Media Release

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Roche receives European approval for Actemra /RoActemra in giant cell arteritis

- **Actemra/RoActemra is the first therapy approved for the treatment of giant cell arteritis (GCA) in Europe**
- **GCA can lead to blindness, aortic aneurysm or stroke if left untreated**
- **The approval was based on the outcome of the phase III GiACTA study**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Commission (EC) has approved Actemra®/RoActemra® (tocilizumab) for the treatment of giant cell arteritis (GCA), a chronic and potentially life-threatening autoimmune condition. Actemra/RoActemra is the first therapy approved for the treatment of GCA in Europe.

"In giant cell arteritis (GCA) the blood vessels in the head and neck, as well as the aorta, become inflamed and thickened, reducing blood flow. This can result in devastating symptoms, including irreversible blindness, and puts patients at risk of permanent organ damage," said Sandra Horning, MD, Roche's Chief Medical Officer and Global Head of Product Development. "We are delighted that Actemra/RoActemra has been approved for the treatment of GCA in Europe. As the first effective non-steroid therapy for GCA, Actemra/RoActemra has the potential to fundamentally change how this condition is treated."

The European approval was based on the outcome of the phase III GiACTA study, which showed that a weekly dose of Actemra/RoActemra, initially combined with a six-month steroid taper, significantly increased the proportion of patients achieving sustained remission at one year (56%; $p < 0.0001$) compared to a six-month steroid taper given alone (14%). The results of the phase III GiACTA study were recently published in the *New England Journal of Medicine* in July 2017.[1]

In May 2017 Actemra/RoActemra was approved for the treatment of GCA by the US Food and Drug Administration (FDA) and New Zealand's Medsafe.

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About the GiACTA study

GiACTA (NCT01791153) is a phase III, global, randomised, double-blind, placebo-controlled trial investigating the efficacy and safety of Actemra /RoActemra (tocilizumab) as a novel treatment for giant cell arteritis (GCA). It is the largest clinical trial ever conducted in GCA and the first to use blinded, variable-dose, variable-duration steroid regimens. The multicentre study was conducted in 251 patients across 76 sites in 14 countries. The primary and key secondary endpoints were evaluated at 52 weeks.

About Giant Cell Arteritis

Giant cell arteritis (GCA) - also known as temporal arteritis (TA) - is a potentially life-threatening autoimmune condition. GCA has a global impact, usually affects those above the age of 50, and is two-to-three-times more likely to affect women than men.[2] GCA is often difficult to diagnose because of the wide and variable spectrum of signs and symptoms. GCA can cause severe headaches, scalp tenderness, jaw pain and visual symptoms and if left untreated, can lead to blindness, aortic aneurysm or stroke.[2] Treatment to date for people with GCA has been limited to high-dose steroids that play a role as an effective 'emergency' treatment option to prevent damage such as vision loss. However, in some cases steroids are unable to maintain long-term disease control (flare-free remission).[3, 4, 5] Due to the variability of symptoms, complexity of the disease and disease complications, people with GCA are often seen by several physicians including rheumatologists, ophthalmologists and neurologists.

About Actemra /RoActemra (tocilizumab)

Actemra/RoActemra is the first approved anti-IL-6 receptor biologic available in both intravenous (IV) and subcutaneous (SC) formulations for the treatment of adult patients with moderate to severe active rheumatoid arthritis (RA). Actemra/RoActemra can be used alone or with methotrexate (MTX) in adult RA patients who are intolerant to, or have failed to respond to, other anti-rheumatic medications. The extensive Actemra/RoActemra RA IV clinical development programme included five phase III clinical studies and enrolled more than 4,000 people with RA in 41 countries. The Actemra/RoActemra RA SC clinical development programme included two phase III clinical studies and enrolled more than 1,800 people with RA in 33 countries. In Europe, Actemra/RoActemra IV and SC is also approved for use in adult patients with severe, active and progressive RA who previously have not been treated with MTX. Actemra/RoActemra IV formulation is approved in most major countries for polyarticular juvenile idiopathic arthritis (pJIA) and systemic juvenile idiopathic arthritis (sJIA) in children two years of age and older. In the United States and New Zealand, Actemra/RoActemra subcutaneous injection is approved for the treatment of giant cell arteritis (GCA). Actemra/RoActemra is the first therapy approved for the treatment of adult patients with GCA.

Actemra/RoActemra is part of a co-development agreement with Chugai Pharmaceutical Co., Ltd and has been approved in Japan since April 2005. Actemra/RoActemra is approved in 116 countries worldwide.

Actemra/RoActemra is also being investigated in a global phase III multicentre, randomised, double-blind, placebo-controlled study (NCT02453256) for patients with systemic sclerosis (SSc) also known as scleroderma. Actemra/RoActemra was granted Breakthrough Therapy Designation for SSc by the FDA in June 2015.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 billion. 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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