Approval of REGPARA® Tablets 12.5mg in Japan

Tokyo, Japan, February 16, 2015—Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") announced today that REGPARA® Tablets 12.5mg (generic name: cinacalcet hydrochloride) has been approved for manufacturing and marketing in Japan on February 10 as an additional formulation.

REGPARA® (tablets 25mg and 75mg) acts on calcium receptors on the parathyroid gland to suppress the secretion of parathyroid hormone (PTH). REGPARA® tablets 25mg and 75mg were launched in January 2008 for secondary hyperparathyroidism (HPT) in patients who are undergoing regular dialysis. In February 2014, the drug had received the approval for hypercalcemia in patients with parathyroid carcinoma, and hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy or who experience recurrent primary HPT.

REGPARA® has been marketed in Japan for seven years and prescribed many patients, but it is also fact that response and tolerance of this drug is some case individual. Therefore, to provide a lower dosage form to allow doctors to more finely adjust the drug dose, Kyowa Hakko Kirin applied for manufacturing and marketing approval of REGPARA® Tablets 12.5mg as additional strength in March 25, 2014 and received an approval of this product in February 10, 2015.

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.

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