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RoActemra Receives Positive Opinion in Europe for the Treatment of Rheumatoid Arthritis

First-in-class therapy represents a novel approach to treat patients with moderate to severe rheumatoid arthritis

Roche today announced that the European Committee on Human Medicinal Products (CHMP) has given a positive recommendation for RoActemra (tocilizumab, known as Actemra outside of the EU), in combination with methotrexate (MTX), for the treatment of adult patients with moderate to severe rheumatoid arthritis (RA) 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) antagonists. In these patients, RoActemra can be given as monotherapy in cases of intolerance to methotrexate (MTX) or where continued treatment with MTX is inappropriate. RoActemra is the first interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody developed for the treatment of RA and is an innovative new therapy option to help tackle this serious disease.

“Today’s positive opinion by the European authorities for the approval of RoActemra for rheumatoid arthritis is an important step forward in the fight against this debilitating disease” said William M. Burns, CEO of Roche’s Pharmaceuticals Division. “Roche will work with the authorities to ensure that this groundbreaking therapy will be available to patients as quickly as possible.”

Rheumatoid Arthritis is a chronic, progressive inflammatory disease of the joints and surrounding tissues that is associated with intense pain, irreversible joint destruction and systemic complications. There are several key cytokines, or proteins, involved in the inflammatory process including tumor necrosis factor (TNF) alpha, interleukin-1 (IL-1) and interleukin-6 (IL-6). IL-6 has been identified as having a pivotal role in the inflammation process.

The CHMP’s positive opinion on RoActemra was based on results from five multi-national Phase III studies which demonstrated that treatment with RoActemra – alone or combination with MTX or other DMARDs–

significantly reduced RA signs and symptoms, compared with current DMARDs alone. These benefits were regardless of previous therapy or disease severity.

About RoActemra/Actemra

RoActemra (known as Actemra outside of the EU) is the result of a research collaboration between Roche and Chugai and the drug is being co-developed globally with Chugai. RoActemra 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 RoActemra. The five studies have reported meeting their primary endpoints. 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.

RoActemra is generally well tolerated. The overall safety profile of RoActemra is consistent across all global clinical studies. The serious adverse reactions reported in RoActemra clinical studies include serious infections, gastrointestinal perforations and hypersensitivity reactions including anaphylaxis. The most common adverse reactions 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 RoActemra, may cause an increase in the risk of malignancies.

About Roche in rheumatoid arthritis

One of the most important drivers for growth at Roche over the next few years is expected to be the company's emerging franchise in autoimmune diseases with rheumatoid arthritis as the first indication. Following the launch of MabThera (rituximab) there are a number of projects in development, potentially allowing Roche to build on further opportunities. MabThera is the first and only selective B-cell therapy for RA, providing a fundamentally different treatment approach by targeting B cells, one of the key players in the pathogenesis of RA. RoActemra/Actemra is Roche's second novel medicine and is a humanised monoclonal antibody to the interleukin-6 (IL-6) receptor, inhibiting the activity of IL-6, a protein that plays a major role in the RA inflammation process. Additional projects creating a rich pipeline include compounds in Phase I, II and III clinical trials. Notably, ocrelizumab, a humanised anti-CD20 antibody, has entered phase III development for RA.

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 totaled 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.

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