

US approves new multiple sclerosis capsules

March 27 2013, by Matthew Perrone

The U.S. Food and Drug Administration said Wednesday it approved a new drug from Biogen Idec to control multiple sclerosis in adults with hard-to-treat forms of the disease.

The twice-a-day capsules, called Tecfidera, offer a new option for multiple sclerosis, a debilitating disease in which the body attacks its own nervous system. U.S. -based Biogen Idec already sells two other drugs for the disease, but both require injections.

There is no cure for multiple sclerosis and most patients experience relapses of symptoms, including loss of balance, weakness in arms and legs, and blurred vision. Over time patients usually become weaker and less coordinated. More than 2 million people worldwide have the disease, with about 400,000 of them in the U.S., according to Biogen.

The FDA said it approved Tecfidera based on two studies showing patients taking the drug had fewer relapses than patients taking a dummy pill.

The approval gives Biogen a new product in an increasingly crowded field of multiple sclerosis drugs.

The biotech drugmaker already sells the once-a-week multiple sclerosis injection Avonex. It also markets the once-a-month injection Tysabri through a partnership with Elan Corp. PLC of Ireland. However, Tysabri's severe side effects have curtailed its use.

Tecfidera is designed to be taken orally, which could make it a preferred option for patients and doctors.

A Biogen executive said Wednesday that its three drugs would be used to treat different groups of patients.

"Multiple sclerosis is a reasonably complex disease and we think there are a lot of needs out there," said Tony Kingsely, a vice president at Biogen. "By having three drugs out there I think we can address a lot of those needs."

Kingsely said the company will announce the pricing of the drug when it begins shipping in the next week.

Novartis launched the first pill-based multiple sclerosis drug, Gilenya, in October 2010. Sanofi won FDA approval for a second pill, its drug Aubagio, last September.

The top-selling drug for the disease worldwide is Copaxone, which is made by Teva Pharmaceutical Industries. That injection had sales of nearly \$4 billion last year, according to Teva's latest financial report.

Avonex and Tysabri had annual sales of \$2.7 billion and \$1.5 billion in 2011, the most recent year for which Biogen has reported annual sales.

Biogen Idec Inc. shares rose \$5.59, or 3.2 percent, to close Wednesday at \$182.68.

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Citation: US approves new multiple sclerosis capsules (2013, March 27) retrieved 22 December 2023 from <https://medicalxpress.com/news/2013-03-fda-multiple-sclerosis-capsules.html>

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