Ardelyx Collaboration Partner, Kyowa Hakko Kirin, Announces Initiation of a Phase 2 Clinical Study of Tenapanor for Hyperphosphatemia Patients on Dialysis in Japan

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Ardelyx to Receive a $5 Million Milestone Payment
Company Narrows Timeline for its PHREEDOM trial and announces AMPLIFY, a new Phase 3 Trial evaluating tenapanor in combination with binders

FREMONT, Calif., Feb. 7, 2019 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX) (Ardelyx) today announced that its collaboration partner in Japan, Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151) (Kyowa Hakko Kirin), has initiated a Phase 2 clinical study in Japan evaluating tenapanor for the treatment of hyperphosphatemia patients on dialysis. The achievement of this development milestone triggers a $5 million payment to Ardelyx. This phase 2 clinical study is a multi-center, open-label, single-arm study evaluating serum phosphorus in patients who switch from one or more phosphate binders to tenapanor to treat hyperphosphatemia patients on dialysis in Japan.

"Kyowa Hakko Kirin is the leader in the development and commercialization of cardiorenal products in Japan and has been an ideal partner for Ardelyx," said Mike Raab, president and chief executive officer of Ardelyx. "We are very pleased with the significant progress made by Kyowa Hakko Kirin towards our goal to provide patients with this first-ever, non-binder treatment option for this severe and highly prevalent condition."

Under the terms of the license agreement with Kyowa Hakko Kirin, Ardelyx received a $30 million upfront payment and is eligible to receive up to $55.0 million in total development milestones and 8.5 billion yen in commercialization milestones. Ardelyx is also eligible to receive high-teen royalties on sales throughout the term of the agreement. Kyowa Hakko Kirin has been granted the exclusive rights to develop, market and commercialize tenapanor for cardiorenal diseases and conditions associated with them, including hyperphosphatemia, in Japan.

Ardelyx also announced today that it currently expects to report, in the fourth quarter of this year, topline results from its ongoing PHREEDOM trial; its second Phase 3 clinical trial evaluating tenapanor for the treatment of hyperphosphatemia in patients with ESRD on dialysis.

Ardelyx plans to commence in early 2019 a new Phase 3 clinical trial, AMPLIFY, designed to evaluate tenapanor in combination with phosphate binders. Results from AMPLIFY are expected in the second half of this year, and if approved, tenapanor would then be the only phosphate lowering therapy indicated both as a monotherapy and as adjunctive therapy for use in combination with binders.

"We entered 2019 with approximately two years of cash on the balance sheet and have an exciting year ahead of us as we come to the end of the tenapanor development program. This will be an important and exciting time for Ardelyx, as we expect data from the PHREEDOM trial in the fourth quarter of 2019, and results from AMPLIFY, in the second half of this year. With these data we can then begin preparation for filing our NDA for hyperphosphatemia in 2020. These results, if positive, combined with all our other clinical data, will position tenapanor to be a potentially indispensable new approach for treating hyperphosphatemia patients on dialysis. Further, with positive results from these Phase 3 trials, we believe that the totality of our clinical results for tenapanor will have advanced the field of hyperphosphatemia management and will demonstrate clear differentiation of tenapanor from phosphate binders," added Mr. Raab.

About Tenapanor for Hyperphosphatemia
Tenapanor, discovered and developed by Ardelyx, is a first-in-class, proprietary, minimally absorbed, oral, experimental medication in late-stage clinical development. It has a unique mechanism of action that, in hyperphosphatemia, acts by blocking the NHE3 sodium transporter in the GI tract, reducing the absorption of dietary sodium and resulting in increased protons within the cells. The increase in protons causes a reduction in phosphate uptake by tightening junctions, or pores, that regulate phosphate absorption in the GI tract. Overall, this mechanism appears to be preferential to phosphate absorption given that Ardelyx has not observed any changes in other ions, other than sodium, in preclinical or clinical studies. In February 2017, Ardelyx announced that the Company's first Phase 3 clinical trial evaluating tenapanor to treat hyperphosphatemia in patients with ESRD on dialysis met its primary endpoint and tenapanor was generally well-tolerated. Tenapanor is being evaluated in a second Phase 3 trial, the PHREEDOM trial, for the treatment of hyperphosphatemia in the same patient population, with topline results expected in the fourth quarter of 2019. This clinical trial includes a 26-week open-label treatment period, with a 12-week placebo-controlled randomized withdrawal period followed by an additional 14-week open-label safety extension period for a total of up to 52 weeks. An active control group, for safety analysis only and consistent with other Phase 3 registration studies for hyperphosphatemia, will receive sevelamer, open-label, for the entire 52-week study period. The Company also plans to evaluate tenapanor in a third Phase 3 trial, the AMPLIFY trial, as adjunctive therapy to phosphate binders for the treatment of hyperphosphatemia in ESRD patients, with topline results expected in the second half of 2019. This clinical trial includes a 2 to 4-week run-in period, with a 4-week randomized, double-blind, placebo-controlled treatment period.

About Ardelyx, Inc.
Ardelyx is focused on enhancing the way people with cardiorenal diseases are treated by developing first-in-class medicines. Ardelyx's cardiorenal pipeline includes the Phase 3 development of tenapanor for the treatment of hyperphosphatemia in people with end-stage renal disease (ESRD) who are on dialysis, 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 has completed Phase 3 development of tenapanor for the treatment of irritable bowel syndrome with constipation (IBS-C) and submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, for the treatment of patients with IBS-C which has been granted a target action date under the Prescription Drug User Fee Act (PDUFA) of September 12, 2019. To efficiently bring its treatments to market, Ardelyx is pursuing strategic collaborations for tenapanor for IBS-C and hyperphosphatemia in certain territories. Ardelyx has established agreements with Kyowa Hakko Kirin in Japan, Fosun Pharma in China and Knight Therapeutics in Canada. For more information, please visit http://www.ardelyx.com/ and connect with us on Twitter @Ardelyx.

About Kyowa Kirin
Kyowa Hakko Kirin Co., Ltd. is a research-based life sciences company, with special strengths in biotechnologies. In the core therapeutic areas of oncology, nephrology and immunology/allergy, Kyowa Hakko Kirin leverages leading-edge biotechnologies centered on antibody technologies, to continually discover innovative new drugs and to develop and market those drugs world-wide. In this way, the company is working to realize its vision of becoming a Japan-based global specialty pharmaceutical company that contributes to the health and wellbeing of people around the world.
You can learn more about the business at: https://www.kyowa-kirin.com.

Forward Looking Statements
To the extent that statements contained in this presentation 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 Ardelyx's product candidates in treating the diseases and conditions for which they are being developed; the potential for Ardelyx's product candidates to receive approval from the FDA for marketing for the indications for which they are currently being developed; Ardelyx's current expectations regarding the timing of receipt of results from its ongoing Phase 3 clinical trial evaluating tenapanor for the treatment of hyperphosphatemia in ESRD patients on dialysis; Ardelyx's current expectations regarding the timing of receipt of results from its ongoing Phase 3 clinical trial evaluating tenapanor in combination with phosphate binders for the treatment of hyperphosphatemia in ESRD patients on dialysis; Ardelyx's current expectations regarding the timing and scope of the NDA for tenapanor for the treatment of hyperphosphatemia in ESRD patients on dialysis; the potential for Ardelyx to receive development, milestone and royalty payments from it collaboration partner, KHK and Ardelyx's expectations regarding the exhaustion of its current capital resources. 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 inherent in research and the clinical development process; the uncertainties associated with the regulatory approval process; and the 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 November 7, 2018, 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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