

Kyowa Hakko Kirin Presented Results of Japan Phase III Clinical Study of Evocalcet at Kidney Week 2017 of the American Society of Nephrology

Tokyo, Japan, November. 6, 2017 --- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") announced today that the results of the phase III clinical trial of evocalcet for secondary hyperparathyroidism in patient on maintenance hemodialysis were presented in Late-Breaking Clinical Trial of Kidney Week 2017, the American Society of Nephrology (ASN), on November 3, 2017.

<Study Design>

The study was a double-blind, active-controlled study to evaluate the efficacy and safety of evocalcet for secondary hyperparathyroidism in patients on maintenance hemodialysis in once-daily administration for 30 weeks, compared with cinacalcet hydrochloride (product name: REGPARA®) which was already approved in Japan.

<Results>

A total of 639 patients were randomly assigned to receive evocalcet (n=317) or cinacalcet (n=317).

The primary efficacy endpoint was the proportion of patients achieving a mean iPTH level of 60-240 pg/mL during the evaluation period. The proportion was 72.7% and 76.7% in the evocalcet and cinacalcet groups, respectively. The difference in achievement rate between the groups was -4.0% (95% CI; -11.4%, 3.5%). As the lower limit of the two-sided 95% CI for the difference was -11.4% which exceeds the non-inferiority margin of -15%, the non-inferiority of evocalcet to cinacalcet was confirmed.

Regarding the safety endpoint, gastrointestinal adverse events defined as nausea, vomiting, abdominal discomfort, abdominal distension, or decreased appetite were observed in 18.6% (evocalcet) vs 32.8% (cinacalcet) of patients (difference -14.2% [95% CI -20.9%, -7.5%], $p < 0.001$). As no important safety concerns were raised, we confirmed the safety profile of evocalcet.

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)

Evocalcet (KHK7580) is a small molecular compound and a novel type of calcimimetic discovered by Mitsubishi Tanabe Pharma Corporation (President & Representative Director, CEO: Masayuki Mitsuka,

"Mitsubishi Tanabe Pharma"). Kyowa Hakko Kirin signed a license agreement for KHK7580 with Mitsubishi Tanabe Pharma for the rights to cooperative research, develop, market and manufacture the product in Japan and some parts of Asia in March 2008.

About the clinical trial in this press release

The clinical trial described in this press release is the same study as that announced on January 31, 2017, which achieved its primary endpoint.