Ardelyx Collaboration Partner, Kyowa Kirin, Announces Submission of New Drug Application for Tenapanor for Hyperphosphatemia in Japan

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Ardelyx to receive an aggregate of $35 million in milestone payments and payments associated with the recent amendment of the license agreement

WALTHAM, Mass., Oct. 31, 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 its collaboration partner in Japan, Kyowa Kirin Co., Ltd. (TSE: 4151, Kyowa Kirin), has submitted a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare (MHLW) for tenapanor for the improvement of hyperphosphatemia in adult patients with chronic kidney disease (CKD) on dialysis. This submission triggers an aggregate of $35 million to Ardelyx in milestone payments and payments under the recent amendment to the license agreement between Ardelyx and Kyowa Kirin. Kyowa Kirin made a public announcement, which is available here: Kyowa Kirin Announces NDA Submission of Tenapanor Hydrochloride (KHK7791) for Improvement of Hyperphosphatemia in Chronic Kidney Disease Patients on Dialysis in Japan

"The NDA submission represents important progress toward making tenapanor available in Japan to treat hyperphosphatemia in patients with CKD on dialysis," said Mike Raab, president and chief executive officer of Ardelyx. "The data generated by Kyowa Kirin in Japan further supports our extensive clinical results demonstrating the importance of having tenapanor in the armamentarium of treatment options for nephrologists. We congratulate our partners on their work, and we would like to express our gratitude to them, the hundreds of patients that participated in their clinical studies in Japan, and the medical staff that supported these patients. Together, we share a common vision for the betterment of patients with kidney disease."

The NDA is supported by data from four Phase 3 clinical trials, conducted by Kyowa Kirin in Japan in patients with hyperphosphatemia on maintenance dialysis. Across Kyowa Kirin's clinical program, tenapanor demonstrated statistically significant reductions in serum phosphorus levels, with tenapanor both as monotherapy and when added to phosphate binders for patients whose serum phosphorus levels were poorly controlled on phosphate binders alone. The results of the studies undertaken by Kyowa Kirin suggest that tenapanor may also reduce the medication burden of phosphorus management utilizing marketed phosphate binders for treating hyperphosphatemia. In these studies, the safety and tolerability profile for tenapanor was consistent with prior studies in Japan, with no new safety signals identified.

In the U.S., Ardelyx is pursuing approval of tenapanor for the treatment of hyperphosphatemia in adult patients with CKD on dialysis, with the brand name XPHOZAH, and has an appeal underway in response to the Complete Response Letter it received from the FDA for its NDA. As part of the appeal process, the FDA will convene an Advisory Committee Meeting to review XPHOZAH on November 16, 2022. For more details please visit: https://www.govinfo.gov/app/details/FR-2022-09-19/2022-20198

About Tenapanor for Hyperphosphatemia

Tenapanor, discovered and developed by Ardelyx, in an investigational first-in-class phosphate absorption inhibitor (PAI). With its unique blocking mechanism of action, tenapanor 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 Hyperphosphatemia

Hyperphosphatemia is a serious condition resulting in an abnormally elevated level of phosphorus in the blood that is estimated to affect more than 745,000 dialysis patients in major developed countries. The kidney is the organ responsible for regulating phosphorus levels, but when kidney function is significantly impaired, phosphorus is not adequately eliminated from the body. As a result, hyperphosphatemia is a nearly universal condition among people with CKD on 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 to control serum phosphorus in adult patients with 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.

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, if approved, to reduce the medication burden of phosphorus management utilizing marketed phosphate binders for treating 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 clinical development and regulatory processes. 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 August 4, 2022, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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