Ardelyx Provides Regulatory Update on New Drug Application for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis

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FREMONT, Calif. and WALTHAM, Mass., July 19, 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 it received a letter from the U.S. Food and Drug Administration (the "FDA") on July 13, 2021, stating that, as part of its ongoing review of the company's New Drug Application ("NDA") for the control of serum phosphorus in adult patients with chronic kidney disease ("CKD") on dialysis, the FDA has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time. The letter stated that the notification does not reflect a final decision on the information under review. The company immediately requested a meeting to discuss the deficiencies and was notified by the FDA today that the request for a meeting was denied.

While the FDA has not provided specific details regarding the deficiencies, the FDA noted that a key issue is the size of the treatment effect and its clinical relevance.

"This is an extremely disheartening and disappointing communication from the FDA, particularly following the weeks of label discussions that occurred in early April, the fact that our NDA submission included three pivotal trials across 1,000 patients, all which met their primary and key secondary endpoints, as well as the additional data analyses we submitted in late April in response to the FDA's requests," said Mike Raab, president and chief executive officer of Ardelyx. "We plan to work with the FDA to learn more about the identified deficiencies and will seek to resolve them as quickly as possible."

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 submitted an NDA to the FDA in June 2020. In April 2021, the FDA extended the PDUFA date to July 29, 2021, following the submission of additional analyses determined to be a major amendment. 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 company's expectations with regard to its interactions and communications with the FDA and its plans and expectations as to the path forward for tenapanor for the control of serum phosphorus in adult patients with chronic kidney disease patients on dialysis. 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, whether the company will be able to address the deficiencies identified by the FDA and obtain regulatory approval for tenapanor. 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 May 6, 2021, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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