Tenapanor for Hyperphosphatemia Approved in Japan

September 25, 2023

Approval announced by Kyowa Kirin, Ardelyx Collaboration Partner

Ardelyx to receive $30 million from Kyowa Kirin in milestone and license amendment payments and $5 million from HealthCare Royalty Partners under a Financing Agreement

WALTHAM, Mass., Sept. 25, 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 its collaboration partner in Japan, Kyowa Kirin Co., Ltd. (TSE: 4151, Kyowa Kirin), has received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for the New Drug Application (NDA) for tenapanor for the improvement of hyperphosphatemia in adult patients with chronic kidney disease (CKD) on dialysis. Tenapanor will be marketed with the brand name PHOZEVEL® in Japan.

This approval triggers an aggregate of $30 million from Kyowa Kirin to Ardelyx in milestone payments and payments under the recent amendment to the license agreement between Ardelyx and Kyowa Kirin. As a result of this approval, Ardelyx will also receive a $5 million payment under the terms of its agreement with HealthCare Royalty Partners. In addition, Ardelyx may also receive an additional $5 million from Healthcare Royalty Partners in the event net sales in Japan exceed a certain target by 2025.

“The approval of tenapanor for hyperphosphatemia in Japan is a historic moment for Ardelyx and CKD patients on dialysis. The Japanese approval marks the very first regulatory approval of tenapanor for hyperphosphatemia, a drug discovered and developed by Ardelyx, which we and Kyowa Kirin believe can have a meaningful benefit for the patients we serve. We are hopeful that with our FDA user goal review date of October 17th of this year, that U.S. approval will quickly follow,” said Mike Raab, Ardelyx president and CEO. “With this approval, nephrologists in Japan will now have an important novel treatment option for the management of elevated serum phosphorus levels in their CKD patients on dialysis. I thank our partners at Kyowa Kirin for their long-standing collaboration and congratulate them for their tireless efforts in getting this approved. We look forward to continuing this important relationship and supporting them as they bring this novel product to patients and the entire Japanese kidney community.”

In the U.S., Ardelyx is pursuing approval of tenapanor for the treatment of hyperphosphatemia in adult patients with CKD on dialysis who have had an inadequate response or intolerance to phosphate binder therapy, with the brand name XPHOZAH, and has user fee goal date of October 17, 2023. Pending approval, Ardelyx expects to launch XPHOZAH in the U.S. in the fourth quarter of 2023.

The NDA in Japan was supported by data from four Phase 3 clinical trials, conducted in Japan by Kyowa Kirin in patients with hyperphosphatemia on maintenance dialysis. Across Kyowa Kirin's clinical program, tenapanor demonstrated statistically significant reductions in serum phosphorus levels, both as monotherapy and when added to phosphate binders, for patients whose serum phosphorus levels were poorly controlled on phosphate binders alone. The results of the studies undertaken by Kyowa Kirin suggested that tenapanor may also reduce the medication burden of phosphorus management utilizing marketed phosphate binders in combination with tenapanor or tenapanor alone for treating hyperphosphatemia. In these studies, the safety and tolerability profile for tenapanor was consistent with prior studies in Japan.

Kyowa Kirin made a public announcement regarding the approval, which is available here: https://www.kyowakirin.com/media_center/news_releases/2023/pdf/e20230925_02.pdf

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 who have an inadequate response or intolerance to a phosphate binder therapy, which has completed three successful Phase 3 trials and an additional two Phase 4 open label 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.

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 tenapanor to provide a meaningful benefit to patients and the potential for U.S. regulatory approval for tenapanor for the treatment of hyperphosphatemia in adult patients with CKD on dialysis who have had an inadequate response or intolerance to phosphate binder therapy to follow shortly from the regulatory approval of tenapanor 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 associated with the regulatory process for, and the 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 2, 2023, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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