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Review

Siponimod: A new approved oral drug to treat multiple sclerosis

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ABSTRACT

The U.S. Food and Drug Administration on 26 March 2019 approved Siponimod tablets to treat adults with relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. The efficacy of Siponimod was shown in a clinical trial of 1,651 patients that compared Siponimod to placebo in patients with Secondary Progressive Multiple Sclerosis (SPMS) who had evidence of disability progression in the prior two years and no relapses in the three months prior to enrollment. The primary endpoint of the study was the time to three-month confirmed progression in disability. The fraction of patients with confirmed progression of disability was statistically significantly lower in the Siponimod group than in the placebo group. Siponimod also decreased the number of relapses experienced by these patients. In the subgroup of patients with non-active SPMS, the results were not statistically significant.

Keywords: Siponimod, multiple sclerosis, relapsing-remitting disease, and active secondary progressive disease

Multiple Sclerosis

MS is a chronic, inflammatory, autoimmune disease of the central nervous system that disrupts communications between the brain and other parts of the body. Most people experience their first symptoms of MS between the ages of 20 and 40. MS is among the most common causes of neurological disability in young adults and occurs more frequently in women than in men.

For most people, MS starts with a relapsing-remitting course, in which episodes of worsening function (relapses) are followed by recovery periods (remissions). These remissions may not be complete and may leave patients with some degree of residual disability. Many, but not all, patients with MS experience some degree of persistent disability that gradually worsens over time. In some patients, disability may progress independent of relapses, a process termed secondary progressive multiple sclerosis (SPMS). In the first few years of this process, many patients continue to experience relapses, a phase of the disease described as active SPMS. Active SPMS is one of the relapsing forms of MS and drugs approved for the treatment of relapsing forms of MS can be used to treat active SPMS. Later, many patients with SPMS stop experiencing new relapses, but disability continues to progress, a phase called non-active SPMS.

Siponimod

Siponimod must be dispensed with a patient Medication Guide that describes important information about the drug's uses and risks. Siponimod may increase the risk of infections, so patients should have a complete blood count taken before treatment is initiated. The drug may cause macular edema, so patients should contact their physician if they experience a change in vision. Siponimod may cause transient decreases in heart rate and may cause a decline in lung function. Liver enzymes should be checked before the initiation of the drug and health care professionals should closely monitor patients with severe liver impairment. Health care professionals should monitor the

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patient's blood pressure during treatment. Women of childbearing potential should use effective contraception during and for 10 days after stopping the drug due to the potential risk of fetal harm. Health care professionals should monitor patients for posterior reversible encephalopathy syndrome and monitor patients that had treatment with immunosuppressive/immune-modulating therapies because there may be unintended additive immunosuppression with Siponimod.

The most common adverse reactions reported by patients receiving Siponimod in the clinical trials include headache, high blood pressure, and liver function test increases.

The FDA granted approval of Siponimod (Mayzent) to Novartis.

Dosage Forms and Strength:

Tablets: 0.25 mg and 2 mg

Indications and Usage:

Siponimod is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

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