Ardelyx Presents Analysis Supporting Long-Term Safety of XPHOZAH at NKF's Spring Clinical Meetings

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WALTHAM, Mass., May 07, 2026 (GLOBE NEWSWIRE) -- Ardelyx, Inc. (Nasdaq: ARDX), a commercial-stage biopharmaceutical company focused on the development and commercialization of innovative medicines that meet significant unmet medical needs, today announced the presentation of a data analysis evaluating the long-term impact of XPHOZAH® (tenapanor) on serum electrolytes and selected nutrition biomarkers at the National Kidney Foundation's (NKF) Spring Clinical Meetings, currently underway in New Orleans.

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 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 present a post hoc analysis of the NORMALIZE and OPTIMIZE open-label clinical trials at the NKF's Spring Clinical Meetings, providing further insight into the long-term safety of an XPHOZAH-based regimen in patients with hyperphosphatemia on maintenance dialysis who were not controlled on binder therapy," said Rajani Dinavahi, MD, Chief Medical Officer of Ardelyx. "Analyses such as these are important not only for understanding treatment outcomes, but also for supporting informed decision-making that can help optimize care and outcomes for these patients."

Previous analysis found that tenapanor inhibition of the sodium hydrogen exchanger (NEH3) did not affect serum electrolyte concentrations other than phosphate. The poster, titled **"Tenapanor Decreases Serum Phosphate Without Altering Other Serum Electrolytes in Patients with Chronic Kidney Disease with Hyperphosphatemia on Dialysis,"** further supports that analysis over an extended period of time. Using data from two open-label trials, an 18-month extension study (NORMALIZE) and a 26-week study (OPTIMIZE), the analysis showed that tenapanor treatment resulted in no clinically meaningful changes in measured serum electrolyte concentrations, other than phosphate reduction, and no significant changes in nutrition, body mass, or blood pressure.

These findings support effectiveness of tenapanor for management of serum phosphate in patients with chronic kidney disease and hyperphosphatemia on dialysis, while also reinforcing reported safety data.

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 a Peer Exchange, titled ***"Treating Hyperphosphatemia and Side Effect Management,"*** on May 8 at 12:15 PM CT, where Lisa Gutekunst, MSEd, RD, CSR, CDN, will facilitate a peer exchange session discussing first-in-class PAI XPHOZAH. The session will review the XPHOZAH mechanism of action, efficacy and safety data, and practical considerations for 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 NORMALIZE
Patients completing the Phase 3 PHREEDOM trial from both the XPHOZAH arm and the sevelamer safety control arm had the option to participate in NORMALIZE, an open-label 18-month extension study. Patients entering the study from the XPHOZAH arm with serum phosphate levels in the normal range were followed with no medication changes. Patients entering the study from the XPHOZAH arm with serum phosphate greater than 4.5 mg/dL had sevelamer tablets added incrementally to achieve normal serum phosphate levels. Patients entering the study from the sevelamer safety control arm had XPHOZAH tablets added to their treatment regimen while reducing sevelamer tablets based on their serum phosphate value to achieve normal serum phosphate levels. The primary objective of the study was to evaluate the ability of XPHOZAH alone or in combination with sevelamer to achieve serum phosphate levels within the normal range (2.5 to 4.5 mg/dL) in patients with CKD on maintenance dialysis whose serum phosphate levels were greater than 6.0 mg/dL at baseline.

About OPTIMIZE
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 initiating XPHOZAH to optimize phosphorus management in both binder-naïve and binder-treated patients. The objective was to evaluate the ability of XPHOZAH, with its novel blocking mechanism, administered as core therapy for the treatment of hyperphosphatemia in adult patients with chronic kidney disease (CKD) on dialysis, alone or in combination with phosphate binders, to achieve target serum phosphorus (s-P) levels ≤5.5 mg/dL. The study enrolled patients with s-P >5.5 and ≤10.0 mg/dL during stable phosphate binder treatment which were randomized in a 1:1 ratio to two different treatment cohorts, as well as patients who were phosphate binder naïve with s-P >4.5 and ≤10.0 mg/dL in a third cohort.

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 is a commercial-stage biopharmaceutical company focused on the development and commercialization of innovative medicines that meet significant unmet medical needs. Ardelyx has two commercial products approved in the United States, IBSRELA® (tenapanor) and XPHOZAH® (tenapanor). The company's pipeline includes the Phase 3 development of IBSRELA for chronic idiopathic constipation (CIC) and RDX10531, a next-generation NHE3 inhibitor with potential application across multiple therapeutic areas. Ardelyx works with its partners to develop and commercialize its products outside of the United States. For more information, please visit https://ardelyx.com/ and connect with us on X (formerly known as Twitter), LinkedIn and Facebook.

Investor Contact:
Lisa Caperelli
SVP, Investor Relations & Corporate Communications
lcaperelli@ardelyx.com

Media Contact:
Lindsey Manuel
Associate Director, Corporate Communications
lmanuel@ardelyx.com

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