Kyowa Hakko Kirin Initiated Phase 2 Clinical Study of Tenapanor (KHK7791) for Hyperphosphataemia Patients on Hemodialysis in Japan.

Tokyo, Japan, February 6, 2019 --- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and COO: Masashi Miyamoto, "Kyowa Hakko Kirin") announced the initiation of a phase 2 clinical study in Japan for tenapanor (Code name: KHK7791), a small molecule compound licensed from Ardelyx, Inc. (Fremont, Calif., USA; CEO & President: Mike Raab, “Ardelyx”). Tenapanor is an oral, minimally systemic NHE3 inhibitor with a unique mechanism that is different from the current phosphate binder therapy.

This phase 2 clinical study is a multi-center open-label, single-arm study evaluating serum phosphorus in hyperphosphataemia patients on Hemodialysis (HD) who switch from phosphate binders to KHK7791 in Japan. Phosphate binders are the current standard treatment for the disease in Japan. The study is to evaluate the efficacy and safety of a switch from phosphate binders to KHK7791.

In addition to this phase 2 clinical study, Kyowa Hakko Kirin also plans to initiate two additional phase 2 clinical trials for KHK7791, a monotherapy dose-response study and a combination therapy with KHK7791 and phosphate binders.

"The initiation of the study marks a great milestone for Kyowa Kirin on delivering a brand-new treatment option for hyperphosphataemia patients on HD in Japan," said Mitsuo Satoh, Ph.D., Executive Officer, Vice President Head of R&D Division of Kyowa Hakko Kirin. "We’ll keep working to prove the efficacy and safety of tenapanor for patients through clinical studies in Japan."

Kyowa Hakko Kirin signed a license agreement with Ardelyx for the exclusive rights to develop and commercialize tenapanor in cardiorenal disease in Japan on November 28, 2017. Ardelyx is currently conducting a Phase 3 clinical study on tenapanor in the U.S. for the treatment of hyperphosphatemia in patients with end-stage renal disease (ESRD) who are on dialysis.

The Kyowa Hakko 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.

<Summary of the Study>

Study Name	A Phase 2, Open-label, Single-arm Switching Study to KHK7791 from Phosphate Binder to Treat Hyperphosphataemia in Patients on HD (Multicenter, open-label, single arm study)
Study Population	Hyperphosphataemia in patients on hemodialysis
Primary Endpoint	Efficacy
Estimated Enrollment	60
Location	Japan
Estimated Study Completion Date	Nov.2019

About Tenapanor (KHK7791) for Hyperphosphatemia

Tenapanor, discovered and developed by Ardelyx, is a first-in-class, proprietary, minimally absorbed, oral, experimental medication in late-stage clinical development. It has a unique mechanism of action that, in hyperphosphatemia, acts by blocking the NHE3 sodium transporter in the GI tract, reducing the absorption of dietary sodium and resulting in increased protons within the cells. The increase in protons causes a reduction in phosphate uptake by tightening junctions or pores that regulate phosphate absorption in the GI tract. Overall, this mechanism appears to be preferential to phosphate absorption given that Ardelyx has not observed any significant changes in other ions, other than sodium, in preclinical or clinical studies.