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Translation

Long-Acting Erythropoiesis Stimulating Agent, "Mircera® Injection Syringe," Approved in Japan

April 22, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter, "Chugai")] announced today that it has obtained manufacturing and marketing approval from the Ministry of Health, Labour and Welfare on April 22, 2011, for a long-acting erythropoiesis stimulating agent (ESA) [brand name: Mircera® Injection Syringe 25μg, 50μg, 75μg, 100μg, 150μg, 200μg, and 250μg; Japan accepted name (JAN): epoetin beta pegol (genetical recombination)], with indication for use in the treatment of renal anemia.

Mircera® Injection Syringe is a long-acting ESA that uses epoetin beta (genetical recombination) which is chemically combined with a single molecule of linear methoxy polyethylene glycol (PEG). It has a longer serum half-life than other currently available ESA such as Epogin® Injection, enabling it to maintain hemoglobin levels targeted under the Guideline for Treatment of Renal Anemia* with once-every-four-week intravenous or subcutaneous dosing. A clinical study of this drug has confirmed that the drug brings about stable anemia improvement and maintenance effects against renal anemia seen in patients who undergo hemodialysis or peritoneal dialysis, as well as those patients who are treated for chronic kidney disease at a prior stage of entering dialysis treatment.

Mircera® Injection Syringe is expected to highly contribute to advancing the treatment of chronic kidney disease, offering improved convenience for the patients such as fewer hospital visits and enhanced quality of life (QOL), and also reducing the burden for healthcare professionals. The drug was approved in Europe in 2007, and is currently being launched in more than 100 countries around the world.

Chugai is determined to conduct research, development, manufacturing and distribution of drugs with the viewpoint of patients and healthcare professionals, and to make continuous endeavors to improve the QOL of patients who are treated with drugs.

"Guidelines for renal anemia in chronic kidney disease," 2008 edition released by the Japanese Society for Dialysis Therapy.