Ardelyx and Kyowa Hakko Kirin Announce License Agreement for Tenapanor for Cardiorenal Diseases in Japan

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Ardelyx to Receive a $30 Million Upfront Payment and Subsequent Milestones

FREMONT, Calif. and TOKYO, Nov. 28, 2017 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX) and Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, "Kyowa Hakko Kirin"), today announced that they have entered into a license agreement that provides Kyowa Hakko Kirin with exclusive rights to develop and commercialize Ardelyx's lead investigational product, tenapanor, for the treatment of cardiorenal diseases, including hyperphosphatemia, in Japan. Tenapanor is an oral, minimally systemic NHE3 inhibitor discovered and developed by Ardelyx that is in Phase 3 development in the United States for the treatment of hyperphosphatemia in patients with end-stage renal disease (ESRD) who are on dialysis.

Under the terms of the license agreement, Ardelyx will receive a $30 million upfront payment and is eligible to receive additional development and commercialization milestones worth up to $130 million. Ardelyx is also eligible to receive high-teen royalties throughout the term of the agreement. Kyowa Hakko Kirin will have the exclusive rights to develop, market and commercialize tenapanor for cardiorenal diseases and conditions associated with them, including hyperphosphatemia, in Japan.

"Kyowa Hakko Kirin is an established leader in the development of cardiorenal products and an ideal partner to develop tenapanor for such diseases in the Japanese market," said Mike Raab, president and chief executive officer of Ardelyx. "This agreement represents the first collaboration under our strategy of evaluating collaborative opportunities to bring tenapanor to patients and physicians across all potential indications as efficiently as possible. We look forward to working with the experienced Kyowa Hakko Kirin team to bring this first-ever, non-binder treatment to the many patients with hyperphosphatemia who need an effective and easy-to-take treatment."

"Developing medicines for renal disease and conditions associated with it is an important aspect of Kyowa Hakko Kirin's strategic focus," said Masashi Miyamoto, Ph.D., director of the board, managing executive officer, director of corporate strategy and planning department. "We are excited to collaborate with Ardelyx, who has deep experience in developing cardiorenal medicines, and for the potential of tenapanor to be a game-changing, first-in-class treatment for patients with hyperphosphatemia. We are looking forward to the opportunity to bring this important product to patients in Japan."

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 in preclinical or clinical studies.

About Ardelyx, Inc.
Ardelyx is focused on enhancing the way patients with cardiorenal and gastrointestinal (GI) diseases are treated by using the gut as the gateway to delivering medicines that matter. The company has established unique cardiorenal and GI business portfolios aimed at bringing new, effective medicines with distinct safety and dosing advantages to underserved patients. Ardelyx's portfolio includes the Phase 3 development of tenapanor for the treatment of hyperphosphatemia in people with end-stage renal disease who are on dialysis and RDX013, a potassium secretagogue program. The company's GI portfolio includes tenapanor for the treatment of people with irritable bowel syndrome with constipation (IBS-C), for which the company anticipates submitting a New Drug Application in the second half of 2018, and RDX8940, a TGR5 agonist. For more information, please visit http://www.ardelyx.com/ and connect with us on Twitter @Ardelyx.

About Kyowa Hakko Kirin Co., Ltd.
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: www.kyowa-kirin.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 Ardelyx's product candidates in treating the diseases and conditions for which they are being developed; the potential for Ardelyx to receive upfront, milestone and royalty payments from Kyowa Hakko Kirin; Ardelyx's expected timing for the filing of its NDA for tenapanor for the treatment of IBS-C, and Ardelyx's ability to establish collaborations in the future. 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, including the regulatory approval 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, 2017, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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