Switch from Boosted PI to Dolutegravir in Suppressed Individuals with Older Age or Elevated Cardiovascular Risk

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

**Study Design**

**Background**: 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

**Inclusion Criteria**
- Age > 50 or Framingham 10-year estimated cardiovascular event risk >10%
- HIV RNA <50 copies/mL
- On 2 NRTI’s + boosted PI
- No prior virologic failure and no genotypic resistance mutations

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

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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>TDF/FTC</td>
<td>134 (65.4%)</td>
<td>135 (64.3%)</td>
</tr>
<tr>
<td>ABC/3TC</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>

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NEAT 022: Results

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

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NEAT 022: Results

Mean Percentage Change in Lipids at 48 Weeks

- Total Cholesterol: -8.7 to -18.4
- LDL: -7.7 to -4.2
- HDL: 1.1 to 2.5
- Triglycerides: 2.0 to 4.2

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.”