

Kyowa Hakko Kirin Submits Application for Approval of Evocalcet (KHK7580) for Secondary Hyperparathyroidism in Maintenance Dialysis Patients in Japan

Tokyo, Japan, April 27, 2017 --- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") announced today that it has been filed an application of manufacturing and marketing approval to Japan's Ministry of Health, Labor and Welfare (MHLW) seeking approval of evocalcet (generic name, code name: KHK7580) which has been developed for secondary hyperparathyroidism in maintenance dialysis patients.

In regard to evocalcet, the results of another two phase 3 clinical studies in Japan, different from the study result announced on Jan. 31, 2017, have indicated the safety and efficacy for secondary hyperparathyroidism receiving hemodialysis or peritoneal dialysis for 52 weeks.

"We are delighted to submit the application for approval of evocalcet." said Mitsuo Satoh, Head of Research and Development Division of Kyowa Hakko Kirin. "We believe evocalcet provides more efficient treatment for secondary hyperparathyroidism on maintenance 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.

About evocalcet

KHK7580 is a small molecular compound and the novel type of calcimimetics discovered by Mitsubishi Tanabe Pharma Corporation (President & Representative Director, CEO: Masayuki Mitsuka, "Mitsubishi Tanabe Pharma"). Kyowa Hakko Kirin signed a license agreement of KHK7580 with Mitsubishi Tanabe Pharma for the rights to cooperative research, develop, market and manufacture the product in Japan and some part of Asia on March 2008.

About the study result announced on Jan. 31, 2017

This study evaluated the efficacy and safety of evocalcet in subjects with secondary hyperparathyroidism receiving hemodialysis in a randomized, double-blind, intra-subject dose-adjustment, parallel-group, multi-center design study with cinacalcet hydrochloride (Product Name: REGPARA®) as an active control. The top-line results indicated the non-inferiority for efficacy and the significant reduction in the incidence of the upper gastrointestinal tract disorder of KHK7580 compared with the active control.