Ardelyx Announces FDA Acceptance and Six-Month Review for Resubmission of its New Drug Application of XPHOZAH® (tenapanor)

May 17, 2023

User Fee Goal Date: October 17, 2023

WALTHAM, Mass., May 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 accepted its resubmission of a New Drug Application (NDA) for XPHOZAH® (tenapanor) for the control of serum phosphate in adult patients with chronic kidney disease on dialysis who have had an inadequate response or intolerance to a phosphate binder therapy. The FDA has determined that the NDA is a class 2 review, which results in a six-month review period from the date of resubmission. The FDA has set a user fee goal date of October 17, 2023. The company expects XPHOZAH to be commercially available in the fourth quarter of 2023, as soon as possible following an approval from the FDA.

“The acceptance of our NDA is a significant milestone in our journey to bring XPHOZAH to patients. We are excited about the prospect of working collaboratively with the FDA to finalize this review over the next few months,” said Mike Raab, president and chief executive officer of Ardelyx. “We are now in full preparation mode and intend to launch XPHOZAH to the physician and patient communities who have patiently waited for access to this novel therapy as soon as possible after we receive an approval notification from the FDA, finally bringing this much-needed treatment to patients.”

The NDA is supported by a comprehensive development program that included more than 1,200 patients in three Phase 3 clinical trials evaluating the safety and efficacy of XPHOZAH, all of which met their primary and key secondary endpoints (PHREEDOM, BLOCK and AMPLIFY), as well as two additional Phase 4 open-label clinical trials (OPTIMIZE and NORMALIZE).

About XPHOZAH® (tenapanor)
XPHOZAH, discovered and developed by Ardelyx, is a first-in-class, phosphate absorption inhibitor that has a novel mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3 (NHE3), reducing phosphate absorption through the paracellular pathway, the primary pathway of phosphate absorption. This novel blocking mechanism enables a one 30mg tablet twice daily dosing regimen. The most common side effect with XPHOZAH in clinical trials was diarrhea.

About Hyperphosphatemia
Hyperphosphatemia is a serious condition resulting in an abnormally elevated level of phosphate in the blood that is estimated to affect the vast majority of the 550,000 patients in the United States with chronic kidney disease (CKD) on maintenance dialysis. The kidney is the organ responsible for regulating phosphate, but when kidney function is significantly impaired, 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).

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’s first approved product, IBSRELA ® (tenapanor) is available in the United States and Canada. Ardelyx is developing XPHOZAH® (tenapanor), a novel product candidate for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis, which has completed three successful Phase 3 trials. Ardelyx has a Phase 2 potassium lowering compound, RDX013, for the potential treatment of elevated serum potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease and an early-stage program in metabolic acidosis, a serious electrolyte disorder in patients with CKD. Ardelyx has established agreements with Kyowa Kirin in Japan, Fosun Pharma in China and Knight Therapeutics in Canada for the development and commercialization of tenapanor in their respective territories. For more information, please visit https://ardelyx.com/ and connect with us on 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 Ardelyx’s current expectation of the review goal date for the NDA and any subsequent commercial launch; and the potential role that tenapanor can play in offering a new treatment option for patients with hyperphosphatemia. 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 process for regulatory approval. 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 3, 2023, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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