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## **Roche's RoACTEMRA Receives EU Approval for Use in Patients with Early Rheumatoid Arthritis (RA)**

- **Treating RA patients with severe, progressive disease in the first two years after diagnosis (early RA) could prevent damage to joints and stop the disease from progressing<sup>1,2</sup>**
- **RoACTEMRA with and without MTX achieved greater inhibition of structural joint damage compared with MTX alone in the early RA population<sup>1</sup>**

Roche announced today that RoACTEMRA (tocilizumab) has received approval from the European Commission for use in patients with severe, active and progressive RA who previously have not been treated with methotrexate (MTX). Treating the disease at this critical early phase may prevent irreversible damage to joints and long-term disability.<sup>1,2</sup> RoACTEMRA is the first interleukin-6 (IL-6) receptor antagonist to be approved for use in Europe in patients with early RA.

“RoACTEMRA is an effective biologic treatment for patients with early RA that may change the course of disease and reduce the likelihood of disability,” said Sandra Horning, M.D., Head of Global Product Development and Chief Medical Officer at Roche. “As the first IL-6 receptor antagonist approved for early RA, RoACTEMRA addresses the need for alternative treatment options to anti-tumor-necrosis-factor (anti-TNF) therapies in this debilitating condition.”

The approval was based on data from the phase III FUNCTION study, which assessed the efficacy, safety and prevention of structural joint damage in patients with early moderate-to-severe RA (defined as  $\leq 2$  years since diagnosis) not previously treated with MTX.<sup>1</sup> The study met its primary endpoint, demonstrating that patients who received RoACTEMRA in combination with MTX or as a single agent therapy (monotherapy) experienced a significantly greater improvement in disease activity (DAS28 remission) after 24 weeks compared to patients who received MTX alone.<sup>1</sup>

The data also demonstrated that treatment with RoACTEMRA with and without MTX achieved greater inhibition of structural joint damage compared with MTX alone.<sup>1</sup> At 24 weeks, the overall safety of RoACTEMRA in this early RA population was consistent with its known safety profile seen previously in other RoACTEMRA studies in RA.<sup>1</sup>

The early RA approval is the fifth update and expansion to RoACTEMRA's European label in three years.

### **About Rheumatoid Arthritis**

RA is an autoimmune disease with prevalence worldwide of approximately 40 million.<sup>3,4</sup> RA causes joints to become chronically inflamed, painful and swollen, and patients can become increasingly disabled as cartilage and bone is damaged.<sup>5</sup> RA patients are often treated with a number of medicines, combining protein-based biologic therapies with MTX, the most common disease-modifying antirheumatic drug (DMARD).<sup>6,7</sup>

### **About RoACTEMRA (tocilizumab)**

RoACTEMRA is the first humanized anti-interleukin 6 (IL-6) receptor antagonist monoclonal antibody approved for use in combination with or as monotherapy without MTX, 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.<sup>8</sup> RoACTEMRA is the first anti-IL-6 approved for both monotherapy and combination use in intravenous and subcutaneous formulations.

The RoACTEMRA intravenous 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.<sup>6</sup> The RoACTEMRA subcutaneous formulation was approved for use in adult patients in Japan, U.S. and Europe in March 2013, October 2013 and April 2014, respectively.

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 300,000 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**

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