CHUGAI PHARMACEUTICAL CO., LTD.
Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome,
Chuo-ku Tokyo, 103-8324 Japan
TEL:+81-(0)3-3273-0881
FAX:+81-(0)3-3281-6607
E-mail:pr@chugai-pharm.co.jp
URL:http://www.chugai-pharm.co.jp

Translation

FDA Accepts Biologics License Application Submitted for Subcutaneous Formulation of ACTEMRA®, a Treatment for Rheumatoid Arthritis

February 26, 2013- Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; Chairman and CEO: 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 biologics license application (BLA) which Genentech, Inc. [Head Office: California, U.S., CEO: Ian T. Clark], a member of the Roche Group, submitted to the FDA in December 2012, for the subcutaneous formulation of the humanized anti-human interleukin-6 (IL-6) receptor monoclonal antibody, Actemra® [generic name: tocilizumab (genetical recombination)] for adult rheumatoid arthritis(RA). 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 2013.

This BLA is based on two phase III studies, SUMMACTA study and BREVACTA study. The SUMMACTA study is a non-inferiority study which was conducted in patients with moderate to severe, active RA who have had an inadequate response to DMARDs therapy that may have included (in up to 20% of patients) one or more anti-TNFs. Patients received either ACTEMRA® 162 mg SC weekly or ACTEMRA® 8 mg/kg IV every 4 weeks. As a result, a similar proportion of RA patients in each group achieved an ACR20 response at Week 24.
The BREVACTA study was conducted in patients with moderate to severe, active RA who had an inadequate response to DMARDs therapy. Patients received either ACTEMRA® 162 mg SC given every 2 weeks versus placebo given every 2 weeks, both in combination with DMARDs. As a result, more patients who received ACTEMRA® 162mg achieved ACR20 response at Week 24, compared to those who received placebo.
In both studies, the safety profile was 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 first launched in intravenous formulation in June 2005 by Chugai for Castleman's disease, following approval in April 2005. 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, and the indication was expanded in October 2012 to “the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more DMARDs”. Currently Actemra® is approved in more than 100 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.

The subcutaneous formulation was submitted in Japan in March 2012, and in Europe in December 2012 at the same timing as the US.