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FDA approves first lower-cost biotech drug (Update)

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Federal health officials have approved the first lower-cost copy of a biotech drug to reach the U.S. market, a long-awaited milestone that could generate billions in savings for insurers, doctors and patients.

Biotech drugs are powerful, injected medicines produced in living cells. They are typically much more expensive than traditional chemical-based drugs.

The Food and Drug Administration approval of Novartis' version of the blockbuster drug Neupogen paves the way for a new market of quasi-generic biotech medicines. Express Scripts, the country's largest prescription benefit manager, estimates Novartis' version of the Amgen drug could save the U.S. health system $5.7 billion over the next decade.

Neupogen, which is used to boost blood cells in cancer patients, had U.S. sales of $839 million last year.

Express Scripts Holding Co. said the average price for a 30-day supply of Neupogen was about $3,500 last year.

Novartis spokeswoman Julie Masow said the company would not announce pricing for its biosimilar until the drug's launch, which is expected later this year. She said the biosimilar would be "competitively priced."

Novartis will sell its new version of the drug as Zarxio, through its

Sandoz subsidiary. The FDA said Friday that it approved the drug for use in several types of patients, including those undergoing bone marrow transplants or receiving certain forms of chemotherapy.

Many newer biotech drugs cost more than $100,000 per year, and together they account for nearly 30 percent of all U.S. drug spending. Since their introduction in the 1980s, biotech drugs never before faced generic competition because the FDA did not have a system to approve copies of such medications.

That finally changed in 2012 when the FDA laid out a regulatory pathway to approve so-called "biosimilars." That's the industry term for generic biotech drugs, used to indicate that they are not exact copies of the original biologic medicines. For years the biotech industry successfully staved off competition by arguing that their drugs were too complex to be reproduced by competitors.

Novartis has sold its version of Neupogen in Europe under the brand name Zarzio since 2009. The Swiss drugmaker also markets two other biosimilar drugs in about 60 countries around the world.

Generic biotech drugs have been available since 2006 in Europe, where the European Medicines Agency has approved about 20 products. The drugs generally cost 20 to 30 percent less than the original products, but uptake has been slower than expected. Doctors and pharmacists cannot switch patients from an original branded drug to a biosimilar, limiting their use. As a result, sales of biosimilar drugs represent less than 1 percent of the $170 billion global market for biotech medicines.

In the U.S. drug companies have the option to apply to the FDA for "interchangeability," a designation that allows pharmacists to switch patients from the original drug to a biosimilar. Novartis did not seek that classification for its drug. But analysts expect other companies to get the

status, expanding the market for biosimilars to $20 billion by 2020, according to analysts from Leerink Swann.

Other biotech blockbuster drugs expected to face U.S. competition include the anti-inflammatory drugs Remicade and Humira and the cancer drugs Herceptin and Avastin. Humira, made by AbbVie Inc., is the world's top-selling drug. It had more than $12.5 billion in sales last year.