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Roche's RoACTEMRA shows long-term efficacy in monotherapy and also benefits in early rheumatoid arthritis

More than 35 abstracts presented at EULAR reinforce strong clinical evidence for RoACTEMRA use in different patient settings

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced data from two phase III studies using RoACTEMRA (tocilizumab) in patients with rheumatoid arthritis (RA): the long-term extension (LTE) follow up of the AMBITION study demonstrated long-term efficacy of RoACTEMRA monotherapy; and the FUNCTION study showed the clinical benefits of the medicine, alone or in combination with methotrexate (MTX), when used to treat patients with early RA.^{1,2} These studies will be presented at the 2013 European League Against Rheumatism (EULAR) Congress.

Results from the AMBITION LTE study showed that long-term treatment with RoACTEMRA alone (monotherapy) showed long-term efficacy in people with RA who, at the time of entering the study, had never received MTX or had not received it in the preceding six months.¹ High remission rates and improvements in disease activity lasted up to 4.6 years. This was shown in people who achieved a 50 percent reduction in their swollen and tender joints at week 24 and who continued treatment with RoACTEMRA monotherapy.¹

The FUNCTION study explored treatment with RoACTEMRA alone or in combination with MTX in people with early RA who had not previously been treated with MTX, a setting in which biologics, such as RoACTEMRA, are not commonly used.³ The study showed that RoACTEMRA (8 mg/kg) when used with or without MTX was superior to MTX alone in achieving disease remission in people at week 24 (as measured by DAS28<2.6).²

“These data show that people with rheumatoid arthritis experienced meaningful clinical improvement when treated with RoACTEMRA in the early stage of RA as well as in more advanced stages of the disease,” said Hal Barron, M.D., chief medical officer and head, Global Product Development. “People who were treated with RoACTEMRA as a single medicine over a long period of time maintained relief from RA joint swelling

and pain.”

RA is an autoimmune disease estimated to affect up to 70 million people worldwide, including children.⁴ Joints 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).^{3,6}

Biologic therapies, like RoACTEMRA, are used to help people affected by RA to control symptoms of the disease, slow RA progression and prevent joint damage.⁷ Approximately one in three patients treated with a biologic treatment such as RoACTEMRA, receive it as monotherapy, largely due to intolerance to MTX.⁸⁻¹¹

Among the more than 35 RoACTEMRA abstracts being presented at EULAR 2013, data from the LITHE study and pooled data from RoACTEMRA registrational and post-approval studies show sustained benefits from the long-term use of RoACTEMRA in patients with moderate to severe RA.^{12,13} The data also suggest that the long-term safety profile for RoACTEMRA is consistent with that observed in previous trials.¹³

About AMBITION LTE

The post hoc exploratory analysis evaluated the efficacy and safety of patients randomised to RoACTEMRA (8 mg/kg) monotherapy in AMBITION who entered the long-term extension (LTE) study. Upon entry to the long-term extension study, DMARDs including MTX, were added in 43 percent of patients (n=104) who did not achieve a 50 percent reduction in swollen joint count (SJC) and tender joint count (TJC) from baseline. Fifty-seven percent of patients (n=139) remained on RoACTEMRA monotherapy.¹

Results from the efficacy analysis over the extended trial period showed that 65 percent of these 139 patients (n=90) remained on monotherapy until week 240. Of these:

- The number of patients achieving remission continued to increase or were maintained over time, with 66.7 percent of patients achieving remission, as measured by DAS28<2.6, by week 240¹
- Disease activity, as measured by SJC and TJC continued to decrease or was maintained up to week 240 (reduction from 19.0 SJC; 32.5 TJC at start of trial, to 1.8 SJC;3.8 TJC at week 240)¹

About FUNCTION

The FUNCTION study evaluated the efficacy and safety of RoACTEMRA in combination with MTX and as monotherapy in early RA patients who had not previously received MTX. Secondary endpoints

demonstrated statistically significant improvements in the signs and symptoms of RA and physical function, and a reduction in structural joint damage at 52 weeks when RoACTEMRA (8mg/kg) was used with MTX. RoACTEMRA (8mg/kg) monotherapy demonstrated superiority to MTX alone in achieving disease remission at week 24, and although statistical significance was not met, clinically meaningful improvements were seen in RA signs and symptoms at week 24 and structural joint damage inhibition to week 52.²

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).¹⁴ 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.¹⁵ The overall safety profile of both medications was consistent with previously reported data.¹⁵

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 Co. 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

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