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Kyowa Hakko Kirin initiates Ph 2 Clinical Study of Tenapanor

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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.

Kyowa Hakko Kirin Co., Ltd. announced the initiation of a phase 2 clinical study in Japan for tenapanor, a small molecule compound licensed from Ardelyx, Inc. 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.