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

CHUGAI
Roche Group

Roche Release, Basel, 15th October 2012

FDA Approves Expanded Indication for ACTEMRA® in Rheumatoid Arthritis

Roche today announced that the U.S. Food and Drug Administration (FDA) has expanded the approved indication for ACTEMRA® (tocilizumab) for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). ACTEMRA can be used both alone as a single-agent therapy and in combination with methotrexate (MTX) or other DMARDs. The expanded indication further supports the safety and efficacy profile of ACTEMRA.

"People with moderately to severely active RA can suffer irreversible joint damage that may be prevented by earlier treatment with a biologic medicine such as ACTEMRA," said Hal Barron, M.D., chief medical officer and head, Global Product Development. “We’re pleased that these patients will now have ACTEMRA as an additional option.”

The expanded indication is based on efficacy and safety data from the Phase III clinical trials which were previously available, safety data collected from the post-marketing experience with ACTEMRA since approval in 2010, as well as data from other clinical studies, including those evaluating ACTEMRA in a real-world setting.

About Previous ACTEMRA Efficacy Trials in DMARD-IR Patients

- OPTION (T**O**cilizumab **P**ivotal **T**rial in Methotrexate **I**nadequate resp**ON**ders) trial:
  - 59 percent and 48 percent of patients who received ACTEMRA 8mg/kg and 4mg/kg plus MTX, respectively, achieved ACR20 at Week 24, compared with 27 percent of patients who received placebo plus MTX
- TOWARD (**T**ocilizumab in c**O**mbination **W**ith traditional DM**ARD** therapy) trial:
  - 61 percent of patients who received ACTEMRA 8mg/kg plus DMARD(s) achieved ACR20 at Week 24, compared with 25 percent of patients treated with DMARDs plus placebo
- LITHE (Toci**LI**zumab Safety and **THE** Prevention of Structural Joint Damage) trial:
  - 56 percent and 51 percent of patients who received ACTEMRA 8 mg/kg or 4 mg/kg plus MTX, respectively, achieved ACR20 at Week 24 compared with 27 percent of patients who received placebo plus MTX. In addition, ACTEMRA 4mg/kg slowed (less than 75 percent inhibition compared to the control group) and ACTEMRA 8 mg/kg inhibited (at least 75 percent inhibition compared to the control group) the progression of structural damage compared to placebo + MTX at week 52, as measured by change in total Sharp-Genant score.

ACR improvement criteria is a standard assessment developed by the American College of Rheumatology to measure the signs and symptoms of RA. ACR20, ACR50, ACR70 represent the percentage of reduction (20 percent, 50 percent, 70 percent) in certain RA signs and symptoms, such as the number of tender and swollen joints, pain, patients' and physicians' global assessments and certain laboratory markers. The Genant-modified Sharp score focuses on 14 specific sites for evidence of bone erosion and 13 sites for narrowing of the joint space, both key measures of ongoing structural damage to the joints. A high score or an increase in the score over time represents a greater extent of damage.

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is an autoimmune disease estimated to affect up to 70 million people worldwide, including children. Joints become chronically inflamed, painful and swollen, and patients can become increasingly disabled as cartilage and bone is damaged.

About ACTEMRA® (tocilizumab)

ACTEMRA is the first humanized IL-6 receptor-inhibiting monoclonal antibody approved for the treatment of adult patients with moderately to severely active RA who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). The extensive ACTEMRA clinical development program included five Phase III clinical studies and enrolled more than 4,000 people with RA in 41 countries, including the United States. In addition, ACTEMRA is also approved for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients two years of age and older.

ACTEMRA is part of a co-development agreement with Chugai Pharmaceutical Co. and has been approved in Japan since June 2005. ACTEMRA is approved in the European Union, where it is known as RoACTEMRA, and several other countries, including India, Brazil, Switzerland and Australia.

Important Safety Information

Some people have serious infections while taking ACTEMRA, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections.

Other serious side effects of ACTEMRA include tears (perforation) of the stomach and intestines, changes in blood test results, hepatitis B infection becoming an active infection again, and nervous system problems.

Serious allergic reactions, including death, can happen with ACTEMRA. These reactions may happen with any infusion of ACTEMRA even if they did not occur with an earlier infusion. Patients must tell their doctor if they have had a previous reaction to ACTEMRA. Patients should not take ACTEMRA if they are allergic to it or any of its ingredients.

Common side effects with ACTEMRA in rheumatoid arthritis include upper respiratory tract infections (common cold, sinus infections), headache, and increased blood pressure (hypertension).

Common side effects with ACTEMRA in SJIA include upper respiratory tract infections (common cold, sinus infections), headache, and diarrhea.

Patients must tell their healthcare providers if they plan to become pregnant or are pregnant. It is not known if ACTEMRA will harm an unborn baby. Genentech has a registry for pregnant women who take ACTEMRA. Patients who are pregnant or become pregnant while taking ACTEMRA must contact the registry at 1-877-311-8972 and talk to their healthcare provider.

Patients must call their healthcare provider for medical advice about any side effects. Patients or caregivers may report side effects to the FDA at 1-800-FDA-1088. Patients or caregivers may also report side effects to Genentech at 1-888-835-2555.

For additional important safety information, including Boxed WARNINGS and Medication Guide, please visit http://www.actemra.com or call 1-800-ACTEMRA (228-3672).

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 personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2011, Roche had over 80,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 42.5 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.