

Translation

Recombinant Human Erythropoietin, Epogin[®] Injection Application for Approval of Additional Indication of Chemotherapy-Induced Anemia

November 19, 2009 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President: Osamu Nagayama (hereafter, Chugai)] announced today that the company filed an application with the Japanese Ministry of Health, Labour and Welfare for the approval of an additional indication of chemotherapy-induced anemia for the recombinant human erythropoietin, "Epogin[®] Injection" [generic name: epoetin beta (genetic recombination)].

In the domestic phase III clinical study that plays a central role in this application, patients with chemotherapy-induced anemia were randomized to receive a weekly dosage of "Epogin[®] Injection" 36,000IU or placebo for 12 weeks to examine efficacy and safety of "Epogin[®] Injection" treatment. As a result, the study met its primary endpoint with patients who received "Epogin[®] Injection" demonstrating a statistically significant reduction in theoretical transfusion rate compared with those who received placebo. Most common adverse effects observed in patients who received "Epogin[®] Injection" included increased blood pressure, hypertension, constipation and diarrhea.

Patients receiving cancer chemotherapy may experience anemia resulting from various adverse reactions including bone-marrow suppression. Nonetheless, blood transfusion has been the only treatment option for such anemia in Japan. Therefore, new treatment options are required.

As the top pharmaceutical company in the field of oncology, Chugai will work for the approval for "Epogin[®] Injection" to provide patients and medical practitioners with new treatment options for chemotherapy-induced anemia as soon as possible.

* The percentage of patients who received blood cell transfusion or had hemoglobin level under 8.0g/dL between four weeks after taking the first dose of treatment and the end of the study.