Ardelyx Announces Submission of New Drug Application to the U.S. FDA for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis

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Application is Supported by Three Positive Phase 3 Clinical Trials for Tenapanor for Hyperphosphatemia, a Condition which affects Approximately 85% of CKD Patients on Dialysis

FREMONT, Calif., June 30, 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 the submission of a New Drug Application (NDA) for tenapanor to the U.S. Food and Drug Administration (FDA) for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis.

"The submission of our NDA is a significant milestone for Ardelyx, positioning us well to fulfill our promise to offer an innovative first-in-class therapeutic for patients with CKD on dialysis with elevated serum phosphorus," said Mike Raab, president and chief executive officer of Ardelyx. "The clinical results we've generated throughout the development program support the potential for tenapanor to serve as the foundational therapy in the management of hyperphosphatemia based on its unique mechanism of blocking phosphorus at the primary pathway of uptake. In addition to the positive monotherapy results demonstrated in our trials, our NORMALIZE and AMPLIFY trials have demonstrated that with tenapanor alone or with adjunctive use of phosphate binders, a far greater percentage of patients are able to achieve, and maintain, target serum phosphorus levels – a goal which has proven to be unattainable for the majority of patients with currently available treatments. We look forward to working with the FDA through the review process and will continue advancing our preparations for launch."

Based on standard FDA review timelines, the company expects to receive notification from the FDA on the acceptance of the filing for substantive review in late August 2020.

The submission is supported by three successful Phase 3 trials involving over 1,000 patients that evaluated the use of tenapanor, which included: two monotherapy trials, including a long-term study, to control serum phosphorus in patients with CKD on dialysis, and one trial using a dual-mechanism approach in dialysis patients who had difficult-to-control hyperphosphatemia (≥5.5 mg/dL) despite phosphate binder therapy.

About Tenapanor for Hyperphosphatemia
Tenapanor, discovered and developed by Ardelyx, is a first-in-class, proprietary, oral medicine for which the company has submitted an NDA to the FDA for the control of serum phosphorus in adult patients with CKD on dialysis. Tenapanor has a unique mechanism of action and 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. Three successful Phase 3 studies demonstrating tenapanor's ability to reduce phosphate levels, as monotherapy and as part of a dual mechanism approach with phosphate binders, have been reported.

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), approximately 70% of CKD patients on dialysis continue to experience elevated phosphorus levels at any point in time (Spherix Global Insights: RealWorld Dynamix, Dialysis 2018). 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 focused on developing innovative first-in-class medicines to improve treatment for people with kidney and cardiovascular diseases. The Ardelyx pipeline includes tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis, for which the company has submitted an NDA, 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.

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, the potential for the use of tenapanor as monotherapy and as part of a dual mechanism approach with tenapanor and phosphate binders for the treatment of hyperphosphatemia, the potential for tenapanor alone or with small doses of phosphate binders to achieve target serum phosphorus levels, and Ardelyx's expected timing of acceptance for substantive review of its NDA for tenapanor for the control of serum phosphorus. 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 May 7, 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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