KYOWA KIRIN

News release

Kyowa Kirin Received Approval for Calcimimetics Agent ORKEDIA® TABLETS 4mg in Japan

Tokyo, Japan, August 30, 2023 --Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE:4151, President and CEO: Masashi Miyamoto) announced that the company has received approval from the Ministry of Health, Labour and Welfare (“MHLW”) for ORKEDIA® TABLETS 4mg (generic name: evocalcet) in Japan.

ORKEDIA® TABLETS is an oral calcimimetics agent which suppresses parathyroid hormone (PTH) secretion by acting on the calcium receptors on parathyroid gland cells. The drug is approved in Japan for the treatment of secondary hyperparathyroidism in patients undergoing maintenance dialysis, hypercalcemia in patients with parathyroid carcinoma, and hypercalcemia in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy or who experience recurrent primary hyperparathyroidism. Its low dosage, ORKEDIA® TABLETS 1mg and ORKEDIA® TABLETS 2mg have helped many patients in Japan since their launch in May 2018. With this higher dose, ORKEDIA® TABLETS 4mg, it is expected to lead to a reduction in the burden of medication for patients and an improvement in the treatment satisfaction.

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.

About ORKEDIA®

ORKEDIA® is a small molecular compound and a novel type of calcimimetics discovered by Mitsubishi Tanabe Pharma Corporation (Representative Director: Akihiro Tsujimura, "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, ORKEDIA® was approved in Japan for the treatment of secondary hyperparathyroidism in dialysis patients and later launched in Japan in May 2018. Furthermore, in December 2019, ORKEDIA® obtained additional approval for the treatment of hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism who are unable to undergo parathyroidectomy or relapse after parathyroidectomy.