Post-Hoc Analysis of the OPTIMIZE Study Supporting XPHOZAH® (tenapanor) to be Presented at the National Kidney Foundation Spring Clinical Meetings

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WALTHAM, Mass., April 10, 2025 (GLOBE NEWSWIRE) -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs, today announced that the company will present a post-hoc analysis of the OPTIMIZE Study, an open-label clinical trial of XPHOZAH ® (tenapanor), as a poster at the National Kidney Foundation (NKF) Spring Clinical Meetings, now underway in Boston. Ardelyx is also hosting an Exhibitor Showcase discussing hyperphosphatemia management.

XPHOZAH is the first and only phosphate absorption inhibitor (PAI) approved by the U.S. Food and Drug Administration to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. XPHOZAH offers a different mechanism of action that blocks phosphate absorption at the primary pathway and is administered as a single tablet taken twice daily.

OPTIMIZE was a randomized, open label study which included 330 patients with chronic kidney disease (CKD) on dialysis with hyperphosphatemia. The study was designed to evaluate different methods of optimizing phosphorus management with XPHOZAH in both binder-naïve and binder-treated patients.

“Now more than one year since the launch of XPHOZAH, we are seeing that patients are receiving the benefits of the treatment and experiencing improved phosphate control,” said David Spiegel, MD, senior vice president, nephrology at Ardelyx. “At the same time, we recognize how important it is to continue to understand the patient experience and provide insights in how to help patients have a positive experience with the therapy to support adherence to treatment and achieve target phosphate goals. Analyses, like the one presented at NKF Spring Clinical Meetings, provide insight into methods that healthcare providers can use to optimize treatment with XPHOZAH. In this case, it was observed that among patients experiencing loose stools on XPHOZAH, those who used an anti-diarrheal medication had a lower rate of treatment discontinuation due to diarrhea.”

Poster #G-310, entitled *“Tenapanor-Treated Patients Using Over-the-Counter Antidiarrheal Agents Saw Decreased Stool Frequency and Improved Stool Consistency,”* is a post hoc analysis of the OPTIMIZE study and evaluated discontinuation rates and changes in stool frequency and consistency in patients receiving tenapanor who self-medicated with the over-the-counter antidiarrheal agent loperamide. The analysis found that among the 40% of patients with reported diarrhea, 9.7% of patients that were also using loperamide discontinued tenapanor due to diarrhea compared to 24.6% of patients not using loperamide. In conclusion, loperamide was identified as a treatment option to improve diarrhea emergent with tenapanor treatment.

Poster presentations are now publicly available and can be accessed on demand here.

In addition to the poster presentation during NKF Spring Clinical Meetings, Ardelyx is sponsoring an Exhibitor Showcase titled: ***“A Different Perspective on Hyperphosphatemia Management: Evaluating Current Strategies”*** on April 11, 2025, from 12:00-12:35 PM EDT, where Dr. Vincent Carsillo, will discuss first-in-class PAI, XPHOZAH. The presentation will review the XPHOZAH mechanism of action, efficacy and safety data from the Phase 3 clinical trial program and will include a discussion about the clinical application of XPHOZAH as add-on therapy for the many dialysis patients on a phosphate binder with serum phosphorus levels above guideline-established targets.

About XPHOZAH® (tenapanor)
XPHOZAH, discovered and developed by Ardelyx, is a first-in-class, phosphate absorption inhibitor with a differentiated mechanism of action that acts locally in the gut to inhibit the sodium hydrogen exchanger 3 (NHE3), thereby reducing phosphate absorption through the paracellular pathway, the primary pathway of phosphate absorption. XPHOZAH is a single tablet, taken twice daily. Diarrhea was the most common side effect experienced by patients taking XPHOZAH in clinical trials. Please see additional full Prescribing Information.

About Hyperphosphatemia
Hyperphosphatemia is a serious condition, defined as elevated levels of phosphate in the blood, which affects the vast majority of the 550,000 patients in the United States with chronic kidney disease (CKD) on maintenance dialysis. The kidneys are responsible for eliminating excess phosphate and as kidney function declines, phosphate is not adequately eliminated from the body. As a result, hyperphosphatemia is a nearly universal condition among people with CKD on maintenance dialysis, with internationally recognized KDIGO treatment guidelines that recommend lowering elevated phosphate levels toward the normal range (2.5-4.5mg/dL).

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS
XPHOZAH is contraindicated in:

- Pediatric patients under 6 years of age
- Patients with known or suspected mechanical gastrointestinal obstruction

WARNINGS AND PRECAUTIONS
Diarrhea
Patients may experience severe diarrhea. Treatment with XPHOZAH should be discontinued in patients who develop severe diarrhea.

MOST COMMON ADVERSE REACTIONS
Diarrhea, which occurred in 43-53% of patients, was the only adverse reaction reported in at least 5% of XPHOZAH-treated patients with CKD on dialysis across trials. The majority of diarrhea events in the XPHOZAH-treated patients were reported to be mild-to-moderate in severity and resolved over time, or with dose reduction. Diarrhea was typically reported soon after initiation but could occur at any time during treatment with XPHOZAH. Severe diarrhea was reported in 5% of XPHOZAH-treated patients in these trials.

INDICATION
XPHOZAH (tenapanor), 30 mg BID, is indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on

therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

For additional safety information, please see full Prescribing Information.

About Ardelyx

Ardelyx was founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs. Ardelyx has two commercial products approved in the United States, IBSRELA® (tenapanor) and XPHOZAH® (tenapanor). Ardelyx has agreements for the development and commercialization of tenapanor outside of the U.S. Kyowa Kirin commercializes PHOZEVEL® (tenapanor) for hyperphosphatemia in Japan. A New Drug Application for tenapanor for hyperphosphatemia has been approved in China with Fosun Pharma. Knight Therapeutics commercializes IBSRELA in Canada. For more information, please visit https://ardelyx.com/ and connect with us on X (formerly known as Twitter), LinkedIn and Facebook.

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Source: Ardelyx, Inc.