

# News release

## **Kyowa Kirin Receives Partial Change Approval for ORKEDIA® in Japan**

Tokyo, Japan, December 20, 2019---Kyowa Kirin Co., Ltd. (TSE: 4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") announces today that it has received the partial change approval for ORKEDIA® (code name: KHK7580, generic name: evocalcet)\*<sup>1</sup> for the treatment of hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism who are unable to undergo parathyroidectomy or relapse after parathyroidectomy\*<sup>2</sup> from the Ministry of Health, Labor and Welfare (MHLW) in Japan.

The approval is based on the result of the Phase 3 clinical trial that evaluates the efficacy of ORKEDIA for hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism who are unable to undergo parathyroidectomy or relapse after parathyroidectomy.

ORKEDIA was also granted Orphan Drug Designation for the treatment of hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism who are unable to undergo parathyroidectomy or relapse after parathyroidectomy by the MHLW on March 4, 2019.

The Kyowa 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.

### **\*1. About ORKEDIA® (evocalcet)**

ORKEDIA is a small molecular compound and a novel type of calcimimetics discovered by Mitsubishi Tanabe Pharma Corporation (President & Representative Director, CEO: Masayuki Mitsuka, "Mitsubishi Tanabe Pharma"). Kyowa Kirin signed a license agreement of ORKEDIA® with Mitsubishi Tanabe Pharma for the rights of cooperative research, develop, market and manufacture of the product in Japan and some parts of Asia in March 2008. In March 2018, Kyowa Kirin received approval of ORKEDIA® for secondary hyperparathyroidism in maintenance dialysis patients and later in May 2018, the product was launched in Japan market, named ORKEDIA® Tablets.

### **\*2. About Hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism who are unable to undergo parathyroidectomy or relapse after parathyroidectomy**

Parathyroid carcinoma and primary hyperparathyroidism (PHPT) are diseases in which serum calcium levels are elevated due to over autonomous secretion of parathyroid hormone (PTH) from tumors of the parathyroid gland. Parathyroidectomy (PTx) is the only reliable method to treat parathyroid carcinoma and PHPT. Control of hypercalcemia can prove challenging in cases of PHPT where PTx cannot be considered because of concomitant diseases or where PHPT recur after PTx and parathyroid carcinoma, although patients with such hypercalcemia are very rare. Hypercalcemia causes symptoms of fatigue, polyuria, thirst, and renal impairment

and severe hypercalcemia can result in death due to a hypercalcemic crisis.