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Phase III study shows Roche's Actemra/RoActemra maintained steroid-free remission in people with Giant Cell Arteritis (GCA)

- **The Phase III study, the largest clinical trial ever conducted in GCA, met its primary and key secondary endpoints**
- **There have been no new treatments for GCA in more than 50 years**
- **Results will be shared with regulatory authorities around the world with the goal of bringing a new treatment to people with GCA**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced positive results from the Phase III study known as GiACTA, which evaluated Actemra®/RoActemra® (tocilizumab) in people with giant cell arteritis (GCA). The study met its primary and key secondary endpoints showing that Actemra/RoActemra, initially combined with a six month steroid (glucocorticoid) regimen, more effectively sustained remission through one year compared to a six or 12 month steroid-only regimen in people with newly diagnosed and relapsing GCA. No new safety signals were observed with Actemra/RoActemra in the study at the time of this analysis. Adverse events were similar to those seen in previous Actemra/RoActemra clinical studies.

GCA is a serious condition where arteries, commonly in the head but also the aorta and its branches, become inflamed.¹

This inflammation can lead to persistent and severe headaches, scalp tenderness and jaw and arm pain. It is difficult to diagnose and if left untreated, GCA may lead to blindness, stroke or aortic aneurysms.¹ Vision problems occur in approximately 30 percent of people with GCA,² and about 15 percent experience permanent vision loss.³

“These results are encouraging for patients with this rare disease, for which there have been no new treatments in more than 50 years,” said Sandra Horning, MD, Chief Medical Officer and Head of Global Product Development. “Currently, long-term high-dose steroids are the mainstay treatment for GCA but

they can cause their own serious adverse effects. If approved, Actemra/RoActemra will provide an important new alternative to long-term steroid use for people with GCA.”

Approximately 80 percent of people with GCA who are exposed to long-term steroid use experience steroid-related side effects such as cataracts, diabetes, fractures, and hypertension.⁴ Reducing the use of steroids in this patient group is an important goal for physicians and people living with GCA.

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 as a novel treatment for GCA. It is the largest clinical trial ever conducted in GCA and the first to use blinded, variable-dose, variable-duration steroid regimens. The multicenter study was conducted in 251 patients across 76 sites in 14 countries. The study's primary and key secondary endpoints were evaluated at 52 weeks.

GiACTA data will be submitted for presentation at an upcoming medical conference and to regulatory authorities around the world for approval consideration.

About Giant Cell Arteritis

The occurrence of GCA has been estimated at over 200 per 100,000 persons in the United States over the age of 50.⁵ An even higher frequency has been reported in northern Europe.⁶ GCA is two to three times more likely to affect women and is often difficult to diagnose due to the wide and variable spectrum of signs and symptoms.¹ With no new treatments in more than 50 years, people with GCA are limited to high-dose steroid treatment that generally fails to cure GCA or induce long-term steroid-free remissions.

About Actemra/RoActemra (tocilizumab)

Actemra/RoActemra is the only approved anti-IL-6 receptor biologic, available in both intravenous (IV) and subcutaneous 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 adults who are intolerant to, or have failed to respond to, other anti-rheumatic medications. In the most recent update to the European League Against Rheumatism (EULAR) RA management guidelines, Actemra/RoActemra is highlighted as the only biologic that has been repeatedly demonstrated to be superior as a monotherapy over MTX or other conventional disease-modifying antirheumatic drugs (DMARDs). 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 Europe, Actemra/RoActemra is also approved for use in patients with severe, active and progressive RA who previously have not been treated with MTX. 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 more than 100 countries worldwide.

About Roche in Immunology

The Roche Group's immunology medicines include rheumatoid arthritis treatments MabThera /Rituxan (rituximab) and Actemra/RoActemra (tocilizumab), Xolair (omalizumab) in asthma, Pulmozyme (dornase alfa) for cystic fibrosis and Esbriet (pirfenidone) for idiopathic pulmonary fibrosis (IPF). In addition, MabThera is approved for the treatment of certain types of small-vessel vasculitis. Roche's late-stage pipeline includes etrolizumab in inflammatory bowel disease (IBD), and lebrikizumab in severe asthma, atopic dermatitis and IPF.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

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. 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.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine 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 seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 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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