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Safety and Efficacy of Siponimod in Patients with Active Secondary Progressive Multiple Sclerosis Identifying As Hispanic from the Expand Study

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Abstract Text:

Background:

In the Phase 3 EXPAND trial siponimod, a selective S1P receptor modulator, significantly reduced risk of 3-month and 6-month confirmed disability progression (CDP) by 31% and 37%, respectively, in patients with active secondary progressive MS (SPMS). Minority groups are persistently underrepresented in clinical trials, resulting in limited data to inform decision-making for minority patients, and presenting an urgent need for clinical evidence.

Objectives:

In an exploratory post hoc analysis, the efficacy and safety profile of siponimod 2 mg daily was analyzed in a subgroup of patients with active SPMS from EXPAND who identified as Hispanic.

Methods:

Active SPMS was defined as having ≥1 relapse in the 2 years before Baseline and/or ≥1 T1 gadolinium-enhancing lesion at Baseline. Proportional hazard and ANCOVA models were applied to the analyses of time to 3- and 6- month CDP (as per EDSS scores) and change in SDMT, respectively. Number and percentage of patients with adverse events (AEs) were reported.

Results:

Of 1651 patients in the overall EXPAND population, 106 (6.4%) identified as Hispanic, of which 40 had active SPMS (siponimod [n=31], placebo [n=9]). Mean (SD) age was 47.4 (7.6), 65.0% were female, mean (SD) duration since MS onset was 15.3 (6.4) years, mean (SD) baseline EDSS score was 5.4 (1.1), and 77.5% of patients had ≥1 MS relapse in the last 2 years prior to Baseline. Siponimod showed a reduction of 42% on 3-month CDP risk (HR [95% CI]: 0.58 [0.17, 1.92]; p=0.37) and of 67% in 6-month CDP risk (HR [95% CI]: 0.33 [0.07, 1.53], p=0.16) vs placebo. At Month 12, the adjusted mean SDMT score changed minimally from Baseline for patients on siponimod, whereas the placebo group had a 4.7 point worsening, with a difference between treatment groups of 4.9 (SE 2.6, p=0.07). Siponimod was generally well tolerated in both treatment groups. Rates of any AE were similar for siponimod and placebo (71.0% vs 77.8%). Rates of serious AEs and AEs leading to discontinuation were similar between treatment groups.

Conclusions:

There was a numeric relative reduction in CDP risk in siponimod-treated patients with active SPMS identifying as Hispanic, consistent with results observed in the overall active SPMS cohort in EXPAND. The study was not designed to detect differences between subgroups, and the small sample size does not allow us to draw conclusions on statistical significance of the results in the

Hispanic subgroup. This brings into focus the challenges of minority under-representation in clinical trials.

Title:
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