

Basel, 30 July 2008

## **FDA Advisory Committee recommends approval of Actemra for the treatment of rheumatoid arthritis**

**First interleukin-6 inhibitor (IL-6) to offer new therapeutic option for rheumatoid arthritis**

Roche announced that the Arthritis Advisory Committee of the U.S. Food and Drug Administration (FDA) by a near unanimous (10-1) vote recommended approval of Actemra (tocilizumab), a novel interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody, for reducing the signs and symptoms in adults with moderate to severe rheumatoid arthritis (RA).

“We are pleased with the FDA advisory committee’s very positive recommendation for Actemra, which helps move this promising new therapy closer to becoming available for patients who suffer from the debilitating symptoms of RA,” said William M. Burns, CEO of Roche’s Pharmaceuticals Division. “Based on the compelling data presented, and this positive recommendation from the committee, we remain hopeful that the FDA will approve Actemra for the treatment of RA and provide a new option to patients who are not achieving adequate symptom relief with current therapies.”

The committee’s vote was made after Roche presented results from five Phase III clinical trials. The clinical development program evaluated the effects of Actemra on signs and symptoms of RA, physical function, progression of structural damage, and health-related quality of life. Of these five studies, three trials were conducted in patients with inadequate response to disease modifying anti-rheumatic drugs (DMARDs), one trial was conducted in patients who failed anti-tumor necrosis factor (TNF) therapy and one monotherapy study comparing Actemra to methotrexate, a current standard of care, was also conducted.

Results of these studies demonstrated that treatment with Actemra, alone or combined with methotrexate or other DMARDs, significantly reduced RA symptoms regardless of previous therapy or disease severity, compared with current DMARDs.

### **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 program of five Phase III trials was designed to evaluate clinical findings of Actemra. The five studies have reported meeting their primary endpoints. Actemra is awaiting approval in the United States and Europe. In Japan, Actemra was launched by Chugai in June 2005 as a therapy for Castleman's disease; in April 2008, additional indications for rheumatoid arthritis, polyarticular-course juvenile idiopathic arthritis and systemic-onset juvenile idiopathic arthritis were also approved in Japan.

Actemra is generally well tolerated. The overall safety profile of Actemra is consistent across all global clinical studies. Serious adverse events reported in Actemra clinical trials include serious infections, diverticular perforations and hypersensitivity reactions including anaphylaxis. The most common adverse events reported in clinical trials were upper respiratory tract infection, nasopharyngitis, headache and hypertension. Increases in liver function tests (ALT and AST) were seen in some patients; these increases were generally mild and reversible, without injuries or any observed impact on liver function. Laboratory changes, including increases in lipids (total cholesterol, LDL, HDL, triglycerides) and decreases in neutrophils and platelets, were seen in some patients without association with clinical outcomes.

### **About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2007 sales by the Pharmaceuticals Division totalled 36.8 billion Swiss francs, and the Diagnostics Division posted sales of 9.3 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested over 8 billion Swiss francs in R&D in 2007. Worldwide, the Group employs about 80,000 people. Additional information is available on the Internet at [www.roche.com](http://www.roche.com).

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- Chugai: [www.chugai-pharm.co.jp](http://www.chugai-pharm.co.jp).

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