Lower-cost biotech drug gets thumbs up from FDA panel (Update)

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This Friday, July 18, 2014, file photo, shows AbbVie's signature drug Humira, in Houston. Humira, the second-biggest selling drug in the world, could soon get some cheaper competition in the U.S., after a federal panel, on Tuesday, July 12, 2016, endorsed an alternative version of the pricey injectable medication used to treat various inflammatory diseases. (AP Photo/David J. Phillip, File)

The second-biggest selling drug in the world could get some cheaper competition in the U.S., after a federal panel endorsed an alternative version of the pricey medication used to treat rheumatoid arthritis and other inflammatory diseases.

A panel of Food and Drug Administration advisers voted unanimously in favor of Amgen's version of AbbVie's Humira, a biotech drug that raked in nearly $15 billion last year, according to IMS Health. While not binding, the recommendation likely paves the way for FDA approval of the knockoff drug.

For years, biotech drugs faced no competition because there was no regulatory way to approve copycat versions, even after patents had expired. If approved, Amgen's drug would join a new wave of so-called biosimilars, which have the potential to generate billions in savings for U.S. insurers, doctors and patients.

But it could take years for those savings to arrive.

Evercore ISI analyst Mark Schoenebaum says the earliest Amgen could launch its product would be March 2017, though that would risk infringing patents which Abbvie says protect its drug until at least 2022. Wall Street analysts expect the patent issue to be fought in court, and then for Amgen's drug to launch sometime between 2018 and 2022.

First approved in 2002, Humira has long been among the most profitable drugs in the world. It accounted for 60 percent of Abbvie's total revenue last year. The injectable drug, which blocks chemicals linked to inflammation, is approved for multiple uses, including rheumatoid arthritis, Crohn's disease and psoriasis.

Thousand Oaks, Calif-based Amgen is seeking FDA approval to market its version, known only as ABP 501, for seven diseases. Amgen is itself a biotech powerhouse, and it too has medications facing competition from cheaper versions. The company is working to hedge those loses by developing lower-cost versions of competitors' drugs.

Biotech drugs are powerful, injected medicines produced in living cells that are typically much more expensive than traditional, chemical-based drugs. In 2015, six of the 10 top-selling medicines globally were biotech drugs, with more than $56 billion in combined sales.

The FDA only approved the first lower-cost biotech drug last March, a Novartis version of the Amgen drug Neupogen. Pfizer won approval to market a second biosimilar in April, a version of Johnson & Johnson's Remicade, but it is not yet for sale.

Questions remain about just how much savings U.S. biosimilars will deliver. Novartis' Zarxio sells for 15 percent less than the original Neupogen. Experts predict biosimilar discounts of 15 percent to 30 percent in the U.S.

In Europe, where governments regulate prices, discounts are higher.

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

On Wednesday, the same panel of FDA advisers will review a Novartis version of Enbrel, which is marketed by Amgen.