

FDA approves lower-cost alternative to biotech drug Humira

September 23 2016, by Matthew Perrone

Federal regulators on Friday approved the first alternative version of the second-best selling drug in the world, Humira, the blockbuster injection used to treat rheumatoid arthritis and other inflammatory diseases.

The Food and Drug Administration cleared a near-copy of the drug, dubbed Amjevita, developed by Amgen Inc. Regulators approved the drug for more than a half-dozen conditions listed on the original drug's label, including severe psoriasis and Crohn's diseases.

Humira posted sales of nearly \$15 billion in 2015 and was for many years the top-selling prescription drug in the world, according to data from IMS Health.

It's the fourth time that the FDA has formally approved a so-called biosimilar, the industry term for a lower-cost version of a biotech drug. Biosimilar drugs, long available in Europe, are thought to have the potential to generate billions in savings for the U.S. health system.

But currently only one biosimilar cleared by the FDA approval pathway is actually on the market in the U.S., Novartis' Zarxio, an alternative to Amgen's Neupogen that sells for about 15 percent less than the original product. The drug helps boost [red blood cells](#) in cancer patients.

Amgen did not discuss plans for the drug's launch or price in a release issued Friday evening.

But Wall Street analysts have noted that AbbVie claims it holds patents protecting Humira until at least 2022. They have previously estimated that Amgen's version could launch sometime between 2018 and 2022, depending on the outcome of court litigation.

First approved in 2002, Humira accounted for 60 percent of AbbVie's total revenue last year. The injectable drug, which blocks chemicals linked to inflammation, is part of a family of biotech drugs including Enbrel and Remicade, which are also facing pending biosimilar competition.

Development of lower-cost anti-inflammatory drugs is considered pivotal in reducing U.S. spending on specialty drugs, which has doubled to \$150 billion since 2010, according to IMS Health.

Thousand Oaks, California-based Amgen is itself a biotech powerhouse, and it too has medications facing competition from cheaper versions. The company is working to hedge those losses by developing lower-cost versions of competitors' drugs.

AbbVie Inc. is based in North Chicago, Illinois.

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