Maraviroc in Treatment-Experienced Patients with non-R5 HIV
A4001029 Trial
Maraviroc in Treatment-Experienced Patients with non-R5 HIV
A4001029: Study Design

**Study Design: A4001029**

- **Background**: Randomized, double-blind, placebo-controlled, phase 2b trials to evaluate safety and efficacy of maraviroc in treatment-experienced patients infected with non-R5 tropic HIV.

- **Inclusion Criteria (n = 190)**
  - Resistance to ≥2 ARV classes, or ≥3 months of treatment ≥3 ARV classes
  - X4, dual, or mixed-tropic HIV

- **Treatment Arms**
  - Maraviroc 300 mg once daily + OBT*
  - Maraviroc 300 mg twice daily + OBT*
  - Placebo + OBT*

*OBT = Optimized Background Therapy (investigator selected, 3-6 agents). MVC dose reduced to 150 mg (daily or BID) in patients taking protease inhibitors (except tipranavir) or delavirdine.

Maraviroc in Treatment-Experienced Patients with non-R5 HIV A4001029: Results

Week 24: Virologic Response*

![Bar chart showing virologic response at Week 24 for three groups: MVC once daily + OBT, MVC twice daily + OBT, and Placebo + OBT. The chart shows the percentage of patients with HIV RNA <50 copies/mL.]

- MVC once daily + OBT: 21
- MVC twice daily + OBT: 27
- Placebo + OBT: 16

*Values for patients with missing data or who discontinued treatment imputed as 0

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A4001029: Results

Week 24: Change in CD4 Cell Count from Baseline*

*Using last observation carried forward method

Conclusions: “In this exploratory study involving extensively treatment-experienced patients with advanced, non-R5 HIV-1 infection, neither superiority nor noninferiority was statistically demonstrated for either maravirocin dosage compared with placebo at 24 weeks of treatment.”

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