

News release

Kyowa Kirin Announces Launch of PHOZEVEL[®] Tablets for Improvement of Hyperphosphatemia in Chronic Kidney Disease Patients on Dialysis in Japan

Tokyo, Japan, February 19th, 2024 –Kyowa Kirin Co., Ltd. (President and CEO: Masashi Miyamoto, TSE: 4151, “Kyowa Kirin”) announced that PHOZEVEL[®] Tablets (Generic name: tenapanor hydrochloride, Development code: KHK7791), licensed from Ardelyx, Inc. (Waltham, Mass., USA; Nasdaq: ARDX, President and CEO: Mike Raab, “Ardelyx”)*¹, will be launched in Japan on February 20th for the improvement of hyperphosphatemia*² in chronic kidney disease patients on dialysis.

Tenapanor hydrochloride, discovered and developed by Ardelyx in the United States, is a first-in-class phosphate absorption inhibitor. Kyowa Kirin entered into an exclusive license agreement with Ardelyx in November 2017 for the development and commercialization rights for cardiorenal diseases in Japan, including hyperphosphatemia. Kyowa Kirin received approval for manufacturing and marketing PHOZEVEL[®] Tablets in September 2023, and will now launch PHOZEVEL[®] Tablets in Japan.

PHOZEVEL[®] Tablets has a novel mechanism of action, distinct from conventional hyperphosphatemia treatment agents, that blocks phosphate absorption through the paracellular pathway by inhibiting the sodium hydrogen exchanger 3 (NHE3) on intestinal epithelial cells in the gut. Kyowa Kirin expects that PHOZEVEL[®] Tablets will provide a new treatment option for the improvement of hyperphosphatemia in chronic kidney disease patients on dialysis and significantly improve the quality of life for patients.

“We are excited to announce the launch of PHOZEVEL[®] Tablets and the positive impact it will have on enhancing the quality of life for patients with chronic kidney disease on dialysis,” said Hiroshi Sonekawa, Managing Executive Officer, Vice President, Head of Sales & Marketing Division at Kyowa Kirin. “We are committed to providing healthcare professionals with information on appropriate use of this medication and raising disease awareness in the therapeutic area of nephrology, in order to deliver more smiles for a greater number of patients.”

The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

***1: 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 has two commercial products approved in the United States, IBSRELA[®] (tenapanor) and XPHOZAH[®] (tenapanor) as well as early-stage pipeline candidates.

***2: About Hyperphosphatemia**

Hyperphosphatemia is a serious condition resulting in an abnormally elevated level of phosphorus in the blood. 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). Over 2 million people worldwide currently receive treatment with dialysis or a kidney transplant to stay alive, yet this number may only represent 10% of people who actually need treatment to live.[#]

[#] Couser WG, Remuzzi G, Mendis S, Tonelli M. The contribution of chronic kidney disease to the global burden of major noncommunicable diseases. *Kidney Int.* Dec 2011;80(12):1258-1270.