To Preserve Patient Access to XPHOZAH®, Ardelyx Chooses Not to File for TDAPA

July 2, 2024

Ardelyx continues support for bipartisan legislation that would extend the exclusion of oral-only medications from entering the CMS Prospective Payment System

Conference call scheduled for 8:00 AM Eastern Time

WALTHAM, Mass., July 02, 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 an effort to preserve patient access to its phosphate absorption inhibitor XPHOZAH® (tenapanor), the Company has chosen not to apply to include XPHOZAH in the Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Transitional Drug Add-on Payment Adjustment (TDAPA).

Ardelyx's analysis of the CMS policy to include oral-only medicines in the PPS and the Calendar Year 2025 ESRD PPS Proposed Rule released on June 27, 2024, revealed that the policy and the manner in which CMS intends to implement it are likely to cause significant restrictions on the use of XPHOZAH for all patients, irrespective of insurance coverage, because it interferes with the essential and appropriate shared decision-making between healthcare professionals and their patients.

"At Ardelyx, we recognize that the only way innovative medicines like XPHOZAH can deliver their proven benefits to patients is by ensuring that those prescribed our medicines have access to them. XPHOZAH is the only therapy approved for patients who have an inadequate response to phosphate binder therapy and during the eight months it has been utilized in clinical practice, it is clear that patients are benefitting from and need continued access to this therapeutic option to reduce elevated serum phosphorus," said Mike Raab, president and CEO of Ardelyx. "We have carefully and thoughtfully considered the potential impact of CMS's decision to add XPHOZAH into the Medicare PPS and have determined that even during the TDAPA period, the restrictions placed on XPHOZAH would be such that patient access to this novel therapy would be effectively eliminated for all patients. We believe that the proposed bipartisan legislation extending the exclusion of oral-only medications from the Medicare ESRD PPS is the best option to ensure continued patient access, and we call on Congress to pass the bill. Our decision not to apply for TDAPA reflects our steadfast commitment to preserving patients' access to our medicines and provides the best optionality for us to continue to explore alternatives to protect all patients."

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.

Conference Call Details
The company will host a conference call today, July 2, 2024, 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, https://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 (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 of the TDAPA period and the ESRD PPS policy on access to XPHOZAH and our current belief that not applying for TDAPA provides the best optionality to explore options to provide access to all patients. 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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Source: Ardelyx, Inc.