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Ardelyx Announces Initiation of Two Clinical Trials for RDX7675 for Treatment of Hyperkalemia

FREMONT, Calif., Jan. 3, 2017 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage company focused on enhancing the treatment of patients with gastrointestinal and cardiorenal diseases, today announced the initiation of a Phase 3 clinical trial and an onset-of-action clinical trial evaluating RDX7675 in patients with hyperkalemia, a potentially life-threatening condition common in patients with cardiorenal disease.

"The Phase 3 study for hyperkalemia marks the start of the fifth Phase 3 clinical trial from our pipeline of internally developed, gut-restricted treatments in development," said Mike Raab, chief executive officer of Ardelyx. "Hyperkalemia is a difficult to treat and potentially devastating condition in patients with chronic kidney disease and/or heart failure. The initiations of the Phase 3 and onset-of-action trials with RDX7675 are important steps forward for our cardiorenal portfolio, as we look to bring better treatments to underserved patients who aren't satisfied with their current care. We look forward to further evaluating its treatment potential and reporting data from the onset-of-action study in the first half of the year."

The Phase 3 clinical trial is a randomized, single-blind, three-part study that will evaluate the efficacy and safety of RDX7675 in approximately 300 adult patients with hyperkalemia and includes a long-term, open-label safety extension. The onset-of-action trial is a single-blind, placebo controlled study evaluating the onset-of-action, safety and efficacy of RDX7675 in 60 patients with hyperkalemia.

About RDX7675

RDX7675 is an oral, non-absorbed potassium-binding polymer that has demonstrated effective binding to potassium in pharmacodynamics studies in healthy volunteers. Using its unique chemistry, Ardelyx has developed RDX7675 as a patented improvement to sodium polystyrene sulfonate (SPS), an FDA approved polymer that has been the standard-of-care for the treatment of hyperkalemia for more than 50 years. The company made several key physical and chemical modifications to eliminate sodium and sorbitol, optimize binding capacity, greatly improve palatability and develop formulations that would taste pleasant and be easier to ingest. Ardelyx believes these improvements offer unique advantages for patients with hyperkalemia and could increase patient satisfaction and compliance.

About Hyperkalemia

Hyperkalemia is defined as the presence of blood potassium levels greater than 5.0 mEq/L. Normal levels are 3.5 to 5.0 mEq/L. When hyperkalemia is severe, or above 7.0 mEq/L, there is a significantly increased risk of death because of the potential for heart conductance problems.

Hyperkalemia can be caused by a variety of sources. Kidney disease can result in the build-up of potassium in the blood. In addition, certain drugs such as the common blood pressure medications known as RAAS inhibitors, can cause hyperkalemia. RAAS inhibitors, though quite effective for controlling blood pressure, are often significantly reduced in patients, such as in those with chronic kidney disease (CKD) and/or heart failure (HF) whose potassium levels are elevated because of the fear that elevated potassium can have serious results including sudden cardiac arrest in severe cases. Reports in the literature suggest that hyperkalemia may affect about 900,000 individuals with CKD Stage 3b or Stage 4 as well as up to an additional 900,000 patients with HF in the United States. Ardelyx's proprietary research also suggests that up to 200,000 patients with end-stage renal disease (ESRD) could benefit from an agent that treats hyperkalemia.

About Ardelyx, Inc.

Ardelyx is focused on enhancing the care and well-being of underserved patients with gastrointestinal (GI) and cardiorenal diseases by using the gut as the gateway to developing high-quality therapeutics. The company has pioneered the development of small molecule therapeutics that act predominantly in the GI tract, thereby avoiding potential negative side

effects on the rest of the body. Ardelyx's platform integrates technology that emulates the human GI tract with its gut-restricted chemistry capabilities allowing for the development of optimized small molecules in a rapid and cost-efficient manner. Using its platform, Ardelyx has discovered and developed multiple portfolios of unique, gut-targeted therapeutics. The company's GI portfolio is led by tenapanor, which is in Phase 3 development for the treatment of irritable bowel syndrome with constipation (IBS-C), and RDX8940, a unique TGR5 agonist that is approaching Phase 1 development. Ardelyx's cardiorenal portfolio includes the Phase 3 development of tenapanor for the treatment of hyperphosphatemia in patients with end-stage renal disease (ESRD) on dialysis, and RDX7675, in Phase 3 development for the treatment of patients with hyperkalemia, or high potassium, a problem prevalent in people with kidney and/or heart disease. The company is also advancing several research programs in its GI and cardiorenal portfolios. For more information, please visit www.ardelyx.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 RDX7675 in treating hyperkalemia, and the expected timing of the results of the onset-of-action clinical trial evaluating RDX7675. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of RDX7675, 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 inherent in research and the clinical development process and the uncertainties in the manufacture of clinical trial material, including process development, and scale up. 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 7, 2016, and its future current and periodic reports to be filed with the Securities and Exchange Commission.