



Ardelyx Shares Positive Data from Studies of XPHOZAH® (tenapanor), a First-in-Class Phosphate Absorption Inhibitor, at ASN Kidney Week 2023

November 3, 2023

WALTHAM, Mass., Nov. 03, 2023 (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 shared positive data on the use of XPHOZAH® (tenapanor) in poster presentations at the American Society of Nephrology (ASN) Kidney Week 2023 meeting, currently being held in Philadelphia, Pennsylvania, and will showcase XPHOZAH in an Exhibitor Spotlight event. Ardelyx's presence at Kidney Week 2023 will honor the memory of Derek Forfang, Chair of the Ardelyx Patient Advisory Council and a passionate advocate for patients with kidney disease.

XPHOZAH, the first and only phosphate absorption inhibitor, was approved by the U.S. Food and Drug Administration on October 17, 2023 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 thrilled to share compelling data highlighting why XPHOZAH, with its differentiated blocking mechanism, may benefit patients who have hyperphosphatemia despite ongoing treatments with currently available therapies," said Laura Williams, M.D., M.P.H., Chief Medical Officer at Ardelyx. "The data being presented at ASN Kidney Week 2023 highlight why we are enthusiastic to bring this medication to patients who struggle to achieve target treatment goals and to their healthcare providers who are in need of a new treatment option."

- The first poster, titled **Optimal Initiation of Tenapanor Treatment Analyzed by Baseline Phosphate Binder Dose: A Sub-analysis of the OPTIMIZE Study**, looked at serum phosphate (sP) control across two cohorts of patients by phosphate lowering pill burden. In OPTIMIZE, Cohort 1 added tenapanor 30 mg twice a day and stopped using phosphate binders, while Cohort 2 added tenapanor 30 mg twice a day and reduced their phosphate binder dose by $\geq 50\%$. The OPTIMIZE study showed that both cohorts experienced improved sP control and improved patient reported quality of life, as well as a reduction in pill burden. This analysis suggests that patients on high phosphate binder dosage (more than six pills per day) may have better early sP control by initiating tenapanor with a 50% reduction in phosphate binder dosage, while patients on lower dosage of phosphate binders had similar early sP control regardless of the tenapanor initiation strategy.
- In a poster titled **Patient Education Improves Adherence to Tenapanor Treatment in OPTIMIZE Study**, researchers looked at the effect of patient education on adherence, using data from the OPTIMIZE study compared to data from two phase 3 clinical studies of tenapanor, BLOCK and PHREEDOM. In the OPTIMIZE study, patients were provided with a patient brochure including information on how to take tenapanor, what they might experience while on the medication, which medications should be discontinued and ways to mitigate potential onset of loose stools or diarrhea. The study found that this educational information improved adherence, and may have specifically reduced medication discontinuation due to changes in bowel habits.
- The third poster, **Safety Analysis of Tenapanor Monotherapy vs Sevelamer Carbonate in Patients on Maintenance Dialysis with Hyperphosphatemia**, reviewed patient data from the PHREEDOM study that evaluated tenapanor for the treatment of hyperphosphatemia in patients with CKD on maintenance dialysis. It aimed to compare adverse events between patients who received tenapanor 30 mg twice a day and patients in the safety population who received sevelamer per standard of care during a 26-week randomized treatment period. The study showed that a lower proportion of patients treated with tenapanor versus sevelamer experienced a serious adverse event (SAE) while the exposure adjusted rates were similar. This analysis also showed that the incidence of adverse events leading to hospitalization (also characterized as an SAE) was lower in the tenapanor arm than the sevelamer arm while the exposure adjusted rates were similar. The analysis concluded that tenapanor has an acceptable safety and tolerability profile in patients with CKD on maintenance dialysis.
- The final Ardelyx poster to be shared at ASN, **Tenapanor in Combination with Phosphate Binders Improves Short and Long-Term Control of Serum Phosphate (sP) in Patients on Dialysis with Hyperphosphatemia (FR-PO318)**, will be available from 10:00am to 12:00pm ET on Friday, November 3, 2023.

These poster presentations are publicly available and can be accessed on demand [here](#).

Additionally, Ardelyx is hosting an XPHOZAH Exhibitor Spotlight at ASN Kidney Week 2023. The session, titled **A New Paradigm: Rethinking Hyperphosphatemia Management** will be held at 11:00 AM on Friday, November 3, 2023 in Theater 2 in Exhibit Hall B of the Pennsylvania Convention Center. The Spotlight will be presented by Arnold Silva, MD, PhD. Director of Home and Peritoneal Dialysis Programs, Boise Kidney & Hypertension Institute, and by David Spiegel, MD, Vice President of Nephrology at Ardelyx.

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, Inc.

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. Ardelyx has agreements for the development and commercialization of tenapanor outside of the U.S. Kyowa Kirin has received approval for 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.