Tenapanor Approved in China for Hyperphosphatemia

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Ardelyx to receive $5 million milestone payment from Fosun Pharma following approval

WALTHAM, Mass., Feb. 26, 2025 (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 the approval of a New Drug Application (NDA) by China's Center for Drug Evaluation of the National Medical Products Administration for tenapanor to control serum phosphorus levels in dialysis patients with chronic kidney disease (CKD) who have an inadequate response or are intolerant to phosphorus binders.

This approval triggers a $5 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). Under the terms of its agreement, Ardelyx is eligible to receive additional developmental and commercialization milestones of up to $100 million and tiered royalty payments on net sales ranging from the mid-teens to 20 percent.

"The approval of tenapanor for hyperphosphatemia in China marks another important milestone in Ardelyx's commitment to bringing our novel therapies to patients with unmet medical needs globally," said Mike Raab, president and chief executive officer of Ardelyx. "I thank our partners at Fosun Pharma for their continued efforts to support this approval. Fosun Pharma is a leading healthcare company in China with a strong focus and track record of successfully marketing cardiorenal medicines in China and shares our commitment to improving the lives of patients. We look forward to further collaboration as Fosun Pharma brings this treatment to patients."

Data indicate that at the end of 2023, there were more than one million patients on maintenance hemodialysis in China, with an annual growth rate of approximately 12%. Among these patients, 76% have hyperphosphatemia, and the rate of achieving target phosphate levels is only 39%[1] (according to China's hemodialysis quality control standards: serum phosphate 1.13–1.78 mmol/L). If the target range for serum phosphate is set at 0.87–1.45 mmol/L, as stipulated by the Chinese guidelines for the diagnosis and treatment of Chronic Kidney Disease Mineral and Bone Disorder, the achievement rate decreases to 26.7%[2].

The NDA in China was supported by data from two studies undertaken by Fosun Pharma, a single pharmacokinetic study and a single pivotal trial in patients with CKD on dialysis, in addition to Ardelyx clinical studies.

Fosun Pharma has the exclusive rights to market and sell tenapanor in China, Hong Kong and Macau. Tenapanor will be marketed with the Chinese trade name Wan Ti Le.

About XPHOZAH® (tenapanor)
XPHOZAH, discovered and developed by Ardelyx, is a first-in-class, phosphate absorption inhibitor with a differentiated mechanism of action that acts locally in the gut to inhibit the sodium hydrogen exchanger 3, thereby reducing phosphate absorption through the paracellular pathway, the primary pathway of phosphate absorption. XPHOZAH is a single tablet, taken twice daily. Diarrhea was the most common side effect experienced by patients taking XPHOZAH in clinical trials. Please see additional full Prescribing Information.

About Ardelyx
Ardelyx was founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs. Ardelyx has two commercial products approved in the United States, IBSRELA® (tenapanor) and XPHOZAH® (tenapanor). Ardelyx has agreements for the development and commercialization of tenapanor outside of the U.S. Kyowa Kirin commercializes PHOZEVEL® (tenapanor) for hyperphosphatemia in Japan. A New Drug Application for tenapanor for hyperphosphatemia has been approved in China with Fosun Pharma. Knight Therapeutics commercializes IBSRELA in Canada. For more information, please visit https://ardelyx.com/ and connect with us on X (formerly known as Twitter), LinkedIn and Facebook.

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, Ardelyx's current expectation regarding the receipt of a $5 million milestone payment from Fosun Pharma and the potential to receive additional development and commercialization milestones under its agreement with Fosun Pharma, the potential for XPHOZAH to provide a meaningful benefit for the control of serum phosphorus in adult patients with chronic kidney disease on dialysis in China, and the growth rate of the population of patients on maintenance hemodialysis in China. 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 development of, regulatory process for, and commercialization of drugs in the U.S. and internationally. 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 February 20, 2025, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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1. Data from the Chinese National Renal Data System (CNRDS 2023)
2. Ya Zhan, et al. Sci Rep. 2022 Oct 6;12(1):16694.

Source: Ardelyx, Inc.