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Roche Roche Group

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Roche's RoACTEMRA Approved in EU to Treat Children with Rare Form of Arthritis

Roche announced today that the European Medicines Agency has approved RoACTEMRA to treat children with polyarticular juvenile idiopathic arthritis (PJIA), a rare, chronic and debilitating form of childhood arthritis. The medicine can be used to treat patients two years of age and older who have not responded adequately to treatment with methotrexate (MTX), a disease-modifying anti-rheumatic drug. RoACTEMRA can be used alone or in combination with MTX.

PJIA, or juvenile idiopathic polyarthritis, is a form of juvenile idiopathic arthritis (JIA), also known as juvenile rheumatoid arthritis.[1] JIA affects approximately 100 in every 100,000 children[2], with PJIA accounting for around 30 percent of cases.[3] PJIA is characterised by inflammation in five or more joints within the first six months of the disease and most commonly affects the small joints in the body, such as those in the hands and feet.[3] This is the second pediatric indication for RoACTEMRA and follows its 2011 approval for systemic juvenile idiopathic arthritis (sJIA), another rare form of juvenile idiopathic arthritis (JIA).

"This approval comes earlier than expected, just one month following the positive CHMP opinion," said Hal Barron, MD, Roche's Chief Medical Officer and Head of Global Product Development. "We can now quickly provide these young patients with this medicine that we hope will help them to better manage their disease symptoms and allow them to pursue an active lifestyle."

The approval is based on phase III CHERISH study data that showed patients treated with RoACTEMRA experienced clinically meaningful improvement in signs and symptoms of PJIA.[4] In addition, safety data collected to date for RoACTEMRA in PJIA patients is consistent with that observed in previous studies in RoACTEMRA-treated patients.[4,5]

About the CHERISH Study

CHERISH is a 104-week, phase III study in patients aged 2-17 years with active PJIA for ≥6 months who have failed treatment with methotrexate (MTX).[4] Treatment with RoACTEMRA was efficacious, with sustained clinically meaningful improvement in signs and symptoms of PJIA, using a monthly regimen at doses of 8 mg/kg if body weight ≥30 kg and 10 mg/kg if body weight <30 kg.[4] The study met the primary endpoint with RoACTEMRA-treated patients experiencing significantly fewer disease flares compared to placebo-treated patients (25.6

percent versus 48.1 percent, respectively).[4]

In the CHERISH study, infections were the most common adverse events (AEs) and serious adverse events (SAEs) over 40-weeks.[4] Laboratory abnormalities known to occur with RoACTEMRA were also observed in this study, including decreases in white blood cell counts and platelet counts, and elevation in ALT and AST liver enzyme levels.[4]

Additional data from CHERISH will be presented at the 2013 European League Against Rheumatism (EULAR) Congress this week.

About RoACTEMRA (tocilizumab)

RoACTEMRA, known as ACTEMRA outside of Europe, is the first humanised interleukin-6 (IL-6) receptor agonist approved for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).[6] The extensive RoACTEMRA clinical development programme included five phase III clinical studies and enrolled more than 4,000 people with RA in 41 countries. In addition, the phase IV ADACTA study showed that monotherapy with RoACTEMRA was superior to monotherapy with adalimumab in reducing signs and symptoms of RA in MTX-intolerant patients or patients for whom MTX treatment was considered ineffective or inappropriate.[7] The overall safety profile of both medications was consistent with previously reported data.[7]

RoACTEMRA is also approved for the treatment of active systemic juvenile idiopathic arthritis (SJIA) and polyarticular juvenile idiopathic arthritis (PJIA) in patients two years of age and older.

RoACTEMRA is part of a co-development agreement with Chugai Pharmaceutical. It has been approved in Japan since April 2005 for Castleman's disease, followed by approvals for RA, SJIA and PJIA in 2008.

RoACTEMRA is approved in the European Union, and several other countries, including the United States, China, India, Brazil, Switzerland and Australia.

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, infectious diseases, inflammation, metabolism and neuroscience. Roche is also the world leader in *in vitro* diagnostics and tissue-based cancer diagnostics, and a frontrunner 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 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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