



## Translation

June 13, 2011

Name of listed company: Chugai Pharmaceutical Co., Ltd.  
Code number: 4519 (1<sup>st</sup> Section of Tokyo Stock Exchange)  
Head office: 1-1, Nihonbashi-Muromachi 2-Chome, Chuo-ku, Tokyo  
President & CEO: Osamu Nagayama  
Inquiries to: Nobuyuki Chiba, General Manager,  
Corporate Communications Dept.  
Tel: +81-(0)3-3273-0881

## Update on the Application of Epogin<sup>®</sup> in Chemotherapy-Induced Anemia

June 13, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President: Osamu Nagayama (hereafter, Chugai)] announced today that the company was notified of the result of the review conducted at the Second Committee on New Drugs, Pharmaceutical Affairs and Food Sanitation Council (hereafter, "the Committee") convened today to discuss on its application for the approval of an additional indication, dosage and administration, and formulation for treatment of "chemotherapy-induced anemia in solid tumor patients who are not eligible for curative surgery" for the recombinant human erythropoietin, "Epogin<sup>®</sup> Injection" [generic name: epoetin beta (genetic recombination)], which had been submitted to the Japanese Ministry of Health, Labour and Welfare (hereafter, "MHLW") in November, 2009.

### [Conclusion of the Committee]

The Committee, held on June 13, 2011, concluded that it is not appropriate that Epogin<sup>®</sup> be approved due to following reasons, and to bring this application up to discussion at the Pharmaceutical Affairs Subcommittee.

1. The Committee acknowledges that expectations exist for the development of a treatment option for "chemotherapy-induced anemia in solid tumor patients who are not eligible for curative surgery" other than red blood cell transfusion.
2. On the other hand, a highly important risk, a worsened prognosis and promotion of cancer cell growth, have been reported associated with the administration of erythropoiesis stimulating agents (ESA) in cancer patients, and currently, there is no evidence that this risk can be mitigated even if the eligibility of patients are strictly restricted with such factors as Hb level.
3. The agent in discussion is to be used together with chemotherapy that aims to prolong lives of patients with solid tumors, or to inhibit cancer cell growth in those patients, however, currently, there is a concern that this agent may worsen the prognosis and promote cancer cell growth. There was an opinion that the agent may be used upon getting consent from patients, however, as a conclusion, it has been decided that the Pharmaceutical Affairs Act, Article 14 -2-(3)-(b) is applicable to this application.
4. Although it is difficult to approve the agent at this stage, additional information on ESAs regarding this indication and new evidence are expected to allow the re-examination of this indication.



*Pharmaceutical Affairs Act, Article 14 -2-(3)-(b)*

*The drug, quasi-drug or medical device in the application is found to have no value as a drug, quasi-drug or medical device because it has harmful action that outweighs its indications and properties.*

As the next step, public comments will be collected by the MHLW, and then the Pharmaceutical Affairs Subcommittee will be held to review this application. Chugai will continue to make effort to gain approval of Epogin®.

There shall be no change in the outlook for fiscal year 2011, ending Dec. 31, 2011.