Raltegravir plus Ritonavir-Boosted Darunavir
NEAT001/ANRS 143 Trial
Darunavir/r + Raltegravir versus Darunavir/r + TDF-FTC

NEAT001/ANRS143: Study Design

Study Design: NEAT001/ANRS 143

**Background:** Randomized, open-label, non-inferiority trial study to evaluate the efficacy and safety of a NtRTI-sparing regimen of raltegravir and boosted darunavir vs. combination tenofovir DF-emtricitabine and boosted darunavir

**Inclusion Criteria (n = 805)**
- Age ≥ 18
- Antiretroviral-naïve
- HIV RNA > 1,000 copies/mL
- CD4 < 500 cells/mm³
- No major resistance mutations

**Treatment Arms**
- Darunavir 800 mg QD + Ritonavir 100 mg QD + Raltegravir 400 mg BID
- Darunavir 800 mg QD + Ritonavir 100 mg QD + TDF-FTC QD

Darunavir/r + Raltegravir versus Darunavir/r + TDF-FTC NEAT001/ANRS143: Result

Week 96: Treatment Failure, by Baseline HIV RNA*

*Kaplan-Meier estimates of proportion of patients reaching endpoints

Darunavir/r + Raltegravir versus Darunavir/r + Tenofovir DF-Emtricitabine

Week 96: Treatment Failure, by Baseline CD4 Count*

*Kaplan-Meier estimates of proportion of patients reaching endpoints

Darunavir/r + Raltegravir versus Darunavir/r + TDF-FTC NEAT001/ANRS143: Result

Week 96: Treatment Failure, by HIV RNA and CD4 Count (combined effects)

Darunavir/r + Raltegravir versus Darunavir/r + TDF-FTC NEAT001/ANRS143: Result

Week 96: Change in Lipids from Baseline

Week 96: Change in Creatinine Clearance from Baseline

Darunavir/r + Raltegravir versus Darunavir/r + TDF-FTC
NEAT001/ANRS143: Substudy Result

Week 48: Changes in Spine and Hip Bone Mineral Density from Baseline

### Genotype Resistance Testing in NEAT001/ANRS143

<table>
<thead>
<tr>
<th>Resistance Testing and Results</th>
<th>RAL + DRV/r (n = 401)</th>
<th>DRV/r + TDF/FTC (n = 404)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients who underwent genotype resistance testing at virological failure</td>
<td>29</td>
<td>13</td>
</tr>
<tr>
<td>Major resistance mutations detected</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Reverse transcriptase</td>
<td>1*</td>
<td>0</td>
</tr>
<tr>
<td>Protease</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Integrase</td>
<td>5**</td>
<td>0</td>
</tr>
</tbody>
</table>

*K65R mutation; **N155H mutation

**Interpretation**: “Our NtRTI-sparing regimen was non-inferior to standard treatment and represents a treatment option for patients with CD4 cell counts higher than 200 cells per µL.”
Acknowledgment

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