Analyses of the Effect of Baseline Age on the Efficacy and Safety of Siponimod in Patients with Active Secondary Progressive Multiple Sclerosis from the Phase 3 EXPAND Study

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OBJECTIVE

Assess efficacy/safety of siponimod in patients with active SPMS in subgroups of patients aged <50 and ≥50 years at Baseline from EXPAND.

BACKGROUND

In EXPAND, for patients with active SPMS, siponimod significantly reduced risk of 3-month (primary endpoint) and 6-month CDP by 31% and 37% vs placebo, respectively.

DESIGN/METHODS

Post hoc analyses were performed in subgroups of patients aged <50 and ≥50 years at Baseline with active SPMS, randomized to siponimod 2 mg daily or placebo. Proportional hazard model was used to analyze time to 3- and 6-month CDP (as per EDSS). Number and percentage of patients with AEs were reported. Analyses for hypothesis generation only.

RESULTS

There were 779 patients with active SPMS: 471 aged <50 years (siponimod, n=326; placebo, n=145) and 308 aged ≥50 years (siponimod, n=190; placebo, n=118). In those <50 years, siponimod reduced 3-month CDP risk by 30.5% vs placebo (siponimod, n=87 (26.7%); placebo, n=52 (35.9%); HR (95% CI): 0.70 (0.49–0.98); p=0.0383), and reduced 6-month CDP risk by 37.9% (siponimod, n=69 (21.2%); placebo, n=46 (31.7%); HR (95% CI): 0.62 (0.43–0.90); p=0.0126). In patients ≥50 years, siponimod reduced 3-month and 6-month CDP risk by 37.7% and 37.4%, respectively, vs placebo (3-month: siponimod, n=42 (22.1%); placebo, n=39 (33.1%); HR (95% CI): 0.62 (0.40–0.96); p=0.0332; 6-month: siponimod, n=30 (15.8%); placebo, n=28 (23.7%); HR (95% CI): 0.63 (0.37–1.0); p=0.0749). Siponimod was generally well tolerated in both subgroups. Rates of any AE were similar for siponimod and placebo in patients <50 years (85.6% vs 80.0%), and slightly higher for siponimod in those ≥50 years (88.9% vs 76.3%). Rates of SAEs and AEs leading to discontinuation were similar between groups.

CONCLUSIONS

Siponimod provided similar clinical benefits in reducing CDP risk in patients aged <50 and ≥50 years with active SPMS. These results are consistent with the overall active SPMS cohort in EXPAND.