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

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Abstract Text:

Background:

Siponimod is a selective S1P receptor (S1P1 and S1P5) modulator, approved in the USA for treatment of relapsing forms of MS, including clinically isolated syndrome, relapsing-remitting MS and active secondary progressive MS (SPMS). In the phase 3 EXPAND trial, for patients with active SPMS, siponimod significantly reduced risk of 3-month (primary endpoint) and 6-month confirmed disability progression (CDP) by 31% and 37% versus placebo, respectively.

Objectives:

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

Methods:

Post hoc analyses were performed in subgroups of patients aged <50 and ≥50 years at Baseline with active SPMS, defined as having at least one relapse in the 2 years before Baseline and/or ≥1 T1 gadolinium-enhancing lesion at Baseline, randomized to siponimod 2 mg daily or placebo. Proportional hazard model was used in the analysis of time to 3- and 6-month CDP (as per EDSS scores). Number and percentage of patients with adverse events (AEs) were reported. Analyses for hypothesis generation only.

Results:

There were 779 patients with active SPMS: 471 patients aged <50 years (siponimod, n=326; placebo, n=145) and 308 patients aged ≥50 years (siponimod, n=190; placebo, n=118). In those <50 years, siponimod reduced risk of 3-month CDP by 30.5% compared with placebo (siponimod, n=87 (26.7%); placebo, n=52 (35.9%); hazard ratio (HR) (95% confidence interval (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 the subgroup of patients ≥50 years, siponimod reduced the risk of 3-month and 6-month CDP by 37.7% and 37.4%, respectively, versus 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 serious AEs and AEs leading to discontinuation were similar between groups.

Conclusions:

Siponimod provided similar clinical benefits in reducing CDP risk in patients aged <50 years and ≥50 years with active SPMS. In addition, these results are consistent with the overall active SPMS

cohort in EXPAND.

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