Maraviroc in Patients with Multiclass Drug Resistance

MOTIVATE 1 and 2 Trials
Maraviroc in Patients with Multiclass Drug Resistance

MOTIVATE 1 and 2: Study Design

**Study Design: MOTIVATE 1 and 2**

- **Background**: Parallel, randomized, double-blind, placebo-controlled, phase 3 trials to evaluate safety and efficacy of maraviroc in treatment-experienced patients.

- **Inclusion Criteria** (n = 1049)
  - Age \( \geq 16 \)
  - Resistance to \( \geq 3 \) ARV classes
  - R-5 tropic virus
  - On stable ARV regimen or no regimen for \( \geq 4 \) weeks with HIV RNA \( \geq 5000 \) copies/ml

- **Treatment Arms**
  - Maraviroc* once daily + OBT**
  - Maraviroc* twice daily + OBT**
  - Placebo + OBT**

**MOTIVATE =** Maraviroc versus Optimized Therapy in Viremic Antiretroviral Treatment-Experienced Patients

- MVC once daily + OBT (n = 414)
- MVC twice daily + OBT (n = 426)
- Placebo + OBT (n = 200)

*MVC dose 300mg daily or BID with PI-containing regimens, 150mg daily or BID with all other regimens
**OBT= Optimized Background Therapy (investigator-selected, 3-6 agents).

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MOTIVATE 1 and 2: Results

Week 48: Virologic Response (ITT, missing=nonresponse)

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MOTIVATE 1 and 2: Results

Week 48: Change in CD4 Cell Count from Baseline

## Maraviroc in Patients with Multiclass Drug Resistance

### MOTIVATE 1 and 2: Result

#### Grade 2-4 Adverse Events (all causes) Occurring in ≥ 5% of Patients (MOTIVATE 1 and MOTIVATE 2 Study Populations Combined)

<table>
<thead>
<tr>
<th></th>
<th>Maraviroc once daily + OBT (n = 414)</th>
<th>Maraviroc twice daily + OBT (n = 426)</th>
<th>Placebo (n = 219)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>43 (10%)</td>
<td>32 (8%)</td>
<td>20 (10%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>13 (3%)</td>
<td>21 (4%)</td>
<td>13 (6%)</td>
</tr>
<tr>
<td>Fever</td>
<td>9 (2%)</td>
<td>24 (6%)</td>
<td>9 (4%)</td>
</tr>
<tr>
<td>Headache</td>
<td>22 (5%)</td>
<td>9 (2%)</td>
<td>12 (6%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>25 (6%)</td>
<td>25 (6%)</td>
<td>15 (7%)</td>
</tr>
<tr>
<td>Upper respiratory infection</td>
<td>16 (4%)</td>
<td>20 (5%)</td>
<td>3 (1%)</td>
</tr>
<tr>
<td>Death</td>
<td>6 (1%)</td>
<td>9 (2%)</td>
<td>2 (1%)</td>
</tr>
</tbody>
</table>

Conclusions: “Maraviroc, as compared with placebo, resulted in significantly greater suppression of HIV-1 and greater increases in CD4 cell counts at 48 weeks in previously treated patients with R5 HIV-1 who were receiving OBT.”

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