Ardelyx Announces Acceptance of New Drug Application for Tenapanor for Hyperphosphatemia in China

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Acceptance of NDA Submission triggers as $2 million milestone payment to Ardelyx by Fosun Pharma

WALTHAM, Mass., July 13, 2023 (GLOBE NEWSWIRE) -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs, today announced that a New Drug Application (NDA) for tenapanor has been accepted for review by China's Center for Drug Evaluation of the National Medical Products Administration (NMPA) for the control of serum phosphorus in adult patients with chronic kidney disease on hemodialysis. This acceptance triggers a $2 million milestone payment to Ardelyx under the terms of the license agreement between Ardelyx and its collaboration partner in China, Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. (Fosun Pharma). A potential approval of the NDA submission in China is expected by the end of 2024.

"The NDA acceptance for tenapanor for hyperphosphatemia in China marks a significant step forward in Ardelyx's commitment to bringing our novel therapies to patients with unmet medical needs and our desire to expand internationally alongside best-in-class partners who complement our capabilities and share our mission," said Mike Raab, president and chief executive officer of Ardelyx. "I commend our collaboration partner, Fosun Pharma, on the impressive clinical results they generated which demonstrate the important role that tenapanor can play in offering a new treatment option for patients with hyperphosphatemia. We look forward to further collaboration as Fosun Pharma brings this treatment to patients."

Under the terms of its agreement with Fosun Pharma, Ardelyx received an upfront payment of $12 million and is eligible to receive additional developmental and commercialization milestones of up to $110 million and tiered royalty payments on net sales ranging from the mid-teens to 20 percent. Fosun Pharma has the exclusive rights to market and sell tenapanor in China, Hong Kong and Macau.

About Ardelyx, Inc.
Ardelyx was founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs. Ardelyx's first approved product, IBSRELA® (tenapanor) is available in the United States and Canada. Ardelyx is developing XPHOZAH® (tenapanor), a novel product candidate for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis, which has completed three successful Phase 3 trials. Ardelyx has a Phase 2 potassium lowering compound, RDX013, for the potential treatment of elevated serum potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease and an early-stage program in metabolic acidosis, a serious electrolyte disorder in patients with CKD. 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 their respective territories. For more information, please visit https://ardelyx.com/ and connect with us on Twitter, LinkedIn and Facebook.

About Fosun Pharma
Founded in 1994, Shanghai Fosun Pharmaceutical (Group) Co., Ltd.* ("Fosun Pharma"; stock code: 600196. SH, 02196. HK) is a global innovation-driven pharmaceutical and healthcare industry group. Fosun Pharma directly operates businesses including pharmaceuticals, medical devices, medical diagnosis, and healthcare services. As a shareholder of Sinopharm Co., Ltd., Fosun Pharma expands its areas in the pharmaceutical distribution and retail business.

Fosun Pharma is patient-centered and clinical needs-oriented. The company continuously enriches its innovative product pipeline through independent research and development, cooperative development, license-in, and in-depth incubation. Fosun Pharma improves the research and clinical development capabilities of FIC (First-in-class) and BIC (Best-in-class) new drugs as well as accelerates the R&D and launch of innovative technologies and products.

Guided by the 4IN strategy (Innovation, Internationalization, Intelligentization, and Integration), Fosun Pharma will uphold the development model of "Innovation Transformation, Integrated Operation and Steady Growth", with the mission of creating shareholder values through strengthening its independent R&D and external cooperation and enriching its product pipelines, as well as promoting the global networks and enhancing operational efficiency. Fosun Pharma will actively promote the digital and physical business layout in the pharmaceutical and healthcare industry and is committed to becoming a first-class enterprise in the global medical and health market.

For more information, please visit our official website: www.fosunpharma.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 role that tenapanor can play in offering new treatment options for patients with hyperphosphatemia; the current expectation for potential review timelines for the NDA for tenapanor for hyperphosphatemia in China; and the potential for Ardelyx to receive additional developmental and commercialization milestone and royalty payments under its license agreements with Fosun Pharma. 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, uncertainties associated with the process for drug development, regulatory approval and commercialization. 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2023, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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