Ardelyx Responds to District Court Decision Granting Motion to Dismiss

November 8, 2024

Inclusion of oral-only phosphate-lowering therapies in the ESRD PPS will put dialysis patients' health at risk

WALTHAM, Mass., Nov. 08, 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 confirmed that Judge Beryl Howell from the U.S. District Court for Washington, D.C. has granted defendants' motion to dismiss the lawsuit filed by Ardelyx, the American Association of Kidney Patients (AAKP) and the National Minority Quality Forum (NMQF), permitting the Centers for Medicare and Medicaid Services (CMS) to proceed with its plan to include XPHOZAH® (tenapanor) and other oral-only phosphate lowering therapies (PLTs) in the End-Stage Renal Disease Prospective Payment System (ESRD PPS).

"We are disappointed and saddened by the Court's decision to grant defendants' motion to dismiss allowing CMS to bring PLTs into the Medicare ESRD PPS beginning on January 1, 2025. This will result in incredible harm to dialysis patients who, as a result of the bundled payment system, are unable to access the best care and medicine they require. Dialysis patients are among those who have historically experienced poorer health outcomes due to negative social determinants of health. And, while addressing health disparities has been a stated goal for CMS, this policy moves us in the opposite direction, resulting in severely restricted access to important medications," said Mike Raab, president and chief executive officer of Ardelyx.

Raab continued, "Today's decision reinforces our commitment to pursue all means for protecting patient access to XPHOZAH, including our choice not to apply for TDAPA in order to preserve the shared decision-making process between patients and healthcare providers who can best determine the best course of therapy to manage hyperphosphatemia. We also urge Congress to act swiftly on the overwhelming pleas from patients, physicians, faith leaders, labor unions and health equity advocates across the nation to pass the Kidney PATIENT Act."

Ardelyx is currently reviewing the District Court's decision and will consider all options related to the lawsuit.

XPHOZAH was approved by the U.S. Food and Drug Administration in October 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. Eighty percent of patients with CKD on dialysis require prescription therapy to lower elevated levels of serum phosphorus. Phosphate binders are not sufficient for a majority of patients to achieve and maintain phosphorus levels within target range. 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.

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 (XPHOZAH)

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.

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 impact that moving XPHOZAH and PLTs into the ESRD PPS will have on patient access, the impact that our choice not to apply for TDAPA will have on the shared decision-making process between patients and healthcare providers, and the clinical benefit of XPHOZAH. 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. and internationally. 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 October 31, 2024, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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Source: Ardelyx, Inc.