Real-World Evidence Studies of XPHOZAH® (tenapanor) Demonstrate Patient Satisfaction and Reduction in Serum Phosphate with XPHOZAH in Data Presented at ASN Kidney Week

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WALTHAM, Mass., Nov. 07, 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 presented data, including results from the first real-world study of XPHOZAH, at American Society of Nephrology's Kidney Week, currently underway in Houston.

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 excited to present new data on XPHOZAH at ASN's Kidney Week, including the first results from our prospective, observational cohort study designed to evaluate the impact of an XPHOZAH-based regimen in a real-world setting, in patients with hyperphosphatemia on maintenance dialysis who were not controlled on binder therapy," said Edward Conner, MD, Chief Medical Officer. "Phosphate management is critical for patients with chronic kidney disease on dialysis, as the failure to do so leads to a higher risk of comorbidities, death, and a potential delay in transplant waitlisting. Our results show the impact XPHOZAH can have in reducing serum phosphorus levels for these patients, and that its' effectiveness extends outside the clinical trial setting and into the real-world."

Poster #TH-PO0221, entitled *"Real-World Effectiveness of Tenapanor (XPHOZAH) for Treatment of Hyperphosphatemia in United States Patients on Dialysis,"* highlights results from the first real-world study of tenapanor for management of serum phosphate, aimed to characterize real-world use and effectiveness in the U.S. dialysis setting. Patients prescribed tenapanor experienced a reduction in serum phosphate of nearly 1 mg/dL on average. Nearly half of participants (45.3%) experienced ≥1 mg/dL reduction in serum phosphorus and 25.1% experienced a reduction of ≥2 mg/dL. Results were similar between all initiators and patients persisting on tenapanor for the entire follow-up period of 120 days. These findings support the real-world effectiveness of tenapanor for management of serum phosphate in patients with end-stage kidney disease (ESKD) and hyperphosphatemia.

Poster #TH-PO0224, entitled *"Treatment Satisfaction with Tenapanor (XPHOZAH): Real-World Survey of Patients with End-Stage Renal Disease and Hyperphosphatemia,"* presents positive patient experiences with tenapanor in a real-world survey collected through the ArdelyxAssist patient services program and associated pharmacy data. Excluding respondents who did not know how their phosphate levels had changed, 63% of patients reported their phosphate levels were better since starting tenapanor. Of the patients who reported a change in serum phosphate levels, 69% indicated that their outlook on serum phosphate control was a little or much better, with 44% attributing the change to better serum phosphate control, 39% to improved bowel movements, and 14% to lower pill burden. These data highlight the positive experiences patients have with tenapanor in the real world, including improved serum phosphate control, bowel movements, and lower pill burden, as well as the need for greater patient education.

Poster #FR-PO0254, entitled *"Etelcalcetide Utilization Rates Decreased and Parathyroidectomy Rates Increased Following the Incorporation of Calcimimetics into the End-Stage Kidney Disease Bundle,"* examines trends in calcimimetic use, including cinacalcet and etelcalcetide (ETEL), and parathyroidectomy (PTX) rates among patients on maintenance hemodialysis during and after the Transitional Drug Add-On Payment Adjustment (TDAPA) period, considering race and dialysis organization (DO) size. It was shown that ETEL use increased during the TDAPA period and decreased sharply when it ended. Conversely, PTX rates declined during the TDAPA period and increased upon its conclusion when ETEL utilization decreased. Results of this study highlight the impact of reimbursement policy on clinical practice and patient outcomes, underlining the unintended consequences of reducing access to effective therapies, increasing health disparities and potentially suppressing future therapeutic innovation.

Poster #TH-PO0223, entitled *"Tenapanor Improves Bowel Movements in Patients with End-Stage Kidney Disease and Mild to Severe Constipation,"* is a post-hoc analysis of the Phase 3 BLOCK study that analyzed the effects of tenapanor on stool frequency and consistency in patients with ESKD who experienced constipation at baseline. Constipation occurs in 30%-40% of patients with ESKD receiving dialysis. The results of the eight-week study showed improved weekly stool frequency (WSF) and stool consistency. Among patients with a baseline WSF of ≤ 3, (Severe Constipation), weekly stool frequency increased to within the normal range and the weekly stool consistency score improved from constipation to normal. Similar reductions in serum phosphate were observed in both groups studied, Severe Constipation and Constipation (WSF ≤ 6).

Poster #FR-PO0255, entitled *"Cost-Effectiveness Analysis of Tenapanor in Japanese Patients with Hyperphosphatemia on Hemodialysis,"* presented by Kyowa Kirin Co., Ltd., Ardelyx's collaboration partner for tenapanor in Japan, is an analysis of the cost-effectiveness for tenapanor in hemodialysis patients from the Japanese public healthcare payer's perspective. It was concluded that in both patient populations analyzed, tenapanor was cost-effective, satisfying the threshold of five million Japanese Yen for the Japanese willingness to pay.

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

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) as well as early-stage pipeline candidates. The company is developing RDX10531, a next-generation NHE3 inhibitor with potential application across multiple therapeutic areas. 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.