Ardelyx, AAKP and NMQF File Lawsuit to Protect Dialysis Patient Choice and Timely Access to Clinically Meaningful Medicines

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Lawsuit challenges CMS's statutory overreach in its determination to include oral-only phosphate-lowering therapies in the End-Stage Renal Disease Prospective Payment System

Inclusion of oral-only phosphate lowering therapies within the ESRD PPS limits patient choice and timely access to important innovations and treatment options for unmet needs

WALTHAM, Mass., July 17, 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, in partnership with the American Association of Kidney Patients (AAKP), the nation's largest independent kidney patient organization, and the National Minority Quality Forum (NMQF), the nation's largest minority healthcare research, education and advocacy organization, it has filed a lawsuit against the U.S. Department of Health and Human Services and the Centers for Medicare and Medicaid Services (CMS), claiming that CMS's plan to include XPHOZAH® (tenapanor), along with all other oral-only phosphate lowering therapies (PLTs), in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) will significantly and negatively impact patient choice of and timely access to important medications.

The lawsuit claims that CMS has violated its statutory and regulatory authority under the Medicare Improvements for Patients and Providers Act (MIPPA), which established the ESRD PPS bundled payment system for dialysis services in 2008. Specifically, the lawsuit claims that CMS's plan to move XPHOZAH, along with all oral-only PLTs, into the ESRD PPS is inconsistent with MIPPA's statutory provision, and contradicts CMS's own regulations. XPHOZAH and other PLTs, which are currently available to patients under outpatient pharmacy benefit plans such as Medicare Part D, are not administered by dialysis providers and cannot be taken during the delivery of maintenance dialysis. The plaintiffs seek relief under the Administrative Procedure Act to enjoin CMS from proceeding with its plan to include XPHOZAH in the ESRD PPS and eliminate coverage under Medicare Part D beginning on January 1, 2025.

"It is abundantly clear that moving XPHOZAH and other PLTs into the ESRD PPS will result in the imposition of severe care choice and timely access restrictions for all dialysis patients. The planned move by CMS will continue to create disincentives for the development of new and important medicines that can improve patient health and address unmet needs in an already underserved therapeautic area," said Mike Raab, president and chief executive officer of Ardelyx. "In the eight months that our first-in-class phosphate absorption inhibitor, XPHOZAH, has been in clinical use, many patients have now been able to achieve and maintain phosphorus levels within the target range. Patients with elevated phosphorus have few options to improve their condition and are now at risk of losing choice and timely access to a brand new, FDA-approved therapy that is providing them a meaningful clinical benefit. This lawsuit attempts to stop CMS's continued harmful statutory overreach and better protect dialysis patients' choice and timely access to important new therapies."

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 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 (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.

About the American Association of Kidney Patients (AAKP)
Since 1969, AAKP has been a patient-led organization driving policy discussions on kidney patient care choice and medical innovations to improve patient lives and prevent avoidable illness and death. AAKP advocates played a central role in the Congressional authorization of the modern ESRD program and coverage for dialysis and transplantation. Over the past decade, AAKP patient advocates have helped advance lifetime transplant drug coverage for kidney transplant recipients (2020); the presidential Executive Order on Advancing American Kidney Health (2019); new job protections for living organ donors under the Family Medical Leave Act (FMLA) via the U.S. Department of Labor (2018); and Congressional legislation allowing HIV-positive organ transplants for HIV-positive patients (2013). Follow AAKP on social media at @kidneypatient on Facebook, @kidneypatients on Twitter, and @kidneypatients on Instagram, and visit http://www.aakp.org for more information.

About National Minority Quality Forum
The National Minority Quality Forum (NMQF) is a 501(c)(3) not-for-profit research and advocacy organization based in Washington, DC. The mission of NMQF is to reduce patient risk by assuring optimal care for all. NMQF's vision is an American health services research, delivery and financing system whose operating principle is to reduce patient risk for amenable morbidity and mortality while improving quality of life. For more information, please visit www.nmqf.org.

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 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 May 2, 2024, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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