Ardelyx Presents Additional Data at the NKF 2024 Spring Clinical Meetings on XPHOZAH® (tenapanor)

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WALTHAM, Mass., May 16, 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 National Kidney Foundation (NKF) 2024 Spring Clinical Meetings, now underway in Long Beach, California. Ardelyx is also hosting an Exhibitor Showcase 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 excited to share this data, as it continues to demonstrate the significant impact XPHOZAH can have for patients with chronic kidney disease on dialysis with serum phosphorus levels above guideline-established levels, as many currently struggle to achieve these goals without a new treatment option,” said David Spiegel, MD, vice president, nephrology at Ardelyx. “Our commitment is to these patients who are living with a life-changing diagnosis, and the data being presented at NKF Spring Clinical Meetings showcases why we believe this treatment will bring advancement and innovation to their care.”

Poster #239, entitled “*Tenapanor Treatment Added to Phosphate Binders Improved Long-Term Serum Phosphate (P) Control as Measured by Reduction in Average Daily P Area Under the Curve,”* reviewed data from an area under the curve (AUC) assessment meant to provide a more comprehensive evaluation of serum phosphate levels than individual serum phosphate measurements. The assessment found that tenapanor added to sevelamer treatment resulted in improved phosphate control as measured by average daily phosphate AUC in sevelamer-treated patients from the PHREEDOM Phase 3 study who continued into the NORMALIZE open-label extension study.

Poster #243, entitled “*Treatment Response to Tenapanor Categorized by Age and Comorbidities: A Post Hoc Analysis of the PHREEDOM Study,”* reported results from a post hoc analysis of the PHREEDOM study to evaluate trends in serum phosphate concentrations in patients on dialysis treated with tenapanor categorized by age and comorbidity status. The analysis demonstrated that patients aged ≥65 years had a lower mean phosphate level at baseline than younger patients, but there was no difference in the mean phosphate reduction from baseline. Tenapanor demonstrated similar efficacy and safety profiles in adult patients on dialysis regardless of age group and comorbidity.

Poster #240, entitled “*Patient Perception of Phosphate-Lowering Treatment Regimen Improves Adherence to Therapy,”* evaluated if an improvement in patient perception of phosphate-lowering treatment may improve adherence to treatment and promote a greater decrease in serum phosphate over time. In the Phase 3 study OPTIMIZE, 80% of patients enrolled answered a question characterizing their phosphate management regimen as improved, unchanged or worsened on tenapanor. By the end of the 10-week treatment period, adherence was greater in patients who perceived their treatment regimen to be improved by adding tenapanor and stopping or decreasing their phosphate binder regimen. Discontinuation rates were also lower among those who felt their phosphate-lowering treatment regimen was improved.

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

In addition to the poster presentations during NKF Spring Clinical Meetings, Ardelyx is sponsoring an Exhibitor Showcase titled ***“A New Paradigm: Rethinking Hyperphosphatemia Management,”*** on May 17, 2024, from 8:30-9:05 AM PDT, where David M. Spiegel, MD and Lisa Gutekunst MSEd, RD, CSR, CDN, FNKF, 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.