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Title: A First Look at the Characteristics of Patients with Multiple Sclerosis Initiating Siponimod Therapy in the United States

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Background: In March 2019, siponimod was approved in the United States (US) for the treatment of relapsing forms of multiple sclerosis (MS) in adults, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. This indication is broader than the secondary progressive MS patient population studied in the pivotal Phase 3 trial.

Objective: To describe characteristics of siponimod users in the first 10 months following US approval using linked pharmacy and medical administrative claims data.

Methods: Adult patients (≥18 years) in IQVIA's longitudinal pharmacy claims database with a siponimod claim between 1 Apr 2019 and 29 Feb 2020 (first claim=index date) and ≥2 medical claims with a MS diagnosis occurring ≥30 days apart in IQVIA's medical claims database were identified. Patient characteristics including comorbid conditions, disability level, MS relapse, durable medical equipment (DME) use, and prior disease modifying therapy (DMT) were assessed during a 1-year baseline period. Disability was assessed through identification of expanded disability status scale (EDSS)-related symptoms, diagnoses and DME claims.

Results: A total of 1,081 siponimod patients were identified. Mean (standard deviation [SD]) age was 53.4 (11.4) years, 76% were female, and mean (SD) Charlson Comorbidity Index score was 0.7 (1.1). Common MS-related comorbidities included depression (19%), urinary tract infection (18%), fatigue (18%), anxiety (13%) and sleep disorders (13%). Most patients had moderate (41%) or severe (21%) disability at siponimod initiation. A MS relapse occurred in 28% of patients in the prior year. DME use was observed in 118 (11%) patients, mostly for wheelchairs (36%) or walkers (32%). Most patients (60%) had no evidence of DMT use in the prior year. Among 430 patients with a prior DMT, 57% used oral medications, 32% used injectables, and 11% were on infusion. The most common DMTs used prior to siponimod were dimethyl fumarate (21%), fingolimod (20%), and glatiramer acetate (19%); 42% of patients with prior DMT use discontinued treatment >60 days before initiating siponimod.

Conclusions: This real-world study of early use of siponimod in MS patients demonstrated use in an older MS patient population with moderate-to-severe disability without relapses in the past year. Most

patients had no DMT use in the year prior to siponimod initiation, suggesting siponimod fulfills an unmet need in this population.