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Chugai Files NDA for a Renal Anemia Agent R744

July 22, 2009 (Tokyo) - Chugai Pharmaceutical Co., Ltd. ("Chugai") [Head Office: Chuo-ku, Tokyo; President Osamu Nagayama] announced that the company filed a new drug application (NDA) for R744, a long-acting erythropoiesis-stimulating agent, for the treatment of anemia associated with chronic kidney disease (renal anemia) with the Japanese Ministry of Health, Labour and Welfare (MHLW) today.

Renal anemia is one of the most frequent complications with chronic kidney disease (CKD), with significant impact on patients' quality of life. R744 is a continuous erythropoietin receptor activator which has a different interaction on the receptor level compared to other erythropoiesis stimulating agents. It was launched outside Japan in 2007 under the product name Mircera[®] as an innovative anti-anemia medication that allows a once-monthly maintenance therapy. With its extended dosing frequency compared to existing therapies, the product is contributing to the advancement of the management of renal anemia overseas.

Chugai conducted clinical trials for R744 in renal anemia patients in Japan. The results of these studies confirmed its efficacy and tolerability in CKD patients with once-every-four-week intravenous or subcutaneous dosing in maintenance therapy, which led to the filing today.

In recent years, there has been a significant increase in CKD patients with underlying diabetes. The increasing prevalence of CKD raises awareness of the importance of earlier treatment of anemia and simplified anemia management in these patients. To support treatment, guidelines have been issued by the Japanese Society for Dialysis Therapy and the Japanese Society of Nephrology in 2008 and 2009, respectively.

The area of renal diseases is one of the strategic focus areas for Chugai. Chugai will continue to focus on obtaining marketing authorization for R744 to make this new treatment option available for anemic patients with CKD and medical professionals in addition to the currently available standard therapy, the recombinant human erythropoietin Epogin[®].

About R744

R744 is a long-acting erythropoiesis stimulating agent (ESA) which has the longest serum half-life among ESAs on the market. The long serum half-life of R744 allows maintenance of hemoglobin level with once-every-four-week dosing for CKD patients, offering simplified anemia management and improved convenience for patients and caregivers. R744 is marketed outside Japan under the product name Mircera[®].