



## Ardelyx to Present Additional Data Supporting First-In-Class XPHOZAH® (tenapanor) for Adults with Chronic Kidney Disease on Dialysis at the National Kidney Foundation 2024 Spring Clinical Meetings

May 1, 2024

WALTHAM, Mass., May 01, 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 National Kidney Foundation (NKF) 2024 Spring Clinical Meetings, to be held May 14-18, 2024, in Long Beach, California. 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.

### Title: **Tenapanor Treatment Added to Phosphate Binders Improved Long-Term Serum Phosphate (P) Control as Measured by Reduction in Average Daily P Area Under the Curve**

Authors: Kevin J. Martin, David M. Spiegel, Yang Yang, David Rosenbaum, Susan Edelstein, Laura Williams

Poster Number: 239

Date/Time: May 15, 2024, from 5:30 PM to 7:00 PM PDT (UTC -7)

### Title: **Treatment Response to Tenapanor Categorized by Age and Comorbidities: A Post Hoc Analysis of the PHREEDOM Study**

Authors: Daniel Weiner, David M. Spiegel, Yang Yang, David Rosenbaum, Susan Edelstein

Poster Number: 243

Date/Time: May 15, 2024, from 5:30 PM to 7:00 PM PDT (UTC -7)

### Title: **Patient Perception of Phosphate-Lowering Treatment Regimen Improves Adherence to Therapy**

Authors: Amy Mosman, Susan Edelstein, David M. Spiegel, Suling Zhao, David Rosenbaum

Poster Number: 240

Date/Time: May 15, 2024, from 5:30 PM to 7:00 PM PDT (UTC -7)

In addition to the poster presentations during NKF Spring Clinical Meetings, Ardelyx is sponsoring an Exhibitor Showcase titled: **"A New Paradigm: Rethinking Hyperphosphatemia Management,"** on May 17, 2024, from 8:30-9:05 AM PDT, where David M. Spiegel, MD and Lisa Gutekunst MSEd, RD, CSR, CDN, FNKF, 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<sup>®</sup> (tenapanor) and XPHOZAH<sup>®</sup> (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 commercializes PHOZEVEL<sup>®</sup> (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](#).

**Investor and Media Contacts:**

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Source: Ardelyx, Inc.