



June 4, 2009 -- Nutley N.J.

ACTEMRA® (tocilizumab) Studies to be Featured at the European League Against Rheumatism (EULAR) Congress

-- Results of Phase III clinical studies highlight benefits of ACTEMRA as a treatment for rheumatoid arthritis--

Roche today announced that oral and poster presentations highlighting results from the extensive multi-national ACTEMRA® (tocilizumab) clinical development program will be presented at the 10th Annual Congress of the European League Against Rheumatism (EULAR), which will take place June 10-13, 2009, in Copenhagen, Denmark. The studies evaluate ACTEMRA, a novel treatment targeting interleukin-6 (IL-6) receptors, in patients with moderately to severely active RA.

Select Platform Presentations/Poster Sessions

- “Tocilizumab Inhibits Structural Joint Damage, Improves Physical Function, and Increases DAS28 Remission Rates in RA Patients Who Respond Inadequately to Methotrexate: The LITHE Study,” will be highlighted in an oral presentation by lead investigator Joel M. Kremer, M.D., Director of Research at The Center for Rheumatology in Albany, New York, on June 12, 10:15 am - 11:45 am CEST in the Bella Center, Hall A2, during the Novel Therapeutic Approaches for RA session.
- “Efficacy of Tocilizumab (TCZ) in Rheumatoid Arthritis (RA): Interim Analysis of Long-term Extension Trials of up to 2.5 Years,” will be highlighted in a poster presentation by Josef S. Smolen, M.D., Professor of Medicine at the University Clinic for Internal Medicine in Vienna, Austria., on June 12, 11:45 am - 1:30 pm CEST in the Bella Center.
- “Efficacy of Tocilizumab (TCZ) vs Methotrexate (MTX) Monotherapy in Patients with Rheumatoid Arthritis (RA) with No Prior MTX or DMARD Exposure,” results from the AMBITION study, will be highlighted in a poster presentation by lead investigator Graeme Jones, M.D., Professor at the Menzies Research Institute, University of Tasmania in Hobart, Australia, on June 12, 11:45 am - 1:30 pm CEST in the Bella Center.

About ACTEMRA® (tocilizumab)

ACTEMRA is the first humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody being studied for the treatment of RA. Studies demonstrate that reducing the activity of IL-6, one of several key cytokines involved in the inflammatory process, relieves both inflammation of the joints and certain systemic effects of RA. The extensive clinical development program

conducted by Roche includes five Phase III clinical studies and has enrolled more than 4,000 patients in 41 countries, including the United States. The five Phase III studies are completed and have reported meeting their primary endpoints. ACTEMRA is currently under review by the FDA in the United States.

ACTEMRA is part of a co-development agreement between Roche and Chugai Pharmaceutical Co. In June 2005, ACTEMRA was launched by Chugai in Japan 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. ACTEMRA (known as RoACTEMRA in Europe), was also recently approved in the European Union, Switzerland and India.

The serious adverse events reported in ACTEMRA clinical studies include serious infections, gastrointestinal perforations and 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 patients; these increases were generally mild and reversible, with no evidence of hepatic injuries. Laboratory changes, including increases in lipids (total cholesterol, LDL, HDL, triglycerides) and decreases in neutrophils and platelets, were seen in patients without association with clinical outcomes. Treatments that suppress the immune system, such as ACTEMRA, may cause an increase in the risk of malignancies.

About IL-6

IL-6 is a common protein found in all joints in the body and is a natural substance that can raise inflammation. Everyone has IL-6 in their body, but people with RA may have too much. When approved, ACTEMRA will be the first and only medication to specifically target IL-6 in patients with RA.

About Rheumatoid Arthritis

RA is a progressive, systemic autoimmune disease characterized by inflammation of the membrane lining in the joints. This inflammation causes a loss of joint shape and function, resulting in pain, stiffness and swelling, ultimately leading to irreversible joint destruction and disability. Characteristics of RA include redness, swelling, pain and movement limitation around joints of the hands, feet, elbows, knees and neck that leads to loss of function. In addition, the systemic symptoms of RA include fatigue, decreased hemoglobin, osteoporosis and may contribute to shortening life expectancy by affecting major organ systems. After 10 years, less than 50 percent of patients can continue to work or function normally on a daily basis. RA affects more than 21 million people worldwide with approximately 1.3 million adults affected in the United States.

About Roche

Hoffmann-La Roche Inc. (Roche), based in Nutley, N.J., is the U.S. pharmaceuticals headquarters of the Roche Group, one of the world's leading research-oriented healthcare groups with core businesses in pharmaceuticals and diagnostics. For more than 100 years in the U.S., Roche has been committed to developing innovative products and services that address

prevention, diagnosis and treatment of diseases, thus enhancing people's health and quality of life. For additional information about the U.S. pharmaceuticals business, visit our website <http://www.rocheusa.com>. Product and treatment information for U.S. healthcare professionals is available at www.RocheExchange.com.

All trademarks used or mentioned in this release are protected by law.

#

Contact

Lindsay Rocco

Roche

Office: 973-235-2802

Cell: 862-596-1304

Lindsay.Rocco@roche.com

" THIS SITE INTENDED FOR U.S. AUDIENCES ONLY"

Copyright © 2002- 2009 Hoffmann-La Roche Inc. All rights reserved. Use and access of this site is subject to the terms and conditions as set out in our [Legal Statement](#) and [PRIVACY Statement](#).