Ardelyx Shares Additional Data Supporting First-In-Class XPHOZAH® (tenapanor) at the American Society of Nephrology's Kidney Week

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WALTHAM, Mass., Oct. 24, 2024 (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 data supporting additional positive clinical observations of XPHOZAH® (tenapanor) was presented in a series of poster presentations at the American Society of Nephrology's (ASN) Kidney Week, currently taking place in San Diego. Ardelyx is also hosting an Exhibitor Spotlight discussing hyperphosphatemia management.

XPHOZAH, the first and only phosphate absorption inhibitor (PAI), is 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.

"We are pleased to be able to continue to expand our understanding of the significant impact XPHOZAH can have to help patients with chronic kidney disease on dialysis with elevated phosphorus," said David Spiegel, MD, senior vice president, nephrology at Ardelyx. "Patients on dialysis and their healthcare providers have long struggled to achieve and maintain serum phosphate levels within guideline-established levels. The addition of XPHOZAH is an important tool in phosphate management and these data demonstrate the benefit that XPHOZAH's blocking mechanism can offer patients."

Poster #TH-PO164, entitled "*Sustained Phosphate Reduction Assessed by P AUC With Tenapanor Is Associated With Reduced Fibroblast Growth Factor 23 in Patients With Chronic Kidney Disease and Hyperphosphatemia on Dialysis,"* is a post-hoc analysis of the PHREEDOM Phase 3 clinical trial, and assessed whether long-term phosphate (P) control measured using average phosphate area under the curve (P AUC) with tenapanor is associated with lower iFGF23. iFGF23 is elevated in patients with chronic kidney disease and is associated with increased cardiovascular mortality. The analysis observed greater percent reductions from baseline in iFGF23 in P AUC categories representative of better P control than categories representative of worse control.

Poster #TH-PO169, entitled "*Tenapanor Reduces Serum Phosphate With Similar Efficacy and Tolerability Profiles When Added to Various Phosphate Binders,"* is a post hoc analysis of data from the AMPLIFY Phase 3 clinical trial and OPTIMIZE open-label clinical trial and examined the efficacy and tolerability of tenapanor when added to different phosphate binders (PBs). The analysis found that tenapanor added to PBs provided a clinically meaningful serum P reduction with similar efficacy and tolerability regardless of the type of PB.

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

In addition to the poster presentations during ASN Kidney Week, Ardelyx is sponsoring an Exhibitor Spotlight titled: ***"A Different Perspective on Hyperphosphatemia Management: Evaluating Current Strategies,"*** on October 25, 2024, from 11:00 – 11:45 AM PDT, where Steven Fishbane, MD, 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 submitted 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.