Ardelyx to Pursue Formal Dispute Resolution for Tenapanor

November 4, 2021

Ardelyx maintains that in its comprehensive development program, tenapanor has demonstrated clinical relevance for the control of serum phosphorus in adult patients with chronic kidney disease on dialysis

FREMONT, Calif. and WALTHAM, Mass., Nov. 4, 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 the company plans to submit a Formal Dispute Resolution Request (FDRR) to appeal the issuance of a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) 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. Formal Dispute Resolution is a pathway in the Center for Drug Evaluation and Research (CDER) by which NDA applicants can seek to resolve scientific and/or medical disputes that cannot be resolved at the division level.

"While we are disappointed that we could not come to a resolution with the Division of Cardiology and Nephrology during the End of Review meeting, the Formal Dispute Resolution process provides an opportunity to raise our scientific disagreement above the division level within CDER," said Mike Raab, president and chief executive officer of Ardelyx. "We believe that this represents the best approach to obtaining approval of tenapanor for the treatment of hyperphosphatemia and bringing this important medicine forward to patients and their treating physicians."

"Phosphorus management is one of the most challenging aspects of caring for patients on dialysis," said Stuart Sprague, DO, FASN, FNKF, chief of the Division of Nephrology and Hypertension at Northshore University Health System, University of Chicago. "Despite our best efforts with currently available therapies, all of which act via the binding mechanism, nearly 80% of patients are unable to consistently achieve target phosphorus levels established by peer-reviewed global treatment guidelines, in spite of taking up to 10-12 pills per day. Thus, there is a strong need for a novel therapeutic approach, such as that of tenapanor, which blocks gastrointestinal phosphate absorption. The tenapanor clinical data package demonstrates that a significant proportion of patients respond to therapy with meaningful reductions in phosphorus with only 2 pills per day, and an acceptable safety and tolerability profile. The clinical relevance of tenapanor is clear. In addition, the meaningful impact tenapanor will have on the patient experience cannot be ignored. The delay in approval by the FDA is not in the best interest of patients. I applaud Ardelyx for their persistence in bringing this much-needed and innovative therapy to patients."

The company expects to submit the FDRR to the FDA's Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN) in the fourth quarter of 2021. The FDA's goal is to consider and decide on all FDRRs in thirty (30) days with some exceptions, including if a meeting is requested. A second appeal to the FDA's Office of New Drugs is possible if the company does not obtain a positive outcome from OCHEN.

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 expectation to submit a FDRR in the fourth quarter of 2021 and Ardelyx's expectations regarding the timing of a decision regarding its FDRR. 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 NDA process, the FDRR process, and appeal resolution with CDER. 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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