# Ardelyx Selected as a Finalist in the Fierce Innovation Awards for the Development of its First-in-Class Product Candidate Tenapanor

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**A New Drug Application for the Review of Tenapanor to Control Serum Phosphorus in Adult Patients with Chronic Kidney Disease on Dialysis has Been Submitted to the FDA**

FREMONT, Calif., Aug. 3, 2020 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), a specialized biopharmaceutical company focused on developing innovative first-in-class medicines to improve treatment for people with kidney and cardiovascular diseases, today announced that tenapanor has been named a finalist in the Fierce Innovation Awards in the category of biotech innovation in a class of therapies identified by experts to have potential for significant impact in the industry. Tenapanor, discovered and developed by Ardelyx, is a first-in-class therapy for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis that is supported by three successful Phase 3 studies. The selection criteria for the award included: effectiveness, technical innovation, competitive advantage, financial impact, and true innovation.

"We are thrilled to be recognized for the scientific innovation that exemplifies tenapanor, especially by the group of distinguished drug developers from major biopharmaceutical companies that participated in the award review," said Mike Raab, president and chief executive officer of Ardelyx. "It is especially rewarding to see that the novel technological approach underlying tenapanor has translated into a promising therapeutic for the many patients with hyperphosphatemia. There is a high unmet need for new therapies that can effectively control phosphorus levels in patients with CKD on dialysis. These patients have up to a 38% increase in the relative risk of hospitalization due to cardiovascular events and up to a 102% increase in the relative risk of mortality. We are motivated and inspired by the possibility to help these patients with tenapanor."

The Fierce Innovation Awards – Life Sciences Edition 2020 is a peer reviewed awards program from the publisher of Fierce Biotech and Fierce Pharma. The competition highlights companies that demonstrated innovative solutions, technologies, and services that have the potential to make the greatest impact for biotech and pharma companies. The awards program's applications were reviewed by an exclusive panel of executives from major biotech and pharma companies including Astellas, Accenture, AstraZeneca, Angiocrine Bioscience, Biotech Research Group, NIHR Clinical Research Network, Medidata Solutions and PPD. Winners will be announced in the 2020 Innovation Report set to publish by Fierce Life Sciences on September 14, 2020.

**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 either monotherapy or 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 focused on developing innovative first-in-class medicines to enhance the lives of patients with kidney and cardiovascular diseases. Ardelyx is advancing tenapanor, a novel product candidate to control serum phosphorus in adult patients with CKD on dialysis, for which the company submitted an NDA to the FDA on June 30, 2020. Ardelyx is also advancing 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 statements regarding the potential for tenapanor to reduce phosphate levels as either monotherapy or as part of a dual mechanism approach with phosphate binders. 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, 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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