**Background**

Dalfampridine extended-release tablets (dalfampridine-ER; known as Zalrotate) were observed to have a favorable tolerability profile that is consistent with prior studies. The most common adverse events (AEs) leading to withdrawal were those related to muscle weakness (11.8% on dalfampridine-ER vs. 8.2% on placebo). Based on the findings from this study, 10 mg twice daily was chosen as the fixed daily dose.

**Methods**

In a double-blind, parallel-group, randomized, placebo-controlled study, patients who had taken any formulation of dalfampridine-ER must have withdrawn from treatment (at randomization) for at least 4 weeks. Women of childbearing potential must have a negative urine pregnancy test at baseline. All patients had a history of relapsing-remitting MS and a sustained relapse (within the previous year). The primary endpoint of this study was the change in the average walking speed (WS) from baseline to Week 4.

**Results**

- **Demographic and clinical characteristics** (Table 1): The subjects were primarily women (70.8%) and the mean age was 51.2 years. The baseline Expanded Disability Status Scale (EDSS) score was 3.7 (2.6) across all randomized patients.

- **Efficacy and tolerability assessments** were performed at all study visits: change from baseline in WS at Week 4, the percentage of patients with a ≥20% improvement in WS, and the percentage of patients achieving a 44.1 feet increase in WS at 8 weeks. Treatment-emergent adverse events (TEAEs) were generally mild or moderate in severity.

- **No statistically significant difference** was found between dalfampridine-ER 10 mg and placebo. However, the difference between dalfampridine-ER 5 mg and placebo was statistically significant (20.5 feet; P=0.014).

- **TEAEs were generally mild or moderate in severity** and were reported in 98.6% of patients. The most common TEAEs were muscle weakness (18.9%), back pain (8.7%), and insomnia (5.6%).

**Conclusions**

- **Dalfampridine ER 5 mg twice daily failed to demonstrate efficacy** in the improvement of walking speed.

- **While the 10 mg dose did not show statistically significant effects using a previously untested outcome measure, significant effects were observed in a post hoc analysis using measures similar to those previously evaluated in clinical trials**.

**Disclosures**

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