascular event risk &gt;10%</td>
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<tr>
<td>- HIV RNA &lt;50 copies/mL</td>
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<tr>
<td>- On 2 NRTI’s + boosted PI</td>
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<tr>
<td>- No prior virologic failure and no genotypic resistance mutations</td>
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</tbody>
</table>

- **Switch Regimen**
  - Dolutegravir + 2 NRTI’s
  - (n = 205)

- **Maintenance Regimen**
  - Boosted PI + 2 NRTI’s
  - (n = 210)

48 weeks (primary endpoint), after which all participants switch to DTG + 2 NRTI’s

Switching from a Boosted PI to Dolutegravir
NEAT 022: Baseline Regimens

<table>
<thead>
<tr>
<th>NRTI Backbone</th>
<th>DTG + 2 NRTI’s  (n = 205)</th>
<th>PI/r + 2 NRTI’s  (n = 210)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenofovir DF-Lamivudine</td>
<td>134 (65.4%)</td>
<td>135 (64.3%)</td>
</tr>
<tr>
<td>Abacavir-Lamivudine</td>
<td>63 (30.7%)</td>
<td>67 (31.9%)</td>
</tr>
<tr>
<td>Other</td>
<td>8 (3.9%)</td>
<td>8 (3.8%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Boosted PI</th>
<th>DTG + 2 NRTI’s  (n = 205)</th>
<th>PI/r + 2 NRTI’s  (n = 210)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Darunavir + ritonavir</td>
<td>105 (51.5%)</td>
<td>107 (51.0%)</td>
</tr>
<tr>
<td>Atazanavir + ritonavir</td>
<td>77 (37.7%)</td>
<td>74 (35.2%)</td>
</tr>
<tr>
<td>Other</td>
<td>22 (10.7%)</td>
<td>29 (13.8%)</td>
</tr>
</tbody>
</table>

Switching from a Boosted PI to Dolutegravir
NEAT 022: Results

Week 48: Virologic Response by FDA Snapshot Analysis (ITT)

Switching from a Boosted PI to Dolutegravir
NEAT 022: Results

Mean Percentage Change in Lipids at 48 Weeks

<table>
<thead>
<tr>
<th></th>
<th>Dolutegravir + 2 NRTI's</th>
<th>Ritonavir-Boosted PI + 2 NRTI's</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cholesterol</td>
<td>-8.7</td>
<td>0.7</td>
</tr>
<tr>
<td>LDL</td>
<td>-7.7</td>
<td>2.0</td>
</tr>
<tr>
<td>HDL</td>
<td>-5.6</td>
<td>1.1</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>-25.2</td>
<td>4.2</td>
</tr>
</tbody>
</table>

Interpretation: “Switching to a dolutegravir regimen in virologically suppressed HIV type 1 patients with high cardiovascular disease risk was noninferior, and significantly improved lipid profiles.”

Acknowledgment

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