

FDA approves first drug for aggressive multiple sclerosis

March 29 2017, by Linda A. Johnson



This photo provided by Genentech shows the company's drug Ocrevus. Late Tuesday, March 28, 2017, the Food and Drug Administration approved Ocrevus, the first drug for an aggressive kind of multiple sclerosis that steadily reduces

coordination and the ability to walk. While there are more than a dozen treatments for the most common form of MS, there's been nothing specifically for people with the type called primary progressive MS. That type of MS is relatively rare, affecting about 50,000 Americans. Ocrevus was also approved for relapsing forms of MS, which progress more slowly. (Genentech via AP)

U.S. regulators have approved the first drug for an aggressive kind of multiple sclerosis that steadily reduces coordination and the ability to walk.

The Food and Drug Administration approved Ocrevus late Tuesday after a large study found it slowed progression of the neurological disease and reduced symptoms.

While there are more than a dozen treatments for the most common form of MS, there's been nothing specifically for people with the type called primary progressive MS. That type of MS is relatively rare, affecting about 50,000 Americans.

The drug was also approved for relapsing forms of MS, which progress more slowly.

It's given intravenously every six months. The drug was developed by Genentech, part of Swiss drugmaker the Roche Group. Genentech, based in South San Francisco, California, said the initial list price without insurance will be \$65,000 a year.

In primary progressive MS, the disease's course varies among patients, but symptoms gradually worsen from the start and there usually are no periods when symptoms subside. Most of the estimated 400,000 Americans with MS have the relapsing-remitting type, in which

symptoms can wane for months, even years, between flare-ups.

Symptoms are caused by the immune system attacking the fatty coverings on nerves in the brain and spinal cord that protect them, much like insulation on electrical wiring. As the coverings deteriorate, nerve "messages" aren't properly transmitted, disrupting movement and muscle control.

For patients with primary progressive MS, life span on average is shortened by six years, said Dr. Fred Lublin, director of the MS center at Mount Sinai Health System in New York City.

Since 1993, 14 drugs have been approved to slow the most common form of MS, but everything tested against primary progressive MS failed until now, said Lublin, a consultant to Genentech who was on the committee overseeing the study.

"This therapy not only provides another treatment option for those with relapsing MS, but for the first time provides an approved therapy for those with primary progressive MS," Dr. Billy Dunn, director of the FDA's Division of Neurology Products, said in a statement.

In the study testing Ocrevus for primary progressive MS, which involved 732 patients, Ocrevus had a "modest but definite slowing effect on the rate at which people develop disabilities," said Lublin.

Compared to study participants getting dummy infusions, patients given Ocrevus infusions had slower declines in walking ability and slower disability progression over nearly 2 ½ years. The Ocrevus group also had fewer new brain-damaging lesions develop but slightly higher rates of certain side effects, including upper respiratory tract infections and tumors developing in various parts of the body.

The drug was also tested in two large studies involving 1,656 patients as a treatment for relapsing forms of MS. In those 96-week studies, patients given Ocrevus had lower relapse rates and reduced worsening of disability compared to participants given Rebif, a standard drug for relapsing MS, according to the FDA.

Ocrevus will be available in the U.S. within two weeks, Genentech said, noting the average price of MS medicines has quadrupled over the past 12 years. As a "first step" in reversing that trend, the company said, it priced Ocrevus 25 percent below Rebif's list price.

The price shouldn't limit access, analyst Jeffrey Holford at Jefferies LLC wrote to investors on Wednesday. He forecasts peak sales of \$5 billion a year.

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Citation: FDA approves first drug for aggressive multiple sclerosis (2017, March 29) retrieved 2 May 2024 from <https://medicalxpress.com/news/2017-03-fda-drug-aggressive-multiple-sclerosis.html>

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