(S114) DALFAMPRIDINE IMPROVES WALKING IN MULTIPLE SCLEROSIS PATIENTS: POOLED DATA FROM THREE CLINICAL TRIALS


1The Schapiro Center for Multiple Sclerosis, Minneapolis Clinic of Neurology, Minneapolis, MN; 2Department of Neurology, University of Rochester Medical Center, Rochester, NY; 3MS Neuro-Rehabilitation, Evergreen Hospital Medical Center, Kirkland, WA; 4Biostatistics and Data Management, Acorda Therapeutics, Inc, Hawthorne, NY; 5Acorda Therapeutics, Inc, Hawthorne, NY

Objectives: To evaluate dalfampridine (Ampyra extended-release tablets) (D-ER) for improvement in walking in patients with multiple sclerosis (MS) as determined by walking speed (WS), using data pooled from three randomized, placebo-controlled, multicenter trials (MS-F202, MS-F203, and MS-F204). D-ER was previously known as fampridine or fampridine-SR. Methods: Data for patients who received the therapeutic dose of D-ER, 10 mg twice a day, in three randomized controlled trials were pooled (n = 394) and compared with placebo (n = 237). Comparative analyses were based on the percent change from baseline in WS using the Timed 25-Foot Walk, where the baseline value was defined as the average of four pretreatment visits, and the treatment value was defined as the average over the double-blind visits. The percent change in WS for the pooled populations for each double-blind visit was evaluated by time interval to account for differences in study schedules (days 1–21, 22–49, 50–77, and 78–end of double-blind phase). The percent changes were analyzed via analysis of variance with effects for treatment group, study, and site within study. Results: Demographic and clinical characteristics were generally similar in the pooled D-ER and placebo groups. The overall percent change in WS improved significantly by 13.4% (95% confidence interval [CI], 11.6%-15.1%) in the D-ER group compared with placebo (5.8%; 95% CI, 3.6%-8.0%; P < .001) relative to baseline values, which were similar in D-ER and placebo (mean [SD], 2.05 (0.76) feet/sec D-ER; 2.09 (0.74) feet/sec placebo). These results were consistent with the individual studies. A significantly greater proportion of patients in the D-ER group than in the placebo group had improvements in WS from their individual baseline that were greater than 10% (54.1% vs. 32.5%, P < .001), 20% (31.5% vs. 13.1%, P < .001), 30% (15.5% vs. 3.8%, P < .001), and 40% (6.6% vs. 2.5%, P < .027). For each double-blind time interval, the percent improvement in WS was significantly greater in D-ER relative to placebo (P < .05), suggesting a consistent treatment effect. Conclusions: The pooled study data demonstrate the efficacy of D-ER for improvement in walking as determined by change of WS from baseline in patients with MS.

Supported by: Acorda Therapeutics


Keywords: symptomatic treatment of MS