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Roche Receives EU Approval for New Subcutaneous Formulation of RoACTEMRA Providing more Treatment Flexibility for Patients with Moderate to Severe Rheumatoid Arthritis

First anti IL-6 receptor biologic now available for subcutaneous and intravenous administration for both monotherapy and combination therapy

Roche announced today that the subcutaneous formulation of RoACTEMRA (tocilizumab) has received approval from the European Commission for the treatment of moderate to severe rheumatoid arthritis (RA) in patients who are either intolerant to or have failed to respond to other RA treatments. This approval makes RoACTEMRA the first anti IL-6 receptor biologic available as subcutaneous and intravenous (IV) formulations for both monotherapy and combination therapy with methotrexate (MTX). It is the fourth update to RoACTEMRA's European label and significantly expands the number of patients who now have access to RoACTEMRA.

"Today's European approval of RoACTEMRA is important because it provides physicians and patients with the flexibility to choose a treatment method that suits their needs," said Sandra Horning, M.D., Head of Global Product Development and Chief Medical Officer at Roche. "Together with their physicians, patients can choose whether to self-inject RoACTEMRA at home or have it administered in their doctor's office."

The approval was based on data from the phase III SUMMACTA and BREVACTA studies.^{1,2} SUMMACTA showed that the efficacy and tolerability of subcutaneous RoACTEMRA was comparable with intravenous RoACTEMRA.¹ In addition, subcutaneous RoACTEMRA demonstrated long-term efficacy and reduced progression of joint damage over 48 weeks compared to placebo in the BREVACTA study.² The subcutaneous formulation of RoACTEMRA will be available via a prefilled syringe. It was approved in Japan and the United States in 2013.

About Rheumatoid Arthritis

RA is an autoimmune disease with prevalence worldwide of approximately 40 million.^{3,4} RA causes joints to become chronically inflamed, painful and swollen, and patients can become increasingly disabled as cartilage and bone is damaged.⁵ RA patients are often treated with a

number of medicines, combining protein-based biologic therapies with MTX, the most common disease modifying anti-rheumatic drug (DMARD).^{6,7}

About RoACTEMRA (tocilizumab)

RoACTEMRA is the first humanized interleukin 6 (IL-6) receptor-antagonist monoclonal antibody approved for use in combination with or without methotrexate, for the treatment of moderate to severe RA in adult patients who have either responded inadequately to, or who are intolerant to, previous therapy with one or more DMARDs or tumor necrosis factor (TNF) antagonists.⁸

RoACTEMRA IV formulation 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.⁸ 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. More than 275,000 patients have been treated with RoACTEMRA since it first launched. RoACTEMRA is approved in more than 100 countries worldwide including countries in the European Union, the United States, China, India, Brazil, Switzerland and Australia. It is available in more than 90 of these countries.

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, immunology, infectious diseases, ophthalmology 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 diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the WHO Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2013 the Roche Group employed over 85,000 people worldwide, invested 8.7 billion Swiss francs in R&D and posted sales of 46.8 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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