Safety and Tolerability of Conversion to Siponimod in Patients with Advancing Relapsing Multiple Sclerosis: A Subgroup Analysis by Race and Ethnicity of EXCHANGE Interim Data

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OBJECTIVE

Report on a subgroup analysis by race/ethnicity of EXCHANGE interim data.

BACKGROUND

Minority groups are persistently underrepresented in clinical trials, resulting in limited data to inform clinical decision-making for these patients. EXCHANGE (NCT03623243) enrolled a diverse patient population and presents opportunity to assess real-world MS treatment patterns and safety/tolerability in conversion to siponimod.

DESIGN/METHODS

EXCHANGE included patients aged 18–65 years with advancing RMS, EDSS 2.0–6.5, and on continuous oral/injectable/infusion DMTs for ≥3 months at time of consent; primary endpoint was drug-related AE incidence. Subgroups were assessed according to patient-reported race/ethnicity.

RESULTS

Of 163 patients in the overall EXCHANGE interim population, 126 (77.3%) identified as White non-Hispanic/Latino, 23 (14.1%) Black/African American, and 36 (22.1%) Hispanic/Latino. Mean (SD) age was 46.6 (10.3) overall, 43.8 (8.6) Black/African American, and 40.3 (11.3) years Hispanic/Latino. Mean (SD) time since MS diagnosis was 12.2 (8.7), 10.5 (7.1), 10.2 (7.7) years; median EDSS scores were 3.5, 3.5, 3.0, respectively. Proportion of patients with no relapses in the year prior to screening were 54.0%, 34.8%, 41.7%. 47.8% of the Black/African American subgroup were on injectable DMTs before switching to siponimod, vs 27.6% overall and 16.7% Hispanic/Latino. 77.8% of the Hispanic/Latino subgroup were on oral DMTs, vs 68.7% overall and 47.8% Black/African American. Patients reporting ≥1 AE possibly related to

siponimod treatment were 31.3% (95%CI: 24.4–39.1) overall, 17.4% (5.7–39.5) Black/African American, and 44.4% (28.3–61.7) Hispanic/Latino. Most common AE by preferred term was headache in the overall population (n=13; 8.0%), 11 of whom were Hispanic/Latino. AEs experienced in Black/African American subgroup were different from the other two groups.

CONCLUSIONS

EXCHANGE enrolled a higher proportion of minority groups vs other recent MS clinical trials. Findings of this analysis may suggest differences in MS treatment patterns and presents limited evidence that a differed safety/tolerability profile may be experienced in minority groups.