Ardelyx Presents New Data Analyses at Kidney Week 2022, Further Supporting the Clinical Relevance of XPHOZAH® (tenapanor), an Investigational, Phosphate Absorption Inhibitor to Control Serum Phosphorus in Adult Patients with Chronic Kidney Disease on Dial

November 3, 2022

XPHOZAH monotherapy lowers serum phosphorus with early responders maintaining response with continued treatment

XPHOZAH monotherapy meaningfully reduced serum phosphorus in patients with severe hyperphosphatemia

XPHOZAH in combination with phosphate binders reduced patients' interdialytic weight gain compared to binders alone

WALTHAM, Mass., Nov. 3, 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 that new analyses of data from its three Phase 3 trials supporting the clinical utility of XPHOZAH (tenapanor) will be presented at the American Society of Nephrology (ASN) Kidney Week 2022, taking place in Orlando, Florida from November 3-6, 2022. XPHOZAH is an investigational first-in-class phosphate absorption inhibitor (PAI) for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis.

"These data continue to support the benefit that novel-mechanism XPHOZAH could have for patients on dialysis with hyperphosphatemia," said David Rosenbaum, Ph.D., chief development officer for Ardelyx. "Notably, early response to XPHOZAH was found to be predictive of continued response throughout the treatment period. This information could help guide treatment decisions that maximize the potential therapeutic benefit of XPHOZAH for these patients. With over 1,100 patients treated with XPHOZAH in clinical studies in the U.S. as well as clinical data generated by our partner Kyowa Kirin in Japan, we believe the impact that this first-in-class treatment could have for CKD patients on dialysis is clear."

New Clinical Analyses Being Presented by Ardelyx:

Poster # PO163 titled "The Predictive Value of Early Response to Tenapanor for the Treatment of Hyperphosphatemia in Patients Receiving Maintenance Dialysis" was based on a post hoc analysis of the Phase 3 PHREEDOM study evaluating if an early reduction in serum phosphorous (sP) following treatment with XPHOZAH would predict continued control of sP during subsequent treatment. Among patients who responded to XPHOZAH (≥1.2 mg/dL decrease in sP from baseline) within the first month and remained on treatment, approximately 80% continued to have at least a 1.2 mg/dL decrease in sP from baseline during weeks 17-26 of the treatment period.

Poster # PO162 titled "Reduction of Serum Phosphorus (sP) with Tenapanor in Patients with Chronic Kidney Disease (CKD) on Dialysis with Severe Hyperphosphatemia" presented post hoc analyses of the two Phase 3 monotherapy studies BLOCK and PHREEDOM to determine the effect of XPHOZAH monotherapy on dialysis patients with severe hyperphosphatemia, which was defined as having a baseline sP ≥7.5 mg/dL. Patients with severe hyperphosphatemia from the BLOCK and PHREEDOM studies had clinically meaningful mean sP reductions of 1.78 and 1.94 mg/dL, respectively, from baseline to the end of the randomized treatment periods or last assessment.

Poster # PO400 titled "Tenapanor Plus Phosphate Binder Reduces Interdialytic Weight Gain (IDWG) in Patients with Chronic Kidney Disease (CKD) on Hemodialysis (HD): Post Hoc Analysis of the AMPLIFY Study" examined pre-HD weights in patients to assess whether treatment with XPHOZAH in combination with phosphate binders decreased IDWG, which is associated with adverse patient outcomes, as compared with patients treated with phosphate binders alone. At week 4, the mean pre-HD weight decreased in patients whose treatment included XPHOZAH, while it increased in patients who received phosphate binders alone.

Ardelyx Exhibitor Spotlight Presentation:

In addition to the poster presentations highlighting tenapanor clinical data, Ardelyx is sponsoring an Exhibitor Spotlight titled: "The Phosphorus Management Puzzle and Need for New Pieces: The Patient and Physician Perspective", on Saturday November 5, 2022, from 12:30-1:15pm ET. During this Exhibitor Spotlight, Geoffrey Block, MD, associate chief medical officer and senior vice president of clinical research and medical affairs at U.S. Renal Care, and Dawn P. Edwards, patient ambassador, co-chair, national forum of ESRD networks kidney patient advisory council, will review the consequences of hyperphosphatemia, the current understanding of phosphate absorption, and the importance of managing hyperphosphatemia, including current management practices and inherent challenges. Dr. Block is also a member of Ardelyx's board of directors.

Clinical Data Being Presented by Kyowa Kirin Co., Ltd. (Kyowa Kirin):

Kyowa Kirin, the company's collaboration partner for tenapanor in Japan, is presenting data from two Phase 3 studies evaluating the efficacy and safety of tenapanor in hemodialysis patients in Japan. The results of the studies are summarized in Kyowa Kirin's press release dated October 20, 2022.

- Poster # PO160 titled "Efficacy and Safety of Tenapanor on Hyperphosphatemia in Japanese Hemodialysis Patients: Results of a Randomized Phase 3 Trial"

- Poster # PO161 titled "Efficacy and Safety of Tenapanor Added to Phosphate Binders for Hemodialysis Patients Who Have Poorly Controlled Hyperphosphatemia on Existing Phosphate Binders: Results of a Randomized Phase 3 Trial"

About XPHOZAH (tenapanor) for Hyperphosphatemia

XPHOZAH (tenapanor), discovered and developed by Ardelyx, is an investigational first-in-class phosphate absorption inhibitor (PAI). With its unique blocking mechanism of action, XPHOZAH 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 XPHOZAH in clinical trials was diarrhea.

About Hyperphosphatemia

Hyperphosphatemia 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 (2.5-4.5 mg/dL).

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.

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 potential therapeutic benefit that tenapanor could have, if approved, in controlling hyperphosphatemia in CKD 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, uncertainties associated with the clinical development and regulatory processes. 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 4, 2022, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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