FDA Approves XPHOZAH® (tenapanor), a First-in-Class Phosphate Absorption Inhibitor

October 17, 2023

XPHOZAH has been approved 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 blocks the absorption of phosphate with a single tablet taken twice daily

Commercial launch underway with product expected to be available in November

Ardelyx to host conference call tomorrow, October 18 at 8:00 am ET

WALTHAM, Mass., Oct. 17, 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 announced that the U.S. Food and Drug Administration (FDA) has approved XPHOZAH® (tenapanor), the first and only phosphate absorption inhibitor, 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. XPHOZAH is a single tablet taken twice daily that offers a first-in-class mechanism of action that blocks phosphate absorption through its primary pathway.

“The approval of XPHOZAH is an important milestone for patients on dialysis, their families and the nephrology care community, as it represents a new mechanism and new option for patients who, despite treatment with phosphate binders, continue to have elevated phosphorus. It is also a significant accomplishment for everyone at Ardelyx,” said Mike Raab, president and chief executive officer of Ardelyx. “Since the founding of the company in 2007, we have been steadfast in our commitment to the kidney community, and today’s approval reinforces the compelling clinical profile and potential benefit that XPHOZAH may provide for so many patients. This therapy was born in our labs in 2008, and to now see it becoming available for patients is truly a testament to the dedication, outstanding execution, and sense of mission of the Ardelyx team. This approval is also a tribute to the patients, families, physicians and clinical trial personnel who participated in the development of XPHOZAH. There is a high level of anticipation and enthusiasm for the launch of XPHOZAH from the kidney community, and our world-class team will enter the marketplace well positioned with a first-in-class product.”

Dr. Glenn Chertow, professor of medicine, Stanford University, added, “Hyperphosphatemia management has been a persistent clinical challenge, as the majority of patients receiving maintenance dialysis are unable to consistently achieve target serum phosphate concentrations despite treatment with phosphate binders. XPHOZAH is not a phosphate binder. XPHOZAH is a phosphate absorption inhibitor. In patients not adequately responding to phosphate binder therapy, XPHOZAH has been shown to help increase the proportion of patients achieving target serum phosphate concentrations. I believe XPHOZAH can advance the care of patients with hyperphosphatemia, providing a new treatment option with a complementary mechanism of action.”

Clinical Data Supporting XPHOZAH
FDA approval of XPHOZAH is based on a comprehensive development program, including a diverse population of more than 1,000 patients in three Phase 3 clinical trials evaluating the efficacy and safety of XPHOZAH, as monotherapy and in combination with phosphate binder therapy, all of which met their primary and key secondary endpoints (PHREEDOM, BLOCK and AMPLIFY). Data from the three clinical trials demonstrated that XPHOZAH significantly reduced elevated serum phosphorus in patients receiving maintenance hemodialysis.

Diarrhea, which occurred in 43 to 53 percent of patients, was the only adverse reaction reported in at least five percent 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 five percent of XPHOZAH-treated patients in these trials.

Ardelyx also completed two open-label clinical trials (OPTIMIZE and NORMALIZE) to evaluate different options for integrating XPHOZAH into clinical practice.

Ardelyx Commitment to Patient Access
Ardelyx is committed to setting new standards in product innovation and to setting new standards for patient support. Ardelyx will integrate XPHOZAH into its established patient services program, ArdelyxAssist™. ArdelyxAssist is an innovative, digital-forward patient services program that provides access and affordability support for patients, with integration into medical office work processes and connectivity to patients and health care providers.

Conference Call Details
The company will host a conference call tomorrow, October 18, 2023, at 8:00 am ET to discuss today's announcement. To participate in the conference call, please dial (844) 481-2838 (domestic) or (412) 317-1858 (international) and ask to be joined into the Ardelyx call. A webcast of the call can also be accessed by visiting the Investor page of the company's website, www.ardelyx.com, and will be available on the website for 30 days following the call.

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 resulting in 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.

Forward Looking Statements
To the extent that statements contained in this press release are not descriptions of historical facts regarding Ardelyx, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor of the Private Securities Reform Act of 1995, including the potential for XPHOZAH to advance the care of patients with chronic kidney disease on dialysis who have elevated levels of serum phosphorus and the potential for ArdelyxAssist to set new standards in patient support. Such forward-looking statements involve substantial risks and uncertainties that could cause Ardelyx's future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, uncertainties associated with the development of, regulatory process for, and commercialization of drugs in the U.S. Ardelyx undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Ardelyx's business in general, please refer to Ardelyx's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 2, 2023, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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