Ardelyx Announces Data Supporting Efficacy and Safety of Tenapanor, a First-in-Class Phosphate Absorption Inhibitor, to be Presented at ASN's Kidney Week 2020

October 12, 2020

--Comprehensive datasets demonstrate tenapanor's ability to control serum phosphorous in patients with chronic kidney disease (CKD) on dialysis--

FREMONT, Calif., Oct. 12, 2020 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company focused on developing first-in-class medicines to improve treatment for people with kidney and cardiovascular diseases, today announced that five abstracts on tenapanor have been accepted for presentation at Kidney Week 2020, the American Society of Nephrology's (ASN) Annual Meeting, to be held October 22-25, 2020. Tenapanor, which was discovered and developed by Ardelyx, is a first-in-class therapy under review for potential marketing approval by the U.S. Food and Drug Administration (FDA) for the control of serum phosphorus in adult patients with CKD on dialysis.

Three poster presentations highlight data from several Phase 3 trials in the U.S., including the BLOCK, AMPLIFY and PHREEDOM studies. Additionally, the company's partner for tenapanor in Japan, Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE:4151), will present results from two Phase 2 studies evaluating the efficacy and safety of tenapanor in Japanese patients on hemodialysis.

Information regarding ASN's Kidney Week, including copies of presentation abstracts, can be found at https://www.asn-online.org/education/kidneyweek.

Ardelyx Poster Presentations:

Title: **Long-term Safety and Efficacy of Tenapanor for the Control of Serum Phosphorus in Patients with CKD on Dialysis**
Abstract Number: 3450189
ePoster Number: PO0384
Date/Time: Thursday, October 22, 10:00 a.m. EDT

Title: **Efficacy of Tenapanor for the Control of Serum Phosphorus in Patients with CKD on Dialysis: Novel Mechanism of Action Allows for Both Monotherapy and Dual Mechanism Approach**
Abstract Number: 3450673
ePoster Number: PO0374
Date/Time: Thursday, October 22, 10:00 a.m. EDT

Title: **Tolerability of Tenapanor, an Investigational, First-in-Class, Non-Binder Therapy for the Control of Serum Phosphorus in Patients with CKD on Dialysis**
Abstract Number: 3450921
ePoster Number: PO0376
Date/Time: Thursday, October 22, 10:00 a.m. EDT

Kyowa Kirin Poster Presentations:

Title: **Dose-Response Efficacy and Tolerability of Tenapanor on Hyperphosphatemia in Japanese Hemodialysis Patients: Results of a Randomized Phase 2 Study**
Abstract Number: 3435825
ePoster Number: PO0382
Date/Time: Thursday, October 22, 10:00 a.m. EDT

Title: **Efficacy and Safety of Add-on Tenapanor to Phosphate Binders for Refractory Hyperphosphatemia in Japanese Patients on Hemodialysis: A Phase 2, Double-Blind Study**
Abstract Number: 3439266
ePoster Number: PO0375
Date/Time: Thursday, October 22, 10:00 a.m. EDT

About our Partnership with Kyowa Kirin
Kyowa Kirin is a Japan-based global specialty pharmaceutical company committed to innovative drug discovery driven by state-of-the-art technologies. The company focuses on discovering and creating new value through advances in four therapeutic areas: nephrology, oncology, immunology/allergy and neurology. In 2017, Ardelyx entered into a license agreement that provides Kyowa Kirin exclusive rights to develop and commercialize tenapanor in Japan for the treatment of cardiorenal diseases. In addition, in 2019, the companies established a two-year research collaboration to advance two of Ardelyx's ongoing research programs focused on the identification and design of compounds for two undisclosed targets.

About Tenapanor for Hyperphosphatemia
Tenapanor, discovered and developed by Ardelyx, is a first-in-class, phosphate absorption inhibitor, for which an NDA is currently under review by the FDA (PDUFA date: April 29, 2021), for the control of serum phosphorus in adult patients with CKD on dialysis. Tenapanor has a unique mechanism of action that acts locally in the gut to inhibit the sodium hydrogen exchanger 3 (NHE3). This results in a conformational change of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate at the primary pathway of phosphate absorption. Tenapanor has been studied in three Phase 3 clinical trials in the U.S., all of which have met their primary endpoint, and support the role of tenapanor as foundational treatment in the management of hyperphosphatemia.

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. Despite treatment with phosphate binders (the only approved therapy for hyperphosphatemia), 77% of CKD patients on dialysis are unable to consistently maintain phosphorus levels ≤5.5 mg/dL over a six-month period (Spherix Global Insights: RealWorld Dynamix, Dialysis 2019). Phosphorus levels greater than 5.5 mg/dL have been shown to be an independent risk factor for cardiovascular morbidity and mortality in patients requiring dialysis (Block 2004), and internationally recognized treatment guidelines recommend lowering elevated phosphate levels toward the normal range (<4.6mg/dL).

About Ardelyx, Inc.
Ardelyx is a biopharmaceutical company dedicated to improving the lives of patients by discovering, developing and commercializing first-in-class targeted therapies that advance patient care. The Ardelyx pipeline includes tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis, for which an NDA is under review by the FDA, and RDX013, a potassium secretagogue program for the potential treatment of high potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease. 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 the respective territories.

About Kyowa Kirin Co., Ltd.
Kyowa Kirin commits to innovative drug discovery driven by state-of-the-art technologies. The company focuses on creating new values in the four therapeutic areas: nephrology, oncology, immunology/allergy and neurology. Under the Kyowa Kirin brand, the employees from 40 group companies across North America, EMEA, and Asia/Oceania unite to champion the interests of patients and their caregivers in discovering solutions wherever there are unmet medical needs. You can learn more about the business of Kyowa Kirin at: https://www.kyowakirin.com.

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 for tenapanor to be approved for marketing by the FDA for the control of serum phosphorus in chronic kidney disease patients on dialysis. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of Ardelyx's product candidates or 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, the uncertainties associated with the regulatory approval process, and uncertainties in the drug commercialization 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 August 6, 2020, 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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