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Actemra approved in Japan to treat patients with rheumatoid arthritis

First approval for Actemra in rheumatoid arthritis worldwide

Roche announced today that their alliance partner company Chugai has received approval in Japan for the use of its innovative treatment, Actemra (tocilizumab), in patients suffering from rheumatoid arthritis (RA).

Actemra was approved by the Japanese authorities for the indication of rheumatoid arthritis (including prevention of structural damage of joints) and two forms of the disease that affect children, known as juvenile idiopathic arthritis and systemic-onset juvenile idiopathic arthritis.

Japan is the first market worldwide to get access to Actemra for the treatment of RA. The approval is based on compelling data from clinical trials conducted in Japan that showed Actemra was highly effective in controlling the symptoms and progression of this serious disease.

“Today’s approval represents a significant milestone for rheumatologists and patients in Japan. The Japanese authorities have recognized that Actemra is a breakthrough drug which addresses an unmet medical need for patients suffering from the debilitating effects of this disease” said William Burns, CEO Roche Pharmaceuticals Division.

Actemra is the first of a new class of drug with a novel mechanism of action that brings new hope to RA patients. It is a humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody, which works by suppressing the activity of IL-6, an important trigger of the inflammatory process. This novel mode of action reduces inflammation of the joints and relieves the systemic effects of RA.

Since 2005, Actemra has been marketed in Japan for the treatment of patients with a rare autoimmune condition known as Castleman's disease. Actemra licence applications have also been filed for treatment of RA in the United States and the European Union in 2007, and are currently under review.

Rheumatoid Arthritis - A High Unmet Medical Need

Rheumatoid arthritis is a progressive autoimmune disease characterized by inflammation of the membrane lining in the joints throughout the body. This inflammation causes distortion of the joint and impaired function accompanied by pain, stiffness and swelling and ultimately leading to irreversible joint destruction and disability. In addition, the systemic symptoms of RA include fatigue, anaemia, osteoporosis and may contribute to shortening life expectancy by affecting major organ systems. Sadly after 10 years, less than 50% of patients can continue to work or function normally on a daily basis.

Juvenile idiopathic arthritis is the collective term for diseases with unknown cause associated with symptoms in joints occurring in children aged below sixteen. While clinical findings of pJIA have many similarities to rheumatoid arthritis, sJIA is accompanied by systemic symptoms, mostly remittent fever, and is considered a very severe disease.

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. Four studies are completed and have reported meeting their primary endpoints. A fifth trial, a two-year study called LITHE (Tocilizumab safety and THE prevention of structural joint damage), is currently underway and is expected to report preliminary first-year data in 2008. 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 2007, additional indications for rheumatoid arthritis, 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. 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 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. 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 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 79,000 people. Additional information is available on the Internet at www.roche.com.

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Further information

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