

## Kyowa Hakko Kirin Receives Approval for ORKEDIA® Tablets (Evocalcet) for the Treatment of Secondary Hyperparathyroidism in Patients on Maintenance Dialysis in Japan

**Tokyo, Japan, March 23, 2018** --- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and COO: Masashi Miyamoto, "Kyowa Hakko Kirin") announced today that ORKEDIA® TABLETS (generic name: evocalcet, code name: KHK7580) has received the manufacturing and marketing authorization from Japan's Ministry of Health, Labor and Welfare (MHLW) for the treatment of secondary hyperparathyroidism in patients on maintenance dialysis.

ORKEDIA® TABLETS is a new type of oral calcimimetics agent. The drug suppresses parathyroid hormone secretion by acting on calcium receptors on parathyroid gland cells in a similar way to the approved drug REGPARA® TABLETS (cinacalcet hydrochloride). Compared with REGPARA® TABLETS, ORKEDIA® TABLETS has demonstrated the non-inferiority for efficacy and a significant reduction in incidence of the upper gastrointestinal tract disorders through its Ph3 clinical studies. A reduction in the risk of co-administration was also observed in the drug interaction study.

"We are very pleased to announce the approval for ORKEDIA® TABLETS in Japan," said Mitsuo Satoh, Ph.D., Head of Research and Development Division of Kyowa Hakko Kirin. "We believe that ORKEDIA® TABLETS may well become a best-in-class drug for the treatment of secondary hyperparathyroidism in patients on maintenance dialysis and will greatly contribute to patients' treatment satisfaction".

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.

### [Product Information]

Product Name	ORKEDIA® TABLETS 1mg, ORKEDIA® TABLETS 2mg
Generic Name	Evocalcet
Indications	Secondary hyperparathyroidism in patients on maintenance dialysis.
Packaging	ORKEDIA® tablet 1mg: [PTP]100 tablets (10 tablets/PTP), box ORKEDIA® tablet 2mg: [PTP]100 tablets (10 tablets/PTP), box
Approval Date	March 23, 2018

### About KHK7580 (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 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 on March 2008.