FDA OKs new drug for multiple sclerosis

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(HealthDay)—A new pill for relapsing forms of multiple sclerosis (MS) has won approval from the U.S. Food and Drug Administration.

Generally, relapsing MS involves periods of worsening symptoms followed by recovery periods. Over time, some disability follows independent of relapses, and this is called secondary progressive multiple sclerosis, or SPMS.

Approval of the medication Mayzent (siponimod) was based on a clinical trial of more than 1,600 patients with SPMS.

"Multiple sclerosis can have a profound impact on a person's life," said Dr. Billy Dunn, director of the FDA's division of neurology products in the Center for Drug Evaluation and Research.

"We are committed to continuing to work with companies that are developing additional treatment options for patients with multiple sclerosis," Dunn added in an agency news release.

Among patients with active SPMS, those who took the drug had fewer relapses and were less likely to have confirmed progression of MS-related disability after three months than those who received a placebo, the FDA noted.

Among patients with non-active SPMS, the differences between those who took the new Novartis drug and those who received the placebo were not statistically significant.

MS is an autoimmune disease of the central nervous system that disrupts communications between the brain and other parts of the body. Symptoms, which can include blurred vision, muscle weakness and difficulty with balance and coordination, typically appear between ages 20 and 40.

The most common side effects reported by patients taking Mayzent included headache, high blood pressure and liver function problems.

The drug may increase the risk of infections, so patients should have a complete blood count taken before treatment begins, the FDA said. Other potential risks include an eye condition called macular edema; decreases in heart rate; declines in lung function; high blood pressure, and fetal harm in pregnant women.

Health care professionals should monitor patients for a treatable illness called posterior reversible encephalopathy syndrome, according to the FDA. They should also closely watch patients who have had treatment with immunosuppressive/immune-modulating therapies because there may be unintended immunosuppression with Mayzent.

MS is one of the most common causes of neurological disability in young adults and occurs more often in women than in men.

More information: FDA

The U.S. National Institute of Neurological Disorders and Stroke has more on multiple

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