Ardelyx Announces FDA Advisory Committee Meeting to Review XPHOZAH® NDA Tentatively Scheduled for November 16, 2022

June 21, 2022

WALTHAM, Mass. , June 21, 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 the U.S. Food and Drug Administration (FDA) has informed the company that a meeting of the Cardiovascular and Renal Drugs Advisory Committee (Advisory Committee) is tentatively scheduled for November 16, 2022. The Advisory Committee will discuss the company's New Drug Application (NDA) for XPHOZAH for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis.

As part of its response to Ardelyx's appeal of the Complete Response Letter received on July 28, 2021, the FDA's Office of New Drugs (OND) stated that additional input from an Advisory Committee, including the addition of input from expert clinicians who care for patients on dialysis, would be valuable in further considering the clinical meaningfulness of the phosphate lowering effect observed in Ardelyx's Phase 3 clinical program in order to reach a decision on the company's formal dispute resolution request. A response from the OND to Ardelyx's appeal is expected within thirty calendar days after the conclusion of the Advisory Committee meeting.

About XPHOZAH (tenapanor) for Hyperphosphatemia

XPHOZAH (tenapanor), discovered and developed by Ardelyx, in an investigational first-in-class phosphate absorption inhibitor (PAI). XPHOZAH, with its unique blocking mechanism of action, acts locally in the gut to inhibit the sodium hydrogen exchanger 3 (NHE3), reducing phosphate absorption through the paracellular pathway, the primary pathway of phosphate absorption. This novel blocking mechanism enables a one 30 mg tablet BID dosing regimen. The most common side effect with tenapanor in clinical trials was diarrhea.

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 has a Phase 2 potassium secretagogue program, 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.

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 timing of the Advisory Committee meeting to consider the NDA for XPHOZAH, and Ardelyx's expectations regarding the timing of a response to its appeal following the conclusion of the Advisory Committee meeting. 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 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 May 5, 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-announces-fda-advisory-committee-meeting-to-review-xphozah-nda-tentatively-scheduled-for-november-16-2022-301571924.html

SOURCE Ardelyx

Kimia Keshtbod, kkeshtbod@ardelyx.com, Sylvia Wheeler, Wheelhouse Life Science Advisors, swheeler@wheelhouselsa.com, Alex Santos, Wheelhouse Life Science Advisors, asantos@wheelhouselsa.com