Ardelyx Announces Extension of the PDUFA Review Period for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis

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FREMONT, Calif. and WALTHAM, Mass., April 29, 2021 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company focused on the discovery, development, and commercialization of innovative first-in-class medicines to improve treatment for people with kidney and cardiorenal diseases, today announced that the Prescription Drug User Fee Act (PDUFA) date for tenapanor for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis has been extended by three months.

Following constructive labeling discussions with the U.S. Food and Drug Administration (FDA) that began in early April, the agency made a recent information request that required the company to submit additional analyses to help the agency better understand the clinical data in light of tenapanor's novel mechanism of action as compared to approved therapies. In response, the company submitted the requested analyses which constitute a major amendment to the New Drug Application (NDA), resulting in an extension of the PDUFA date by three months to July 29, 2021.

"While disappointed in the delay, we understand the impact that the COVID-19 pandemic has had on the operations of the agency," said Mike Raab, president and chief executive officer of Ardelyx. "We appreciate the constructive labeling discussions with the agency over the past month and believe that the additional analyses submitted in response to recent dialogue with the agency reinforce the extensive clinical evidence we generated on tenapanor. We look forward to continuing to work closely and constructively with FDA during the remainder of the review process. We are confident in the comprehensive data set, are well prepared for the launch of tenapanor upon potential approval and are dedicated to bringing this important medicine to patients."

The NDA for tenapanor for the control of serum phosphorus is supported by a comprehensive development program involving more than 1,000 patients, including three Phase 3 clinical trials, all of which met their primary and key secondary endpoints.

About Tenapanor for Hyperphosphatemia

Tenapanor, discovered and developed by Ardelyx, is a first-in-class, proprietary, oral medicine for which an NDA is under review by the FDA for the control of serum phosphorus in adult patients with CKD on dialysis. Hyperphosphatemia is a serious condition that is an independent predictor of morbidity and mortality in dialysis patients. Despite treatment with currently available drugs, 40% of patients continue to have phosphorous levels outside of target ranges in any given month. Recent data has shown that 77% of patients are unable to consistently maintain target phosphorus levels over a six-month period. Tenapanor has a unique mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3 (NHE3). This results in a proposed conformational change of the epithelial cell tight junctions, thereby significantly reducing paracellular permeability to phosphate and decreasing phosphate absorption through this primary pathway. Ardelyx is conducting NORMALIZE, an ongoing extension study of the PHREEDOM Phase 3 monotherapy study, which is designed to evaluate the ability of tenapanor, as monotherapy or in combination with sevelamer, to achieve serum phosphorus levels in the normal range (2.5 – 4.5 mg/dL) in patients with chronic kidney disease (CKD) on dialysis. Planned analyses have demonstrated that the use of tenapanor as a foundational approach, as monotherapy or in combination with sevelamer carbonate, produces a significant phosphorus-lowering effect. Preliminary data from the NORMALIZE trial demonstrates that after ~20 months of treatment with tenapanor alone or with low doses of sevelamer, patients exhibited a mean serum phosphorus reduction of 2.33 mg/dL, from a mean baseline phosphorus of 7.27 mg/dL at the beginning of the PHREEDOM trial to a mean of 4.94 mg/dL.

About Ardelyx, Inc.

Ardelyx is focused on discovering, developing and commercializing innovative first-in-class medicines to enhance the lives of patients with kidney and cardiorenal diseases. Ardelyx is advancing tenapanor, a novel product candidate to control serum phosphorus in adult patients with CKD on dialysis, for which the company's NDA is currently under review by the FDA. 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. In addition, Ardelyx received FDA approval of IBSRELA® (tenapanor) on September 12, 2019. 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. 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, the uncertainties associated with 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 March 8, 2021, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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