Ardelyx Announces FDA Plan to Convene Advisory Committee for XPHOZAH® (tenapanor)

April 25, 2022

- *Ardelyx welcomes the opportunity for the company, patients, and practicing* nephrologists *to speak to clinically meaningful results in treating* hyperphosphatemia -

WALTHAM, Mass., April 25, 2022 /PRNewswire/ -- 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 Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA), has provided an interim response to Ardelyx's second level of appeal of the Complete Response Letter (CRL) received on July 28, 2021, for XPHOZAH. The OND noted that additional input from the Cardiovascular and Renal Drug Advisory Committee in general, and specifically, from experts, including expert clinicians, would be valuable in further considering the clinical meaningfulness of the phosphate lowering effect observed in Ardelyx's phase 3 clinical program for XPHOZAH. Accordingly, the OND intends to direct the Division of Cardiology and Nephrology to bring the XPHOZAH New Drug Application (NDA) to the Cardiovascular and Renal Drugs Advisory Committee, and to provide a response to Ardelyx's appeal within thirty (30) days after the conclusion of the Advisory Committee meeting. Ardelyx is seeking approval for XPHOZAH for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis.

"We view the interim response that we received from the OND as an important next step in our ongoing pursuit of approval of XPHOZAH," said Mike Raab, president and chief executive officer of Ardelyx. "We are pleased that the OND has acknowledged the importance of including input from expert clinicians, as part of an Advisory Committee meeting in order to further evaluate the clinical meaningfulness and significance of the phosphate reduction we have demonstrated with XPHOZAH. The nephrology community has been steadfast in its belief of the important role XPHOZAH, with its novel mechanism of action, can play by providing a different approach to managing hyperphosphatemia in patients. While we await direction from the OND on the timing of this meeting, we look forward to the opportunity to further discuss XPHOZAH with the Cardiovascular and Renal Drugs Advisory Committee."

About XPHOZAH (tenapanor) for Hyperphosphatemia

XPHOZAH (tenapanor), discovered and developed by Ardelyx, in an investigational first-in-class phosphate absorption inhibitor (PAI). XPHOZAH, with its unique blocking mechanism of action, 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 30 mg tablet BID dosing regimen. The most common side effect with tenapanor in clinical trials was diarrhea.

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. Ardelyx is developing XPHOZAH® (tenapanor), a novel product candidate to control serum phosphorus in adult patients with CKD on dialysis, which has completed three successful Phase 3 trials. Ardelyx is also advancing RDX013, a potassium secretagogue, for the potential treatment of elevated serum potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease and has 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.

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 regarding the FDA's plan to convene an Advisory Committee meeting to consider the NDA for XPHOZAH, Ardelyx's expectations regarding the timing of a response to its appeal following the conclusion of the Advisory Committee meeting and Ardelyx's expectations regarding the role that XPHOZAH may play, if approved, in the management of 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 drug development process and the regulatory approval process. 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 February 28, 2022, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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