Kyowa Hakko Kirin Announces Top-Line Results of Phase 3 Clinical Study of KHK7580 with Secondary Hyperparathyroidism in Japan

Tokyo, Japan, January 31, 2017 --- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") announced today that top-line results of the Japanese Phase 3 trial of KHK7580 met its primary endpoint.

This study to evaluate the efficacy and safety of KHK7580 orally administered once daily for 30 weeks in subjects with secondary hyperparathyroidism receiving hemodialysis in a randomized, double-blind, intra-subject dose-adjustment, parallel-group design study with cinacalcet hydrochloride (Product Name: REGPARA®), which was already approved in Japan, 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.
The details of the study results will be presented at upcoming scientific congresses and/or in scientific journals.

“We are delighted with the positive top-line results from pivotal Phase 3 study of KHK7580 in secondary hyperparathyroidism patients receiving hemodialysis.” said Yoichi Sato, Managing Executive Officer, Vice President, Head of Research and Development Division of Kyowa Hakko Kirin. “We believe KHK7580 has the potential to provide more efficient treatment for secondary hyperparathyroidism.”

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.

＜Outline of the study design＞

Target Population	Secondary hyperparathyroidism receiving hemodialysis
Design	Randomized, double-blind, intra-subject dose-adjustment, parallel-group, study design
Administration Group	KHK7580, cinacalcet hydrochloride
Number of subjects	634
Primary endpoint	Percentage of subjects in the evaluation period achieving a mean intact parathyroid hormone (iPTH) level of ≥ 60 pg/mL and ≤ 240 pg/mL
Study Location	Japan

About KHK7580
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 incidence of the upper gastrointestinal tract disorder
In the study, the incidence was defined as nausea, vomiting, abdominal discomfort, abdominal distension, or decreased appetite.