

Kyowa Hakko Kirin Launches ORKEDIA® TABLETS (Evocalcet) for the Treatment of Secondary Hyperparathyroidism in Patients on Maintenance Dialysis in Japan

Tokyo, Japan, May 22, 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 been listed on the National Health Insurance (NHI) Drug Price List and launched for the treatment of secondary hyperparathyroidism in patients on maintenance dialysis in Japan.

ORKEDIA® TABLETS is a new type of oral calcimimetics agent. The drug suppresses parathyroid hormone secretion by acting on the calcium receptors on parathyroid gland cells in a similar way to the approved drug REGPARA® TABLETS (cinacalcet hydrochloride). Manufacturing and marketing authorization for ORKEDIA TABLETS was granted by from Japan's Ministry of Health, Labor and Welfare (MHLW) on March 23 2018. Compared with REGPARA® TABLETS, ORKEDIA® TABLETS have demonstrated a significant reduction in incidence of the upper gastrointestinal tract disorders through its Ph3 clinical study. A reduction in the risk of co-administration was also observed in the drug interaction study.

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
Date of NHI price listing	May 22, 2018
NHI drug price	1 mg/tablet: 280.70 yen, 2 mg/tablet: 412.10 yen

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.