Translation

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Update on FDA Registration of Actemra®, a Humanized Anti-Human IL-6 Receptor Monoclonal Antibody for Rheumatoid Arthritis

December 4, 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 today that the U.S. Food and Drug Administration (FDA) has provided further guidance on requirements for the Biologics License Application (BLA) for Actemra®, the humanized anti-human IL-6 (interleukin-6) receptor monoclonal antibody as a treatment for moderately to severely active rheumatoid arthritis (RA).

As a result of the FDA's evolving Risk Evaluation and Mitigation Strategy (REMS) requirements for medications, the Agency has clarified that a REMS plan is required to help ensure that health care professionals prescribe and administer Actemra® correctly, and that patients understand the potential benefits and risks associated with this medication. Additionally, based on the evolving requirements for approval of new biologics, the FDA has asked Roche for non-clinical animal model data, beyond what was included in the Actemra BLA. Roche is performing the requested pre-clinical studies to confirm the published literature suggesting that Actemra® does not affect peri- and post-natal development, and fertility. The FDA has not requested additional clinical studies prior to approval. The FDA Office of Compliance has also completed its evaluation of the manufacturing facility in Japan, and has indicated that it is acceptable to manufacture Actemra®.

The BLA was filed with the FDA in November 2007, and the FDA issued a Complete Response Letter in September, 2008. Since then, Roche has been engaged in productive discussions with the FDA and recently met with Agency representatives to receive clarification on the outstanding components of the Actemra BLA. The resubmission is anticipated to be made in the third quarter of 2009.

In EU, it is under review by the European Medicines Evaluation Agency (EMEA), and the Committee on Human Medicinal Products (CHMP) has given a positive recommendation in November 2008. In Switzerland, the authorities approved RoACTEMRA® for the treatment of moderately severe to severe, active rheumatoid arthritis on December 3, 2008.

About Actemra®

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 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 conducted 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 EMEA, based on results and extension studies from four out of five of these trials, and the interim analysis of the remaining ongoing trial. In July, 2008, the Arthritis Advisory Committee of the FDA voted 10-1 to recommend approval of Actemra®. In September, the FDA issued a Complete Response Letter regarding Actemra® BLA. In Europe, the CHMP has given a positive recommendation in November 2008, and has been approved in Switzerland on December 3, 2008.

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.