Ardelyx Announces FDA Advisory Committee Votes that the Benefits of XPHOZAH® (tenapanor) Outweigh its Risks for the Control of Serum Phosphorus in Adult Patients with Chronic Kidney Disease on Dialysis

November 16, 2022

The Advisory Committee voted 9:4 in favor of XPHOZAH as a monotherapy and 10:2 in favor of XPHOZAH in combination with phosphate binders

The Office of New Drugs is expected to provide a response to Ardelyx's appeal within thirty (30) days

If approved, XPHOZAH will be the first and only phosphate absorption inhibitor, reducing serum phosphorus with one pill taken twice daily

Conference call to be held tomorrow, November 17, 2022, at 8:00 AM ET

WALTHAM, Mass., Nov. 16, 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 the vote of the U.S. Food and Drug Administration's (FDA) Cardiovascular and Renal Drugs Advisory Committee (CRDAC) meeting for XPHOZAH for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis. The CRDAC voted nine to four that the benefits of treatment with XPHOZAH outweigh its risks for the control of serum phosphorus in adults with CKD on dialysis when administered as a monotherapy and voted ten to two, with one abstention, that the benefits of treatment with XPHOZAH in combination with phosphate binder treatment outweigh its risks.

"Today's vote by the CRDAC is a promising development for the chronic kidney disease community, as patients continue to struggle to control serum phosphorus levels despite use of currently available therapies, which are all limited to the phosphate binder class," said Mike Raab, president and chief executive officer of Ardelyx. "We are confident that the data from three Phase 3 clinical trials involving more than 1,200 patients support the approval of XPHOZAH in the U.S. for the control of serum phosphorus in adult patients with CKD on dialysis. We want to thank the patients, physicians and the advocacy community who shared their valuable insights today and throughout the development program. We are hopeful following today's discussion that the data, the opinion of the advisory committee, the needs of patients, and the compelling voice of the broader nephrology community will be reflected in the FDA's decision on our appeal."

Sharon Moe, M.D., chief of the division of nephrology and hypertension, Indiana University School of Medicine, added, "XPHOZAH is a novel treatment that provides a clinically meaningful effect on serum phosphate. I am encouraged by the committee's vote. The nephrology community is enthusiastic to have access to this therapy with its novel mechanism of action to help our patients."

The CRDAC review of XPHOZAH for the control of serum phosphorus in adult patients with CKD on dialysis was based on findings from a comprehensive development program including more than 1,200 patients in three Phase 3 clinical trials evaluating the safety and efficacy of XPHOZAH, all of which met their primary and key secondary endpoints (PHREEDOM, BLOCK and AMPLIFY).

The CRDAC's recommendations, while not binding, will be considered by the Office of New Drugs (OND), Center for Drug Evaluation and Research of the FDA, when making its decision on Ardelyx's second level appeal of the Complete Response Letter received on July 28, 2021, for XPHOZAH. The OND is expected to provide a response to Ardelyx's appeal within thirty (30) days.

About XPHOZAH (tenapanor) for Hyperphosphatemia

XPHOZAH (tenapanor), discovered and developed by Ardelyx, is an investigational first-in-class phosphate absorption inhibitor (PAI). XPHOZAH, with its unique blocking mechanism of action, 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 (twice) daily dosing regimen. The most common side effect with tenapanor in clinical trials was diarrhea.

About Hyperphosphatemia

Elevated levels of serum phosphorus in the blood, or hyperphosphatemia (HP), 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).

Conference Call Information

The company will host a conference call on November 17, 2022, at 8:00 AM ET to discuss the results of the Advisory Committee meeting. To participate in the conference call, please call (866) 374-5140 (toll-free) or (404) 400-0571 (toll) and reference call ID number 85570129#. A webcast of

the call can also be accessed by visiting the Investor page of the company's website at www.ardelyx.com and will be available on the website for 30 days following the call.

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. For more information, please visit https://ardelyx.com/ and connect with us on Twitter @Ardelyx, LinkedIn and Facebook.

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 whether the outcome of the Advisory Committee meeting will be reflected in FDA's decision on its appeal and Ardelyx's current expectation regarding the timing of the OND's decision on its appeal. 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 regulatory approval process. 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 November 3, 2022, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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SOURCE Ardelyx

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