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Roche Roche Group

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FDA Approves ACTEMRA® for Children Living with a Rare Form of Arthritis

Medicine Offers a New Option for the Treatment of Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Roche announced today that the U.S. Food and Drug Administration (FDA) has approved ACTEMRA® (tocilizumab) for the treatment of polyarticular juvenile idiopathic arthritis (PJIA). The medicine can be used in children two years of age and older with active disease. ACTEMRA can be given alone or in combination with methotrexate (MTX) in people with PJIA.

PJIA is a form of juvenile idiopathic arthritis (JIA), also known as juvenile rheumatoid arthritis, a chronic disease of childhood. [1] JIA affects approximately 100 in every 100,000 children[2] of which PJIA accounts for around 30 percent. [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 the hands and feet. [3]

“Polyarticular juvenile idiopathic arthritis is a rare debilitating condition in children that worsens over time,” said Hal Barron, M.D., chief medical officer and head, Global Product Development. “We are pleased to offer ACTEMRA to doctors and parents of children aged two or older to help improve the signs and symptoms of this often painful disease.”

This FDA approval marks the second ACTEMRA indication in children and is the first FDA approval for the treatment of PJIA in approximately five years. The EU Committee for Medicinal Products for Human Use (CHMP) also announced a positive opinion for this indication on Friday, April 26. The final approval from the European Medicines Agency (EMA) is expected this summer.

About the CHERISH Study

The expanded indication for ACTEMRA was based on positive data from the Phase III CHERISH study in children with PJIA, which had an open label phase, followed by a randomised double-blind placebo-controlled withdrawal phase. The study demonstrated that patients treated with ACTEMRA experienced clinically meaningful improvement in signs and symptoms of PJIA. A total of 91 percent of patients taking ACTEMRA plus MTX and 83 percent of patients taking ACTEMRA alone achieved an ACR 30 response at week 16 compared to baseline. In the randomised double-blind placebo-controlled withdrawal phase of the trial, ACTEMRA-treated patients experienced significantly fewer disease flares

compared to placebo-treated patients [26 percent (21/82) vs. 48 percent (39/81)].

The safety data collected to date for ACTEMRA in PJIA patients is consistent with that observed in previous studies in ACTEMRA-treated patients.[4] In the CHERISH study, infections were the most common adverse events (AEs) and serious adverse events (SAEs) over 40-weeks. Laboratory abnormalities known to occur with ACTEMRA 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.

About ACTEMRA® (tocilizumab)

ACTEMRA is the first humanised interleukin-6 (IL-6) receptor antagonist monoclonal antibody 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 antirheumatic drugs (DMARDs). The extensive ACTEMRA clinical development programme included five Phase III clinical studies and enrolled more than 4,000 people with RA in 41 countries, including the United States. In addition, ACTEMRA is also approved for the treatment of active systemic juvenile idiopathic arthritis (SJIA) in patients two years of age and older and in the United States for polyarticular juvenile idiopathic arthritis (PJIA) in patients two years of age and older who have responded inadequately to previous therapy with MTX.

ACTEMRA is part of a co-development agreement with Chugai Pharmaceutical Co. and has been approved in Japan since June 2005. ACTEMRA is approved in the European Union, where it is known as RoACTEMRA, and several other countries, including 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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