**Translation**

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

July 31, 2009 (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 FDA has accepted the complete response resubmission that Roche made to the U.S. Food and Drug Administration (FDA) for the Biologics License Application (BLA) for Actemra®, the humanized anti-human IL-6 (interleukin-6) receptor monoclonal antibody, following the receipt of the Complete Response Letter in September 2008.

Following is an update released by Roche on July 31, 2009.

## FDA accepts complete response resubmission for ACTEMRA (tocilizumab)

Roche announced today that the U.S. Food & Drug Administration (FDA) has accepted the resubmission for the ACTEMRA® (tocilizumab) Biologics License Application (BLA), following the company's receipt of a complete response in September 2008. The FDA has designated a Class II, or six-month, review timeline for the resubmission, according to Prescription Drug User Fee Act (PDUFA) guidelines. ACTEMRA is the first interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA).

Roche has worked diligently to fulfill the FDA's requirements for ACTEMRA and has submitted the complete response resubmission earlier than anticipated in the third quarter of 2009. As requested by the FDA, key elements of the complete response resubmission include a proposed Risk Evaluation and Mitigation Strategy (REMS) to help ensure that health care professionals prescribe and administer ACTEMRA correctly, and that patients understand the benefits and known and potential risks associated with this medication. The resubmission also includes the requested non-clinical studies evaluating the effect of ACTEMRA on peri- and post-natal development, and fertility.

The BLA for ACTEMRA is based on the results of an extensive multi-national clinical development programme, which included more than 4,000 patients in 41 countries, including the U.S. These studies demonstrated that ACTEMRA, alone or in combination with methotrexate or other disease-modifying anti-rheumatic drugs (DMARDS), significantly reduced the signs and symptoms of RA, regardless of previous therapy or disease severity, compared to DMARDS alone. In July 2008, the Arthritis Advisory Committee of the FDA voted 10-1 to recommend the approval of ACTEMRA.

**About ACTEMRA**

ACTEMRA is part of a co-development programme between Roche and Chugai Pharmaceutical Co. An extensive clinical development programme of five Phase III trials was designed to evaluate clinical findings of ACTEMRA, all of which are completed and have reported meeting their primary endpoints. 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, juvenile idiopathic arthritis and systemic-onset juvenile idiopathic arthritis were also approved in Japan. RoACTEMRA 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 DMARDs or TNF inhibitors. It is also approved for use in several other countries, including India, Brazil, Switzerland and Australia.

ACTEMRA is generally well tolerated. The overall safety profile of ACTEMRA is consistent across all global clinical studies. The serious adverse events reported in ACTEMRA clinical studies include serious infections, gastrointestinal perforations and hypersensitivity reactions including anaphylaxis. The most common adverse events reported in clinical studies were upper respiratory tract infection, nasopharyngitis, headache, hypertension and increased ALT. Increases in liver enzymes (ALT and AST) were seen in some patients; these increases were generally mild and reversible, with no evidence of hepatic injuries or any observed impact on liver function. Laboratory changes, including increases in lipids (total cholesterol, LDL, HDL, triglycerides) and decreases in neutrophils and platelets, were seen in some patients without association with clinical outcomes. Treatments that suppress the immune system, such as ACTEMRA, may cause an increase in the risk of malignancies.

**About Roche**

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients.

In 2008, Roche had over 80,000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.