Novartis gains FDA approval for new MS drug

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(AP) -- Federal health regulators have approved the first pill to treat the underlying causes of multiple sclerosis, a debilitating nervous system disorder that has traditionally been treated with injectable drugs.

The Food and Drug Administration approved Swiss drugmaker Novartis' treatment Gilenya to reduce relapses in patients with multiple sclerosis, who experiences loss of balance, muscle spasms and other movement problems.

There is no cure for the disease, but steroids can reduce the duration and severity of symptoms in the short term, and seven treatments on the market have had success in reducing recurrence of symptoms.

All involve daily or regular injections, which doctors say discourages some patients from keeping up with their treatment.

"One of the things Gilenya offers is an alternative to injection or infusion administration," said Dr. Nick LaRocca, of the National Multiple Sclerosis Society. "Many people prefer to take a capsule because they don't like to stick needles into themselves."

Multiple sclerosis causes the body's immune system to attack the protective coatings of the brain and spinal cord. Gilenya works to reduce a type of white blood cell that often attacks the nervous system.

The FDA reviewed the drug under a priority timetable reserved for

groundbreaking therapies.

In June, an FDA panel voted 25-0 that Gilenya helps reduce relapses of multiple sclerosis.

Despite the overwhelming endorsement, panelists also had questions about side effects and said patients should receive their first dose under doctor supervision because of the possibility of sudden heart irregularities.

Additionally, panelists said patients should receive routine lung function tests.

Those side effects were less common when patients received the lower of two doses tested by Novartis.

Novartis said Wednesday the FDA approved a 0.5-milligram daily dose of Gilenya.

About 2.5 million people around the world have multiple sclerosis, with an estimated 400,000 of them in the U.S. In the most common form of the disease, patients experience periods of well-being followed by periodic relapses.

Physicians who treat multiple sclerosis are mindful of safety problems with other recent treatment for the disease. Biogen Idec's drug Tysabri was approved for the condition in November 2004 and pulled from the market the next year after cases of a rare but lethal brain inflammation in some patients. It was reintroduced in 2006 under an FDA-approved distribution program.

Novartis said it is pursuing regulatory approval in Europe and the rest of the world.

The company's stock climbed 33 cents to $56.79 in pre-market trading Wednesday.