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Roche Group

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ADACTA Study Showed ACTEMRA Improved Signs and Symptoms of Rheumatoid Arthritis Significantly More Than Adalimumab as a Single-Agent Therapy

-- In addition, data from 17 ACTEMRA studies, including ADACTA, to be presented at ACR Annual Meeting --

Genentech, a member of the Roche Group, today announced that results from the ADACTA study will be presented on November 11 during an oral presentation at the 2012 American College of Rheumatology (ACR) Annual Scientific Meeting in Washington, D.C.

Results from the study showed ACTEMRA® (tocilizumab) improved signs and symptoms (DAS28 score reduction) of rheumatoid arthritis (RA) significantly more than adalimumab when used alone as a single-agent therapy (without other disease-modifying antirheumatic drugs (DMARDs), including methotrexate).

RA patients are often treated with a combination of medicines that typically include a biologic medicine, such as ACTEMRA or adalimumab, plus methotrexate. However, about one in three patients on a biologic treatment such as ACTEMRA or adalimumab receive it as a single-agent therapy, largely due to intolerance to methotrexate.

"The goal of the ADACTA study was to evaluate the potential differences of ACTEMRA versus Humira when used as single-agent therapies for people with RA," said Hal Barron, M.D., chief medical officer and head, Global Product Development. “Data being presented at ACR further support the efficacy and safety profile of ACTEMRA."

In addition to data from the ADACTA study, long-term follow-up of patients from AMBITION, a large Phase III study, will be presented at ACR. Together, these studies support the use of ACTEMRA alone as a single-agent therapy for RA patients who are either intolerant to methotrexate or in whom methotrexate use would not be appropriate.

About the ADACTA Study (Abstract #772)

ADACTA (ADalimumab ACTemrA) is a Phase IV multi-center, randomized, double-blind, parallel group study designed to compare the reduction in signs and symptoms of RA in adult patients treated with either ACTEMRA or adalimumab as a single-agent therapy. Patients participating in the study had severely active RA and either an intolerance to methotrexate or were not appropriate candidates for continued methotrexate treatment. Of note, patients participating in the study had not previously received a biologic medicine for RA.

In the study, 326 patients were randomized (1:1) to receive ACTEMRA 8 mg/kg intravenously (IV) every four weeks (plus placebo adalimumab) or adalimumab 40 mg subcutaneously (SC) every two weeks (plus placebo ACTEMRA) for 24 weeks.

The study met its primary endpoint of a significantly greater reduction in the mean change from baseline in the DAS28 score in patients receiving ACTEMRA as a single-agent therapy compared to those receiving adalimumab as a single-agent therapy at 24 weeks. Specifically:

- Patients achieved a significantly greater DAS28 score reduction of 3.3 with ACTEMRA compared to 1.8 with adalimumab and also had a significantly greater proportion of patients achieving DAS28 low disease activity with a rate (DAS28 < 2.6) of 40 percent versus 11 percent, at 24 weeks respectively.
- Patients also achieved significant responses in favor of ACTEMRA with ACR20, 50 and 70 responses of 65 percent, 47 percent and 33 percent with ACTEMRA versus 49 percent, 28 percent and 18 percent with adalimumab at 24 weeks.

In the United States, the recommended dose for ACTEMRA in RA is 4 mg/kg (IV) every four weeks followed by an increase to 8 mg/kg (IV) every four weeks based on clinical response. The recommended dose for adalimumab in RA is 40 mg administered subcutaneously every other week. Some patients not taking concomitant methotrexate may derive additional benefit from increasing the dosing frequency of adalimumab to 40 mg every week.

Adverse event (AE) profiles in the two treatment groups were comparable and the safety profile of ACTEMRA in ADACTA was consistent with previous ACTEMRA RA clinical trials.

About the Long-Term Follow-Up of AMBITION Study Participants
(Abstract #454)
A post hoc analysis of patients from the Phase III AMBITION study who enrolled into the ongoing long-term extension GROWTH96 study confirmed that single-agent therapy with ACTEMRA provided durable efficacy up to 240 weeks, as demonstrated by the increasing number of patients who achieved significant reduction in signs and symptoms of RA and/or DAS28 <2.6 or low disease activity over time. The post hoc analysis was designed to evaluate the long-term efficacy of intravenous (IV) ACTEMRA 8 mg/kg in patients with moderately to severely active RA who remained on single-agent therapy.

About ACR 20, 50, 70
American College of Rheumatology (ACR) scores represent the percentage of reduction (20 percent, 50 percent, 70 percent) in tender and swollen joint counts, in addition to a corresponding improvement in three of the following five parameters:
· Acute phase reactant (such as erythrocyte sedimentation rate)
· Patients Global Assessment of Disease Activity
· Physicians Global Assessment of Disease Activity
· Pain scale
· Health Assessment Questionnaire (HAQ)

About DAS28
DAS28 is a measure of disease activity in RA. The score is calculated by a complex mathematical formula, which includes the number of tender and swollen joints (out of a total of 28), the erythrocyte sedimentation rate (a marker of systemic inflammation), and the patient's 'global assessment of global health' (indicated by marking a 10 cm line between 'very good' and 'very bad'). A DAS28 score greater than 5.1 indicates severe active disease, less than 3.2 suggests low disease activity, and less than 2.6 is considered DAS remission.

About Rheumatoid Arthritis (RA)
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.

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).

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.

About Genentech
Founded more than 30 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, Calif. For additional information about the company, please visit http://www.gene.com.