

Basel, 25 May 2009

Two-year data reinforce effectiveness of ACTEMRA in inhibiting joint damage and improving physical function in patients with rheumatoid arthritis

Roche announced today that new two-year data from the LITHE study¹ demonstrate that ACTEMRA (tocilizumab, known as RoACTEMRA within the EU) continues to be highly effective at inhibiting joint structural damage and maintaining consistently high remission rates. Reducing the structural damage to joints in patients with rheumatoid arthritis (RA) is a critical measure of effectiveness of an RA treatment.

William M. Burns, CEO Roche Pharmaceuticals Division, outlined the implications of the results: “These new data build on the one-year results, demonstrating that, in most patients, Actemra inhibited the progression of structural joint damage which is a major cause of disability and loss of physical function for RA patients. LITHE is the fifth large study from a comprehensive development program and demonstrates that ACTEMRA offers rheumatoid arthritis patients the chance of achieving a long-lasting remission from the disease.”

The two-year data showed that a greater proportion of patients treated with ACTEMRA in combination with methotrexate (MTX), the current standard therapy, benefited from a significant inhibition of structural damage during 24 months of therapy, compared to patients in the control arm. The outcome was determined by x-ray evidence of the progression of bone erosions and narrowing of joint spaces. This benefit is important to patients as damage to the joints caused by the disease leads to the disability and pain associated with RA.

Additionally, patients on ACTEMRA reported they improved in their ability to perform normal daily activities, as assessed by Health Assessment Questionnaire (HAQ) scores². In the study, ACTEMRA was generally well tolerated and the overall safety profile after two years of treatment was consistent with previously reported trial data. Full data from this two-year trial will be used to support global regulatory filings for labelling claims of inhibition of the progression of structural damage and improvement of physical function. It will also be submitted for presentation at a future international scientific meeting.

About the LITHE study

The LITHE study, a randomized, double-blind, placebo-controlled trial was designed to evaluate the efficacy of TCZ plus MTX in preventing structural joint damage and improving physical function over 2 years. LITHE is an international study, including 15 countries and 1196 patients with moderate to severe RA who had an inadequate response to MTX. In this randomized study, patients received either ACTEMRA (4 mg/kg or 8 mg/kg, one infusion every four weeks) in combination with methotrexate or methotrexate alone. Results from the 12-month analysis showed that at 52 weeks, total Genant-modified Sharp Score change from baseline for the ACTEMRA 8mg + MTX, 4mg +MTX, and MTX alone groups were: 0.29, 0.34 and 1.1 respectively. The percentage of patients achieving no progression in total Genant-modified Sharp Score were 85%, 81% and 67%. The HAQ-DI AUC change from baseline, adjusted mean scores were: -144.1, -128.4 and -58.1 respectively. DAS28 clinical remission (<2.6) was 47%, 30% and 8%.

About ACTEMRA

ACTEMRA is the result of research collaboration by Chugai and is being co-developed globally with Chugai. ACTEMRA is the first humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody. An extensive clinical development programme of five Phase III trials was designed to evaluate clinical findings of ACTEMRA, all of which met their primary endpoints. ACTEMRA 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, juvenile idiopathic arthritis and systemic-onset juvenile idiopathic arthritis 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 TNF inhibitors. It is also approved for use in several other countries, including India, Brazil, Switzerland and Australia.

ACTEMRA is generally well tolerated. The overall safety profile of ACTEMRA is consistent across all global clinical studies. The most common, non-serious, adverse events reported are upper respiratory tract infection, nasopharyngitis, headache and hypertension. As with other biological disease modifying anti-rheumatic drugs (DMARDs), serious infections and hypersensitivity reactions including a few cases of anaphylaxis, have been reported in some patients treated with ACTEMRA. Increases in liver transaminases (ALT and AST) were seen in some patients; these increases were generally mild and reversible, with no hepatic injuries or any observed impact on liver function.

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 personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients.

In 2008, Roche had over 80'000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 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.

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About rheumatoid arthritis: www.roche.com/media/media_backgrounder/media_ra.htm

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References:

- (1) LITHE refers to the TociLizumab safety and THE prevention of structural joint damage trial
- (2) HAQ, or the Health Assessment Questionnaire Disability Index, is a patient self-report functional status (disability) measurement used to assess the patient's functional ability and discomfort during the past week. It is a commonly used instrument in many disease areas, including RA