Ardelyx Receives Complete Response Letter from U.S. FDA for New Drug Application for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis

July 29, 2021

Conference call and webcast to be held at 5:00 PM ET

FREMONT, Calif. and WALTHAM, Mass., July 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 it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the company's New Drug Application (NDA) for tenapanor for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis.

According to the CRL, while the FDA agrees that "the submitted data provide substantial evidence that tenapanor is effective in reducing serum phosphorus in CKD patients on dialysis," they characterize the magnitude of the treatment effect as "small and of unclear clinical significance." Additionally, the FDA noted that for the application to be approved, Ardelyx needs "to conduct an additional adequate and well-controlled trial demonstrating a clinically relevant treatment effect on serum phosphorus or an effect on the clinical outcome thought to be caused by hyperphosphatemia in CKD patients on dialysis." There were no safety, clinical pharmacology/biopharmaceutics, CMC or non-clinical issues identified in the CRL.

The FDA indicated it is willing to meet with Ardelyx to discuss options for obtaining approval. To that end, the company intends to request a Type A meeting as soon as possible to discuss the CRL and determine potential paths forward for the approval of tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis.

"We are saddened by this communication from the FDA and what it means for the patients and the physicians who treat them," said Mike Raab, president and chief executive officer of Ardelyx. "We continue to believe tenapanor represents an important, first-in-class treatment option for patients with elevated phosphorus. We do not agree with the FDA's subjective assessment on the clinical relevance of the treatment effect of tenapanor in our studies which met all clinical endpoints agreed upon by the FDA. In our view, the serum phosphorus lowering data generated with tenapanor in all of our clinical studies is meaningful and clinically significant. We will work with the agency to address the issues raised and, to the extent possible, find an expeditious path forward."

Arnold Silva, M.D., Ph.D., director of Clinical Research at Boise Kidney and Hypertension Institute, added, "Lowering serum phosphorus is a priority for me in managing my patients on dialysis, and is an established standard of care driven by the peer-reviewed globally accepted KDIGO clinical practice guidelines. Years of research have demonstrated the negative consequences associated with even slight elevations in serum phosphorus. Despite our best efforts with currently available therapies, managing phosphorus remains a significant challenge. We need new tools. I've closely followed the extensive clinical development of tenapanor, not only as an interested nephrologist, but also as a clinical investigator. I've seen the clinical benefits of tenapanor first-hand in my patients and I'm stunned that the FDA is not granting approval of this novel mechanism drug, despite extensive clinical data demonstrating its safety and efficacy."

"Neither peritoneal nor hemodialysis provides adequate control of serum phosphorus, obligating the use of medications," said Glenn Chertow, M.D., M.P.H., division chief of nephrology and professor of medicine at Stanford University. "Unfortunately, phosphate binders – individually or in combination – rarely yield consistent control of serum phosphorus concentrations, and persistent hyperphosphatemia leads to dystrophic calcification, accelerated arteriosclerotic vascular disease, fractures, and other complications that profoundly affect patients' lives. The effect of tenapanor on serum phosphorus observed in the Phase 3 trials is clinically meaningful. Tenapanor would enable a substantially larger fraction of patients to reach target serum phosphorus concentrations and would yield significant clinical benefit to this vulnerable population."

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

At the end of the second quarter ended June 30, 2021, Ardelyx had $171.8 million in cash and cash equivalents (unaudited).

Conference Call Details

The company will host a conference call today, July 29, 2021, at 5:00 PM ET to discuss today's announcement. To participate in the conference call, please call (855) 296-9612 (toll-free) or (920) 663-6277 (toll) and reference call ID number 6823689. A webcast of the call can also be accessed by visiting the Investor page of the company's website www.ardelyx.com and will be available on the website for 30 days following the call.

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 developing 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. 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 Ardelyx's expectation with regard to its interactions and communications with the FDA and its plans and expectations as to the possibility of a pathway to approval of 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, whether additional trials will be necessary and if so, the scope of those trials. 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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