Translation

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Name of listed company: Chugai Pharmaceutical Co., Ltd.
Code number: 4519 (1st 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

Anti-Human IL-6 Receptor Monoclonal Antibody "Actemra®" Subcutaneous Injection Demonstrates Efficacy in Rheumatoid Arthritis in Phase III Clinical Study

Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku Tokyo; President: Osamu Nagayama (hereafter, "Chugai")] announced today that subcutaneous injection of its humanized anti-human interleukin-6 (IL-6) receptor monoclonal antibody "Actemra®" [generic name: tocilizumab] has demonstrated non-inferiority in efficacy compared to intravenous infusion, in its phase III clinical study for rheumatoid arthritis (RA).

The phase III clinical study consists of a double-blind, randomized, parallel group study and subsequent open label long-term extension administration with the subcutaneous formulation. The first part is a 24 week study to compare the efficacy and safety between subcutaneous injection of Actemra® 162 mg once every two weeks and intravenous infusion of Actemra® 8 mg/kg once every four weeks. The second part is an open label roll-over extension study to evaluate the efficacy and safety of the long-term administration of the subcutaneous formulation. This time, the initial-24-week study has demonstrated non-inferiority of efficacy, defined by the ACR20 response which is the primary endpoint, by subcutaneous injection compared with that by intravenous infusion. The clinical safety profile of the subcutaneous injection was consistent in nature with that observed with the intravenous infusion. The details of the study results will be presented at major upcoming conferences or in future publications.

The application for approval of Actemra® for subcutaneous injection is planned to be filed in Japan in 2012 based on the results of this study.

RA is a systemic inflammatory disease for which the cause is unknown. It appears more commonly in females in their 40s and 50s. The disease causes serious psychological and social problems not only for the patients but also for their families, and measures to counter the disease are seriously needed.

Subcutaneous injection does not require intravenous access, no need to provide infusion facilities, and it may be administered at home if self-injection is approved. Further, it requires a shorter time for administration when compared to intravenous injection. In combination with the already approved intravenous infusion, the subcutaneous injection will offer additional treatment options so that individual patients can choose an administration form that suits their life style, contributing to improved convenience.

Actemra®, the first antibody drug (humanized monoclonal antibody) originating from Japan, was created by Chugai in collaboration with Osaka University, utilizing genetic recombinant technology to produce a monoclonal antibody against the IL6 receptor. It works by inhibiting biological activity of IL-6 through competitively blocking the binding of IL-6 to its receptor.

"Actemra®" was first approved in Japan, and launched by Chugai in June 2005 as a therapy for Castleman's disease. In April 2008, additional indications for rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and systemic-onset juvenile idiopathic arthritis were also approved in Japan. "Actemra®" was approved in the European Union in January 2009 for the treatment of RA in patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease modifying anti-rheumatic drugs (DMARDs) or TNF inhibitors. It is also approved in over 90 other countries, including India, Brazil, Switzerland, and Australia. "Actemra®" was approved in the United States in January 2010 for the treatment of adult patients with moderate to severe RA who have had an inadequate response to one or more TNF inhibitors. In April 2011.Actemra was also approved for the treatment of sJIA in the United States. The subcutaneous injection formulation is developed by Chugai in Japan, and is codeveloped by Chugai and F. Hoffmann-La Roche Ltd. [Head Office: Basel, Switzerland; CEO: Severin Schwan] outside of Japan.