Ardelyx Provides Corporate Update Following Type A Meeting with FDA

October 13, 2021

- Despite Type A Meeting, Ardelyx continues to await clarity from FDA on path forward for approval of tenapanor for hyperphosphatemia
- Company reduces staff by 65%

FREMONT, Calif. and WALTHAM, Mass., Oct. 13, 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 company has met with the U.S. Food and Drug Administration (FDA) in a Type A meeting, but was not provided sufficient clarity on what constitutes "clinical relevance of the magnitude of treatment effect" and continues to await additional information regarding the path forward for 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.

"Given that we have conducted the requisite registration studies, which met all primary and key secondary endpoints with no safety or other identified issues, we continue to be extremely disappointed and surprised by the lack of clarity from the FDA on the next steps to resubmit our NDA," said Mike Raab, president and chief executive officer of Ardelyx. "In order to preserve our cash resources and extend our cash runway, we have made the extremely difficult decision to implement a restructuring plan that includes a significant reduction in force. We have retained key employees needed to continue to support the regulatory process and work to achieve our goal to gain approval for tenapanor for hyperphosphatemia. While a setback for our company, we believe the delay in approval represents a more significant hardship for patients who are being denied access to tenapanor, a much-needed, novel therapeutic alternative with a different mechanism of action. We remain dedicated to providing these underserved patients, of which 77% are unable to maintain target phosphorus levels despite active treatment with currently available therapies, another treatment option."

The company announced that on October 12, 2021, it began implementing a restructuring plan to further reduce operating costs and better align the company's workforce with the needs of its business following the receipt of a complete response letter (CRL) from the FDA on July 28, 2021, regarding the company's NDA for the control of serum phosphorus in adult patients with CKD on dialysis, and the results to date of the subsequent Type A meeting. The restructuring plan is expected to be completed in December 2021. In connection with the restructuring, the company estimates that it will incur aggregate restructuring charges of approximately $2.3 million, which will be recorded primarily in the fourth quarter 2021, related to severance payments and other employee-related costs. The company expects that the workforce reduction will decrease its annual cash compensation costs by approximately $18.1 million. At the end of the third quarter ended September 30, 2021, Ardelyx had $141.7 million in cash and cash equivalents (unaudited).

In July 2021, Ardelyx announced that it had received a CRL from the FDA regarding the company's NDA for tenapanor for the control of serum phosphorus in adult patients with 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.

While Ardelyx has yet to receive minutes from the Type A meeting held October 1, 2021, the discussion at the meeting did not provide clarification on the key requirements: the FDA's definition of clinical significance and relevant treatment effect.

About Hyperphosphatemia

Hyperphosphatemia is a serious condition resulting in an abnormally elevated level of phosphorus in the blood that is estimated to affect the vast majority of the 550,000 patients in the United States with CKD on dialysis. 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 Tenapanor for Hyperphosphatemia

Tenapanor, discovered and developed by Ardelyx, has a unique mechanism of action and 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 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, tenapanor has already received FDA approval for the treatment of irritable bowel syndrome with constipation (IBS-C) under the tradename IBSRELA®. 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 statements regarding the expected costs associated with the restructuring plan and the expected reduction in annual cash compensation costs resulting from its workforce reduction. 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 risks related to cost reduction efforts. In addition, the company's workforce reduction costs may be greater than anticipated. 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 13, 2021, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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Investor and Media Contacts: Kimia Keshtbod, kkeshtbod@ardelyx.com; Sylvia Wheeler, Wheelhouse Life Science Advisors, swheeler@wheelhouselsa.com; Alex Santos, Wheelhouse Life Science Advisors, asantos@wheelhouselsa.com