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Roche Roche Group

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Roche Reports Positive Study of RoACTEMRA Given by Subcutaneous Injection

Roche today announced that the SUMMACTA study met its primary endpoint, showing comparable efficacy of the subcutaneous (SC) formulation of RoACTEMRA (tocilizumab, known as ACTEMRA outside Europe) 162 mg weekly compared to 8 mg/kg RoACTEMRA intravenous (IV) formulation every 4 weeks. A similar proportion of rheumatoid arthritis (RA) patients in each group achieved an ACR20 response at Week 24, a measure indicating improvement in the number of tender and swollen joints, pain scale, patients' and physicians' assessment of improvement and certain laboratory markers.

"We are very pleased with these data showing that subcutaneous administration of RoACTEMRA provides clinically meaningful and comparable results to the IV infusion," said Hal Barron, M.D., Head of Global Product Development and Chief Medical Officer for Roche. "This may provide patients and their doctors with an important additional treatment option."

Preliminary safety analysis showed that the adverse event profiles of the SC and IV groups were comparable, with no new clinically meaningful safety signals identified. Data from SUMMACTA will be submitted for presentation at an upcoming medical meeting. The results of BREVACTA, a second study assessing RoACTEMRA SC administered every two weeks versus placebo SC, are anticipated later in 2012. Following completion of the two studies Roche will evaluate plans to file SUMMACTA and BREVACTA data with the health authorities globally.

About SUMMACTA

SUMMACTA is a randomized, double-blind, active controlled, parallel group, multicentre 2-year study with a double-blind period of 24 weeks with 2 treatment arms, followed by an open-label period of 72 weeks with some SC and IV switching. The trial is a non-inferiority design and randomized 1262 patients with moderate to severe, active RA who have had an inadequate response to DMARD therapy that may have included (in up to 20% of patients) one or more anti-TNFs into 2 treatment arms. Patients in group A received RoACTEMRA 162 mg SC weekly and those in group B received RoACTEMRA 8 mg/kg IV every 4 weeks.

Secondary endpoints include assessments at Week 24 of the proportion of patients in each group with an ACR50 response; an ACR70 response; DAS28 remission; a decrease of ≥ 0.3 in HAQ-DI from baseline to Week 24 and the proportion of patients who withdrew due to lack of therapeutic response. Further analysis will assess long-term safety and efficacy; pharmacokinetics (PK) and pharmacodynamics (PD); immunogenicity; and the effect of switching from one formulation to another on the safety, efficacy, PK and PD of RoACTEMRA.

About RoACTEMRA / ACTEMRA

RoACTEMRA (tocilizumab, known as ACTEMRA outside Europe) is the result of research collaboration by Chugai and is also being co-developed globally with Chugai. RoACTEMRA is the first humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody. RoACTEMRA 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 (RA), polyarticular juvenile idiopathic arthritis (pJIA) and systemic-onset juvenile idiopathic arthritis (sJIA) 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 disease modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) inhibitors. It is also approved for use in over 90 other countries, including India, Brazil, Switzerland, and Australia. RoACTEMRA was approved in the United States in January 2010 for the treatment of adult patients with moderately to severely active RA who have had an inadequate response to one or more TNF inhibitors. In addition, RoACTEMRA is now approved in the EU, United States and Mexico for the treatment of active sJIA in patients two years of age and older.

The safety and efficacy of RoACTEMRA in RA have been characterized in an extensive clinical development program including five phase III clinical studies that enrolled more than 4,000 people with RA in 41 countries, including the United States. The overall safety profile of RoACTEMRA is consistent across all global clinical studies. The serious adverse events reported in RoACTEMRA clinical studies include serious infections, gastrointestinal perforations and serious 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. Laboratory changes, including increases in lipids (total cholesterol, LDL, HDL, triglycerides) and decreases in neutrophils and platelets, were seen in some patients. Treatments that suppress the immune system, such as RoACTEMRA, 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 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.