Generic Name:
Siponimod
Trade Name:
Mayzent
Company:
Novartis
Notes:

FDA has approved siponimod for treatment of adults with relapsing forms of multiple sclerosis (MS), including secondary progressive multiple sclerosis (SPMS) with active disease, relapsing remitting multiple sclerosis, and clinically isolated syndrome. SPMS is a debilitating form of MS characterized by progressive and irreversible neurological disability. Patients will not require a first dose observation (cardiac monitoring upon initiation) unless they have certain preexisting cardiac conditions.

Approval was based on groundbreaking data from the Phase III EXPAND study, a randomized, double-blind, placebo-controlled study comparing the efficacy and safety of siponimod versus placebo in people living with SPMS. Patients enrolled in EXPAND were representative of a typical SPMS population. At study initiation, patients had a mean age of 48 years and had been living with MS for approximately 16 years. More than 50% had a median Expanded Disability Status Scale score of 6.0 and relied on a walking aid.

Siponimod significantly reduced the risk of 3-month confirmed disability progression (CDP), meaningfully delayed the risk of 6-month CDP, and reduced the annualized relapse rate by 55%. Furthermore, EXPAND showed significant favorable outcomes in other relevant measures of MS disease activity, including cognition, MRI disease activity, and brain volume loss.

The most common adverse reactions (incidence >10%) were headache, hypertension, and transaminase increase.

Medication Monitor Categories:
New Drug Approvals