Translation

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Name of listed company: Chugai Pharmaceutical Co., Ltd.
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FDA Advisory Committee Votes in Favor to Recommend Approval of Actemra®, a Humanized Anti-Human IL-6 Receptor Monoclonal Antibody, for Rheumatoid Arthritis

July 30, 2008 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President Osamu Nagayama (hereafter, "Chugai")] and F. Hoffmann-La Roche Ltd. [Head Office: Basel, Switzerland. CEO: Severin Schwan (hereafter "Roche")] announced that the Arthritis Advisory Committee of the U.S. Food and Drug Administration (FDA) voted ten to one for the approval of Actemra®, the humanized anti-human IL-6 (interleukin-6) receptor monoclonal antibody, filed with the FDA in November 2007 as a treatment for rheumatoid arthritis (RA). The FDA is not bound by the committee's recommendation to approve the drug, however, it generally follows its advice.

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 anti-IL6 receptor. It works by inhibiting biological activity of IL-6 through competitively blocking the binding of IL-6 to its receptor.

In Japan, 200mg preparation of Actemra® was launched in June 2005 by Chugai, as an orphan drug for Castleman's disease, following approval in April, the same year. Subsequently, it was approved for the additional indications of RA (including prevention of structural damage of joints), polyarticular-course juvenile idiopathic arthritis and systemic juvenile idiopathic arthritis in April 2008. 80mg and 400mg preparations were launched additionally in June 2008. Outside of Japan, five phase III clinical trials, including extension studies in RA are going on in 40 countries involving more than 4,000 patients worldwide under co-development between Chugai and Roche. The submissions were made to the FDA and the European Medicines Evaluation Agency (EMEA), based on results and extension studies from four out of five of these trials, and the interim analysis of the remaining ongoing trial.

RA is a systemic inflammatory disease in which the cause is unknown. The main symptoms are multiple joint inflammation and progressive joint damage. Millions of patients are suffering from the pain and debilitating effects of the disease In the United States. Chugai focuses on bone and joint diseases area as one of the strategic domains, and is committed to contribute to the treatment by providing new therapeutic options for medical professionals and patients.