



Ardelyx to Present Additional Data Supporting First-In-Class XPHOZAH® (tenapanor) for Adults with Chronic Kidney Disease on Dialysis at the American Society of Nephrology's Kidney Week

October 15, 2024

WALTHAM, Mass., Oct. 15, 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 additional data supporting XPHOZAH® (tenapanor) will be presented at the American Society of Nephrology's (ASN) Kidney Week, to be held October 24-27, 2024, in San Diego.

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.

Information regarding ASN's Kidney Week, including copies of presentation abstracts, can be found [here](#).

Title: Sustained Phosphate Reduction Assessed by P AUC With Tenapanor Is Associated With Reduced Fibroblast Growth Factor 23 in Patients With Chronic Kidney Disease and Hyperphosphatemia on Dialysis

Authors: Kevin J. Martin, Simon Higgins, Yang Yang, David P. Rosenbaum, David M. Spiegel

Poster Number: TH-PO164

Date/Time: October 24, 2024, from 10:00 AM – 12:00 PM PDT (UTC –7)

Title: Tenapanor Reduces Serum Phosphate With Similar Efficacy and Tolerability Profiles When Added to Various Phosphate Binders

Authors: Stuart M. Sprague, David P. Tietjen, Jesslyn Roesch, Yang Yang, Suling Zhao, Susan A. Edelstein, David P. Rosenbaum, David M. Spiegel

Poster Number: TH-PO169

Date/Time: October 24, 2024, from 10:00 AM – 12:00 PM PDT (UTC –7)

In addition to the poster presentations during ASN Kidney Week, Ardelyx is sponsoring an Exhibitor Spotlight titled: ***"A Different Perspective on Hyperphosphatemia Management: Evaluating Current Strategies,"*** on October 25, 2024, from 11:00 – 11:45 AM PDT, where Steven Fishbane, MD, 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.