Ardelyx Collaboration Partner, Kyowa Kirin, Announces Initiation of Phase 3 Clinical Studies of Tenapanor for Hyperphosphatemia in Japan

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Ardelyx to Receive a $5 Million Milestone Payment

FREMONT, Calif. and WALTHAM, Mass., April 14, 2021 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company focused on developing innovative first-in-class medicines to improve treatment for people with kidney and cardiorenal diseases, today announced that its collaboration partner in Japan, Kyowa Kirin Co., Ltd. (TSE: 4151, Kyowa Kirin), has initiated four Phase 3 clinical studies in Japan evaluating tenapanor for hyperphosphatemia. The achievement of this development milestone triggers a $5 million payment to Ardelyx.

The Phase 3 clinical trials consist of a multi-center, randomized, double-blind, placebo-controlled, parallel-group comparative study; a phosphate binder-combination parallel-group comparative study; an open-label, single-arm study evaluating hyperphosphatemia patients on peritoneal dialysis; and a long-term study evaluating serum phosphorus in patients who switch from one or more phosphate binders to tenapanor for hyperphosphatemia in Japan.

"As we approach our April 29 PDUFA date for tenapanor for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis and prepare for potential commercialization in the U.S., we are pleased to see the significant progress made by our partner Kyowa Kirin," said Mike Raab, president and chief executive officer of Ardelyx. "We are thrilled to have key strategic partners like Kyowa Kirin, along with our partners in Canada and China, to support development of, and once approved, patient access to, tenapanor globally."

Under the terms of the license agreement for tenapanor with Kyowa Kirin, which was signed in 2017 Ardelyx received a $30 million upfront payment and is eligible to receive up to $55.0 million in total development milestones and 8.5 billion yen in commercialization milestones. Ardelyx is also eligible to receive high-teen royalties on sales throughout the term of the agreement. Kyowa Kirin has been granted the exclusive rights to develop, market and commercialize tenapanor for cardiorenal diseases and conditions associated with them, including hyperphosphatemia, in Japan.

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. 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 conformational change of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate at the primary pathway of phosphate absorption. 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. 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, with a PDUFA date of April 29, 2021. 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, including the potential for tenapanor in controlling serum phosphorus in chronic kidney disease patients on dialysis as monotherapy or in combination with Sevelamer carbonate. Such forward-looking statements involve substantial risks and uncertainties that could cause Ardelia'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 drug development, regulatory approval and commercialization 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 Ardelia's business in general, please refer to Ardelia'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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