Ardelyx and Kyowa Kirin Amend License Agreement for Tenapanor

April 11, 2022

WALTHAM, Mass., April 11, 2022 /PRNewswire/ -- 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 it has reached an agreement with its Japanese collaboration partner, Kyowa Kirin Co. Ltd., to amend the license agreement, originally executed in 2017, that grants to Kyowa Kirin exclusive rights to develop and commercialize Ardelyx's tenapanor for the treatment of cardiorenal diseases, including hyperphosphatemia, in Japan.

Under the agreement, in consideration for a reduction in the royalty rate due Ardelyx upon net sales in Japan, Kyowa Kirin has agreed to pay Ardelyx consideration of up to additional U.S. $40 million payable in two tranches, with payment due following Kyowa Kirin's filing with the Japanese Ministry Health, Labour and Welfare (MHLW) of its application for marketing approval for tenapanor and the second payment due following Kyowa Kirin's approval to market tenapanor for hyperphosphatemia in Japan. Kyowa Kirin is finalizing its Phase 3 clinical program for tenapanor for hyperphosphatemia and has disclosed its current expectation to file for approval with Kyowa Kirin in the second half of 2022 and its current expectation that it will receive a decision from Kyowa Kirin regarding its application in the second half of 2023. The royalty rate at which Kyowa Kirin will make payments on net sales to Ardelyx under the License Agreement will be reduced from the high teens to low double digits for a two-year period, and then to mid-single digits.

"We are pleased to amend our longstanding agreement with Kyowa Kirin in a mutually beneficial way," said Mike Raab, president and chief executive officer of Ardelyx. "We believe that this agreement is reflective of both the positive clinical data Kyowa Kirin has generated for tenapanor and the attractive opportunity for treating hyperphosphatemia in dialysis patients in Japan."

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. Ardelyx is developing XPHOZAH® (tenapanor), a novel product candidate to control serum phosphorus in adult patients with CKD on dialysis, which has completed three successful Phase 3 trials. Ardelyx is also advancing RDX013, a potassium secretagogue, for the potential treatment of elevated serum potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease and has 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.

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 expectation regarding the timing of Kyowa Kirin's filing for marketing approval for tenapanor for hyperphosphatemia in Japan and Ardelyx's expectations regarding the potential timing for Kyowa Kirin's marketing approval in Japan. 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 in the drug development and regulatory processes in Japan. 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 28, 2022, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

View original content to download multimedia:https://www.prnewswire.com/news-releases/ardelyx-and-kyowa-kirin-amend-license-agreement-for-tenapanor-301522479.html

SOURCE Ardelyx

Investor and Media Contacts: Kimia Keshtbod, kkeshtbod@ardelyx.com; Sylvia Wheeler, Wheelhouse Life Science Advisors, swheeler@wheelhouselsa.com; Alex Santos, Wheelhouse Life Science Advisors, asantos@wheelhouselsa.com