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Translation

FDA Accepts Supplemental Biologics License Application Submitted for ACTEMRA®, a Humanized Anti-Human IL-6 Receptor Monoclonal Antibody, Regarding Adult Rheumatoid Arthritis Indication

February 21, 2012- 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] announced today that the U.S. Food and Drug Administration (FDA) accepted the supplemental biologics license application (sBLA) which Genentech, Inc. [Head Office: California, U.S., CEO: Ian T. Clark], a member of the Roche Group, submitted to the FDA in December 2011, for the humanized anti-human interleukin-6 (IL-6) receptor monoclonal antibody, Actemra® [generic name: tocilizumab (genetical recombination)]. The review period is scheduled to be ten months, based on the Prescription Drug User Fee Act (PDUFA) and the anticipated action date comes in October 2012.

This sBLA seeks to broaden the approved patient population of Actemra® for the treatment of moderately to severely active rheumatoid arthritis (RA), to patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more DMARDs. This extension would lift the limitation of usage in patients with moderately to severely active RA “who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies,” as stated in the current label, but instead allow patients to receive Actemra® as first-line biologic treatment.

The sBLA submitted this time is based on a quite comprehensive safety data, including data from extensive clinical trial programs conducted prior to approval, their extension studies which are on-going, and data collected in the clinical settings after the initial approvals in the world. The data suggest that even after a long and extensive usage of Actemra®, the safety profile is consistent with the previous findings.

RA is a systemic inflammatory disease, with the main symptoms of multiple joint inflammation and progressive joint damage, and millions of patients are suffering from the pain and debilitating effects of the disease in the United States. Actemra®, created by Chugai in collaboration with Osaka University, utilizes genetic recombinant technology to produce monoclonal antibody from mouse anti-IL-6 receptor monoclonal antibody. It works by inhibiting IL-6 biological activity through competitively blocking the binding of IL-6 to its receptor.

In Japan, 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 (sJIA) in April 2008. In the EU, approval was granted as brand name RoActemra® in January 2009 for the treatment of adult RA in people who have either responded inadequately to, or who were intolerant to, previous therapy with one or more DMARDs or TNF inhibitors. In the US, in January 2010, Actemra® was approved as the treatment of adult patients with moderately to severely active RA who have had an inadequate response to one or more TNF antagonist therapies. Currently Actemra® is approved in more than 90 countries including India, Brazil, Switzerland and Australia. It was also approved in US in April 2011 and in EU in August 2011, for the treatment of active sJIA in patients two years of age and older.