Ardelyx Announces Publication of 52-Week Phase 3 PHREEDOM Trial

September 3, 2021

Publication highlights clinically meaningful reduction in mean serum phosphorus from 7.7 mg/dL to 5.1 mg/dL at end of 26-week treatment period in the efficacy analysis set.

FREMONT, Calif. and WALTHAM, Mass., Sept. 3, 2021 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company focused on the discovery, development, and commercialization of innovative first-in-class medicines to improve treatment for people with kidney and cardiorenal diseases, today announced the publication of the company's long term 52-week Phase 3 PHREEDOM trial in the American Society of Nephrology journal, Kidney360.

"The PHREEDOM trial, a 52-week randomized Phase 3 trial that evaluated tenapanor monotherapy, was the third of three Phase 3 trials we conducted in our comprehensive evaluation of tenapanor for the control of serum phosphorus in patients with chronic kidney disease on dialysis," said Mike Raab, president and chief executive officer of Ardelyx. "The PHREEDOM data demonstrate the ability of tenapanor to provide significant phosphorus reduction with long-term safety comparable to active control. This study, together with data from our AMPLIFY trial which evaluated tenapanor in combination with binders in patients who require more aggressive phosphate management, supports the central role tenapanor, with its novel blocking mechanism, can play across a broad range of patients and treatment regimens for the management of hyperphosphatemia in patients with chronic kidney disease on dialysis."

Arnold Silva, M.D., Ph.D., director of Clinical Research at Boise Kidney and Hypertension Institute, added, "As an investigator in this clinical trial and an author on this publication, I have had the opportunity to see both first-hand and in aggregate the impact of tenapanor on the control of serum phosphorus. I believe this novel mechanism therapy will play a key role in advancing the management of hyperphosphatemia in our patients with CKD on dialysis, an area where treatment options have been limited, and a significant proportion of patients have phosphorus levels above target ranges despite active treatment with currently available therapies. Additionally, a one pill twice daily therapy that blocks phosphorus absorption, whether used alone or in combination with phosphate binders, has the potential to reduce treatment burden, which will be a very meaningful benefit to patients."

About the PHREEDOM Study

PHREEDOM is a 52-week monotherapy trial that demonstrated a clinically meaningful decrease in mean serum phosphorus in tenapanor-treated patients from 7.7 mg/dL at baseline to 5.1 mg/dL at the end of the 26-week treatment period in the efficacy analysis set (n=131), and a clinically meaningful decrease in mean serum phosphorus in the tenapanor-treated patients from 7.4 mg/dL at baseline to 5.9 mg/dL at week 26 in the intent-to treat analysis set (n=248). Additionally, in the efficacy analysis set (n=131), the difference in estimated mean change in serum phosphorus level between tenapanor and placebo from the beginning to the end of the randomized withdrawal period was −1.4 mg/dl (P<0.0001). Furthermore, there were median relative reductions from baseline of 23% for iFGF23 and 14% for cFGF23 at the end of the randomized 26-week treatment period for participants randomized to tenapanor. Diarrhea was the only drug related AE reported for more than 5% of patients and resulted in drug discontinuation in 16% of patients.

About Tenapanor

Tenapanor, discovered and developed by Ardelyx, has a unique mechanism of action and 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 30mg tablet BID dosing regimen. The most common side effect with tenapanor in clinical trials was diarrhea.

About Hyperphosphatemia

Hyperphosphatemia is a serious condition resulting in an abnormally elevated level of phosphorus in the blood that is estimated to affect the vast majority of the 550,000 patients in the United States with CKD on dialysis. The kidney is the organ responsible for regulating phosphorus levels, but when kidney function is significantly impaired, phosphorus is not adequately eliminated from the body. As a result, hyperphosphatemia is a nearly universal condition among people with CKD on dialysis with internationally recognized KDIGO treatment guidelines that recommend lowering elevated phosphate levels toward the normal range (2.5-4.5mg/dL).

About Ardelyx, Inc.

Ardelyx is focused on discovering, developing and commercializing innovative first-in-class medicines to enhance the lives of patients with kidney and cardiorenal diseases. Ardelyx is developing 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. In addition, tenapanor has already received FDA approval for the treatment of irritable bowel syndrome with constipation (IBS-C) under the tradename IBSRELA®. 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 the potential for tenapanor to advance the management of phosphorus in patients with chronic kidney disease patients on dialysis. 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 and uncertainties associated with the drug development 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 August 13, 2021, 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-publication-of-52-week-phase-3-phreedom-trial-301368919.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