EXHIBIT 5
FDA OK's new Remicade copycat but no launch planned

By Suzanne Elvidge • Dec. 15, 2017

Dive Brief:

- Pfizer Inc.'s Ixifi, the company's second Remicade biosimilar, got its go ahead in the U.S. on Wednesday evening from the Food and Drug Administration.

- Pfizer sought approval of Ixifi, despite already having an approval with partner Celltrion for another Remicade biosimilar, called Inflectra. Yet, the company said it has no plans to launch the new drug, which it owned prior to acquiring Inflectra in its buyout of Hospira.

- Ixifi is the ninth biosimilar approved by the U.S. and the third copycat for Johnson & Johnson's Remicade. Ixifi can be used for all of the same indications as Remicade.

Dive Insight:

Pfizer already supplies Celltrion Healthcare's Inflectra (infliximab-dyyb) in the U.S. and elsewhere; the South Korean company's agent was the first Remicade biosimilar to the market. This was then followed by Renflexis from Samsung Bioepis and Merck & Co.

Inflectra's sales haven't exactly been flying high, with little damage to Remicade's marketshare so far. In the third quarter, Remicade's global sales were $1.65 billion, beating analysts' expectations by 6%. Pfizer has blamed Johnson & Johnson's contracts with payers for the originator drug for its lack of success. Pfizer launched a lawsuit in September in the U.S.
District Court for the Eastern District of Pennsylvania accusing J&J of conducting anti-competitive practices and violating antitrust laws, but decisions on the progress of the case aren't expected until the second quarter of 2018.

To gain a better share of the market, Pfizer and Celltrion have pushed for interchangeability for Inflectra, based on the FDA's draft guidance.

Perhaps unsurprisingly, Pfizer has elected not to cannibalize itself, and won't be launching Ixifi (infliximab-qbtx) in the U.S. Ixifi was already in development in-house at Pfizer when the big pharma acquired Hospira, Celltrion's partner, and the focus then shifted to Inflectra, which was further along.

"We are pleased with the FDA approval of Ixifi as the first Pfizer developed biosimilar in the U.S. and we are currently evaluating our strategic options for this medicine. Pfizer does not plan on launching Ixifi in the U.S.," said the company in a statement to BioPharma Dive.

Pfizer did not elaborate on what its plans are for the drug, but said it will continue to make sure Inflectra is available for patients.
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