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RoActemra Offers a New Option for Children Living with a Rare and Severe Form of Arthritis

Roche gains positive opinion in Europe for RoActemra (tocilizumab) for the treatment of systemic juvenile idiopathic arthritis (sJIA)

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for an extension to the RoActemra (tocilizumab) rheumatoid arthritis label in Europe for the treatment of active Systemic Juvenile Idiopathic Arthritis (sJIA) in patients two years of age and older who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. RoActemra (known as ACTEMRA outside Europe) can be given alone or in combination with methotrexate in patients with sJIA. Final approval from the European Commission is expected in July 2011.

The submission to expand the label was based on positive data from a Phase III study known as TENDER. The study assessed the short term safety and efficacy of RoActemra versus placebo, in reducing signs and symptoms in patients (aged 2 – 17years) with active sJIA.

The current EU RoActemra licence is for the treatment of RA in people who have either responded inadequately to, or who were intolerant to, previous therapy with one or more DMARDs or tumour necrosis factor (TNF) inhibitors.

SJIA is the rarest form of Juvenile Idiopathic Arthritis (JIA), also known as Juvenile Rheumatoid Arthritis (JRA).¹ The disease affects about 10 -20 percent of children with JIA,² with the peak age of onset between 18 months and two years,^{2,3} although the disease can persist into adulthood. SJIA has a 2 - 4 percent overall estimated mortality rate, and accounts for almost two thirds of all deaths among children with arthritis.¹

TENDER study

The TENDER study results showed that 85 percent (64/75) of children with sJIA receiving RoActemra experienced a 30 percent improvement (JIA ACR30) in the signs and symptoms of sJIA and an absence of fever after 12 weeks of therapy, compared with 24 percent (9/37) of children receiving placebo (p<0.0001).⁴

About RoACTEMRA / ACTEMRA

RoACTEMRA (tocilizumab) is the result of research collaboration by Chugai and is also being co-developed globally with Chugai. RoACTEMRA is the first humanised interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody. 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 (RA), polyarticular juvenile idiopathic arthritis (pJIA) and systemic-onset juvenile idiopathic arthritis (sJIA) 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 tumour necrosis factor (TNF) inhibitors. It is also approved for use in over 90 other countries, including India, Brazil, Switzerland, and Australia. ACTEMRA was approved in the United States in January 2010 for the treatment of adult patients with moderately to severely active RA who have had an inadequate response to one or more TNF inhibitors. In addition, ACTEMRA is now approved in the United States and Mexico for the treatment of active SJIA in patients two years of age and older.

The safety and efficacy of RoACTEMRA in RA has been established in an extensive clinical development program including five Phase III clinical studies that enrolled more than 4,000 people with RA in 41 countries, including the United States. The overall safety profile of RoACTEMRA is consistent across all global clinical studies. The serious adverse events reported in RoACTEMRA 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 some patients; these increases were generally mild and reversible. Laboratory changes, including increases in lipids (total cholesterol, LDL, HDL, triglycerides) and decreases in neutrophils and platelets, were seen in some patients. Treatments that suppress the immune system, such as RoACTEMRA, may cause an increase in the risk of malignancies.

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 2010, Roche had over 80,000 employees worldwide and invested over 9 billion Swiss francs in R&D. The Group posted sales of 47.5 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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References

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