January 5, 2016

Ardelyx Reports Positive Clinical Results of RDX022 for the Treatment of Hyperkalemia

RDX022, Ardelyx's proprietary potassium binder, demonstrates clinically relevant fecal potassium binding in a pharmacodynamic study in healthy volunteers, supporting Phase 3 clinical plans
Initiation of a Phase 3 clinical program with RDX022 is expected in 2H2016
Conference call and webcast today at 8:00am ET

FREMONT, Calif., Jan. 5, 2016 /PRNewswire/ --Â Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on gastrointestinal and cardio-renal diseases, today announced positive results of an open label clinical study evaluating the pharmacodynamic (PD) activity of RDX022 in healthy adult volunteers. The study demonstrated that RDX022, Ardelyx's proprietary potassium binder for the treatment of hyperkalemia, effectively binds potassium in the gastrointestinal tract supporting plans to proceed with a Phase 3 clinical program currently expected to begin in the second half of 2016. RDX022 was generally well-tolerated at all doses administered (up to 27.5 g/day) in the study.

"The magnitude of effect seen with RDX022 in healthy adults supports our belief that, if approved following the completion of the Phase 3 clinical program, RDX022 will be an important agent in treating patients with hyperkalemia.Â We believe that RDX022 may be able to address many of the limitations of current and recently approved therapies due to the absence of sodium as a counter-ion in RDX022 as well as its improved palatability," said Mike Raab, President and Chief Executive Officer of Ardelyx. "We have leveraged the long-standing experience of our management team in creating, developing, and commercializing polymer-based drugs to create a proprietary, differentiated potassium binder that we believe can be brought to market utilizing the 505(b)(2) regulatory pathway.Â We look forward to starting a Phase 3 clinical program in the second half of 2016.Â We are fully committed to developing high-impact and important products for patients with cardio-renal diseases. We believe that RDX022 will complement our efforts with tenapanor, our small molecule drug candidate currently in Phase 2b for the management of hyperphosphatemia in dialysis patients."

Results from the PD study

This open-labeled pharmacodynamic (PD) study of RDX022 consisted of a two-day treatment-free baseline period and a four-day treatment period.Â The study included four cohorts, and in each cohort, 12 subjects received RDX022 and three subjects received a similar dose of sodium polystyrene sulfonate (SPS) for a total of 60 subjects.

RDX022 was administered at 4.6 g BID (9.2 g/day), 6.9 g BID (13.8 g/day), 4.6 g TID (13.8 g/day) and 9.2 g TID (27.5 g/day), and resulted in a mean increase of fecal potassium from baseline of 888 mg/day, 1,791 mg/day, 1,408 mg/day, and 1,670 mg/day, respectively. RDX022 was generally well-tolerated at all doses and demonstrated comparable results to those observed with sodium polystyrene sulfonate (SPS). Other fecal electrolytes were monitored during the study and no unexpected changes were observed; in particular, fecal magnesium remained unchanged from baseline. Â The results of the study will be presented in a future scientific format.

Mr. Raab also noted, "As we considered alternatives, we made the decision to formulate RDX022 with a calcium counter-ion. Given that we are trying to accomplish the management of hyperkalemia in chronic kidney disease and heart failure patients, we believe calcium is a more appropriate counter-ion than is sodium.Â It is clear that increasing the daily intake of sodium in these patients is counter to best clinical practice.Â Additionally, we have focused on improving both the physical properties of the polymer and the formulation of RDX022.Â Our goal for RDX022 is to develop as optimal a potassium binder as possible by combining innovation with existing technologies in a delivery form that aims to improve patient adherence and compliance.Â We believe these qualities would provide RDX022 with the potential to give us an advantage in this growing and important marketplace," commented Mr. Raab.

About RDX022

RDX022 is Ardelyx's proprietary oral, non-absorbed, potassium-binding polymer based on polystyrene sulfonate, a well-

known and well-characterized polymer, also known as Kayexalate®.Ä Ardelyx has made numerous improvements to the polymer by engineering into RDX022 several key physical and chemical modifications in an effort to improve various properties. In a separate single center, randomized, crossover study to evaluate various oral formulations of RDX022 in healthy subjects, RDX022 consistently outperformed SPS in all aspects of the taste assessments, including mouth feel, texture and flavor.Â Ardelyx has filed a patent application covering the composition of matter of these modifications.

Plans for RDX022

In the second half of 2016, Ardelyx expects to initiate a Phase 3 clinical program for RDX022.Â The Phase 3 clinical study will enroll patients with chronic kidney disease (CKD), with or without heart failure (HF), who are taking drugs that inhibit the renin-angiotensin-aldosterone system (RAAS) and are diagnosed with hyperkalemia, a common side effect that occurs with patients taking those drugs.

Based on discussions with the FDA, the Company is pursuing a 505(b)(2) regulatory pathway for RDX022.

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. Also, 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 CKD and HF, whose potassium levels are elevated because of the fear that elevated potassium can cause significantly worse problems than hypertension including sudden cardiac arrest in severe cases.Â 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 heart failure in the United States. The Company's proprietary research also suggests that up to 200,000 patients with ESRD could benefit from an agent that treats hyperkalemia.Â

Conference Call & Webcast Information

ArdelyxÂ management will host a live conference call and webcast today at 8:00 am Eastern TimeÂ to discuss the RDX022 clinical trial results. The live webcast and a replay can be accessed by visitingÂ Ardelyx'sÂ website on the investor page of the Company's website atÂ http://ir.ardelyx.com/.

Please connect to the Company's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call (855) 296-9612 (US) or (920) 663-6277 (International) to listen to the live conference call. The conference ID number for the live call is 19315898. Please dial in approximately 10 minutes prior to the call. Following the webcast, an archived version of the call will be available thirty days.

About Ardelyx

ArdelyxÂ is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of innovative, minimally-systemic, small molecule therapeutics that work exclusively in the gastrointestinal tract to treat gastrointestinal and cardio-renal diseases.Â ArdelyxÂ has developed a proprietary drug discovery and design platform enabling it, in a rapid and cost-efficient manner, to discover and design novel drug candidates. Utilizing this platform,Â ArdelyxÂ has discovered and designed tenapanor, which it is evaluating for the treatment of constipation-predominant irritable bowel syndrome (IBS-C) and for the control of hyperphosphatemia in CKD patients on dialysis. In addition to tenapanor,Â ArdelyxÂ is developing RDX022, a non-absorbed polymer for the treatment of hyperkalemia, or high potassium, in kidney and heart disease patients.Â ArdelyxÂ is also advancing several research programs focused in gastrointestinal and cardio-renal diseases.Â ArdelyxÂ is located inÂ Fremont, California. For more information, please visitÂ Ardelyx'sÂ website atÂ www.ardelyx.com.

Forward Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regardingÂ 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 RDX022 in treating hyperkalemia in kidney and heart disease patients, Ardelyx's future development plans for RDX022 and the timing and regulatory plans in connection with such development, the expected timing for the commencement of the RDX022 Phase 3 clinical study, and

the design of the RDX022 Phase 3 clinical study. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of RDX022, or Ardelyx'sÂ 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 andÂ the uncertainties in the manufacture of clinical trial material, including process development and scale up of manufacturing processes.Â ArdelyxÂ 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 toÂ Ardelyx'sÂ business in general, please refer toÂ Ardelyx's quarterly report on Form 10-Q filed with theÂ Securities and Exchange CommissionÂ onÂ November 12, 2015, and its future current and periodic reports to be filed with theÂ Securities and Exchange Commission.

LogoÂ - http://photos.prnewswire.com/prnh/20140619/119451

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/ardelyx-reports-positive-clinical-results-of-rdx022-for-the-treatment-of-hyperkalemia-300199205.html

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