Ardelyx Announces Publication of Two Plain Language Summaries from XPHOZAH® (tenapanor) Clinical Trials in Current Medical Research and Opinion

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WALTHAM, Mass., July 31, 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 the publication of plain language summaries of results from two clinical trials on XPHOZAH® (tenapanor), NORMALIZE and OPTIMIZE, in *Current Medical Research and Opinion.* The plain language summaries were developed by the authors to help adult patients with chronic kidney disease receiving dialysis, and their family members and caregivers, better understand some of the safety and efficacy data related to XPHOZAH.

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, blocking phosphate absorption at the primary pathway and is administered as a single tablet taken twice daily.

“We are proud to provide the clinical trials results for both the NORMALIZE and OPTIMIZE studies to patients in a format that is both useful and relevant to their needs. Plain language summaries, like these, help patients and their caregivers better understand their options and the potential impact XPHOZAH may have on lowering their serum phosphorus levels,” said Laura Williams, MD MPH, chief medical officer of Ardelyx. “Our entire Ardelyx team would like to express our gratitude to the patients who participated in these clinical trials, whose contributions are now helping other patients better understand the complications associated with elevated serum phosphorus and this new treatment option. We would also like to recognize the study authors who worked with our partners in the patient advocacy community to ensure that these plain language summaries could be made available to our patients.”

Current Medical Research and Opinion is an international journal that publishes research focused on new and existing drugs and therapies, best practices in patient care, developments in diagnostic medicine and medical technology, and innovations in medical and scientific publishing. The first article, titled “Tenapanor improves long-term control of high phosphate concentrations in the blood in patients receiving maintenance dialysis: a plain language summary of the NORMALIZE study,” describes results from the NORMALIZE study, is available online and can be found here. The second article, titled “Effectiveness of tenapanor for treating hyperphosphatemia in patients receiving dialysis: a plain language summary of the OPTIMIZE study” provides a review of the OPTIMIZE study, is available online and can be found here. Both articles are summaries of data originally published in *Kidney360.*

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 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.