Ardelyx Resubmits New Drug Application to U.S. Food and Drug Administration for XPHOZAH® (tenapanor)

April 18, 2023

Company expects to receive goal review date in mid-May

WALTHAM, Mass., April 18, 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 the resubmission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the approval of 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. An Acknowledgement of Receipt letter from the FDA, confirming the resubmission is complete, is expected in mid-May. We expect that the letter will include the classification of the resubmission and the review goal date.

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 it will receive confirmation from the FDA that its resubmission of the NDA for XPHOZAH is complete and the timing thereof, and Ardelyx's current expectation that such confirmation will also include the review goal date for the NDA. 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2023, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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