BIOPHARMADIVE

DIVE BRIEF

After long journey, Ardelyx gets FDA OK for kidney disease drug

The biotech appealed a 2021 rejection of the therapy, now called Xphozah, and late last year, secured the backing of FDA advisers for its eventual approval.

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Dive Brief:

- Ardelyx has won Food and Drug Administration approval for a new kind of kidney disease drug, announcing Tuesday the agency's clearance of Xphozah after a yearslong regulatory journey.
- The FDA approved Xphozah to reduce levels of phosphorus in the blood in adults with chronic kidney disease who are on dialysis and don't respond well to drugs designed to block phosphorus absorption.
- Ardelyx, which has been developing the therapy for more than a decade, expects to make Xphozah available in November and is hiring new sales staff to support the drug's launch in the U.S. The drug ingredient in Xphozah, tenapanor, is already approved for irritable bowel syndrome and is sold as Ibsrela for that use.

Dive Insight:

Typically, an FDA rejection is the end of the regulatory road for an experimental drug. With Tuesday's approval of Xphozah, Ardelyx is the rare company to overcome such a hurdle, some two years after it received a complete response letter from the agency in July 2021.

"It's been a long, sometimes arduous path to this day," said Ardelyx's Chief Development Officer David Rosenbaum, who worked on Xphozah for the past 13 years, on a call with investors Wednesday morning.

A pivotal moment on that path was an FDA advisory committee meeting last November, when a panel of experts backed approval of the drug for kidney disease patients. At the time, analysts noted how it was rare for the FDA to call such a meeting after a rejection, and rarer still for advisers to disagree with the FDA's original decision.

Xphozah joins a number of existing treatments for hyperphosphatemia, which is a common occurrence in people with kidney disease. Elevated phosphorus levels can remove calcium from the body, leading to low calcium levels and other problems.

However, the current drugs work the same way, blocking the absorption of phosphorus by binding to the mineral in the gut. Xphozah works by blocking absorption in a different way. Importantly, it is taken twice daily as a single tablet, compared to the more frequent dosing with larger pills required for existing phosphate binders.

Under the FDA's labeling, Xphozah can only be used in people who don't respond well to phosphate binders, or who can't take any dose of phosphate binder therapy.

Approval was based on a trio of late-stage studies testing Xphozah in more than 1,000 patients as both a standalone treatment and in

combination with phosphate binders. Results showed Xphozah could reduce serum phosphorus levels, albeit with diarrhea as a common side effect.

Ardelyx did not disclose the price it plans to charge for Xphozah, indicating it would do so during an upcoming earnings call. Analysts expect a price similar to those for branded phosphate binders, which have list prices around $1,500 per month.

To support the launch, Ardelyx has secured additional debt financing from SLR Capital Partners, giving it access to an initial $50 million and, potentially, another $50 million at a later date.

Shares in Ardelyx rose by around 15% in Wednesday morning trading on news of the approval. The company held cash and short-term investments of about $128 million at the end of June, and expects to record around $75 million in revenue from Ibsrela sales this year.