Basel, 12 November 2016

Phase III GiACTA study shows Roche’s Actemra/RoActemra is superior to steroids alone in maintaining steroid-free remission for people with giant cell arteritis

- 56% of patients treated with Actemra/RoActemra achieved steroid-free disease remission at one year, versus 14% with a six-month steroid only taper regimen
- Results will be submitted to regulatory authorities around the world by end of 2016
- Actemra/RoActemra enabled sustained remission at one year without ongoing steroids for 6 months and if approved, could have the potential to redefine the management of GCA

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced positive results from the phase III GiACTA study, which evaluated Actemra®/RoActemra® (tocilizumab) in people with giant cell arteritis (GCA). GiACTA met its primary and key secondary endpoint, demonstrating that Actemra/RoActemra – initially in combination with a six month steroid (glucocorticoid) taper – enabled significantly more patients to achieve sustained disease remission while also significantly reducing steroid exposure compared with steroids alone.1 Data results will be presented in an oral session on Sunday, 13 November at the 2016 American College of Rheumatology (ACR) and Association for Rheumatology Health Professionals (ARHP) Annual Meeting.

“Treatment to date for GCA has been limited to high-dose steroids to rapidly control inflammation and prevent serious complications such as vision loss,” said Sandra Horning, MD, Chief Medical Officer and Head of Global Product Development. “However, steroid treatment often fails to control disease in the long term and can be associated with severe side effects. If approved, Actemra/RoActemra could have the potential to fundamentally change the way people with GCA are treated.”

The primary endpoint of the study was met, with Actemra/RoActemra - initially combined with a six month steroid taper regimen - significantly increasing the proportion of patients achieving sustained remission at one year (56% [QW; p<0.0001] and 53.1% [Q2W; p<0.0001]) versus 14% with a six month steroid taper regimen given alone.1
The study also met its key secondary endpoint, demonstrating that Actemra/RoActemra - initially combined with a six month steroid taper regimen - significantly increased the proportion of patients achieving sustained remission at one year (56% [QW; p <0.0001] and 53.1% [Q2W; p= 0.0002]) compared to 17.6% with a 12 month steroid taper regimen given alone.¹

No new safety signals were observed¹ and these results are consistent with Actemra/RoActemra’s documented safety profile in rheumatoid arthritis (RA).

A 104-week open label extension study from GiACTA is still ongoing. Data from this analysis will quantify Actemra/RoActemra’s long-term safety and maintenance of efficacy beyond one year, as well as any potential long-term steroid sparing effects. Actemra has been granted Breakthrough Therapy Designation for GCA by the US Food and Drug Administration (FDA). This designation is designed to expedite the development and review of medicines intended to treat serious diseases, and to help ensure patients have access to them as soon as possible. GiACTA builds on our wealth of knowledge and experience with Actemra/RoActemra in RA and demonstrates Roche’s commitment to follow the science, and to do now what patients need next.

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 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 and usually affects those above the age of 50, and the disease 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, jaw pain and visual symptoms and if 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, steroids do not always maintain long-term disease control (flare-free remission) and can be associated with severe side effects.³,⁶ Due to the variety of symptoms, complexity of the disease and its complications, people with GCA are often seen by several physicians including rheumatologists, neurologists and ophthalmologists.
About Actemra/RoActemra

Actemra/RoActemra is the only 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 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). The extensive Actemra/RoActemra RA IV clinical development program 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 program 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. 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 115 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). Actemra/ RoActemra was granted Breakthrough Therapy Designation for SSc by the US Food and Drug Administration (FDA) in June 2015.

About Roche in Immunology

The Roche Group’s immunology medicines include: Actemra/RoActemra (tocilizumab) for rheumatoid arthritis and juvenile idiopathic arthritis; Rituxan/MabThera (rituximab) for rheumatoid arthritis granulomatosis with polyangiitis and microscopic polyangiitis; Xolair (omalizumab) in allergic asthma; Pulmozyme (dornase alfa) for cystic fibrosis; and Esbriet (pirfenidone) for idiopathic pulmonary fibrosis. Roche’s immunology pipeline includes: RG7625, a cathepsin S antagonist; RG6125, a monoclonal antibody targeting cadherin-11; RG7845 (GDC-0853), a novel Bruton’s tyrosine kinase (BTK) inhibitor; obinutuzumab for lupus nephritis and hypersensitised patients with end-stage renal disease; etrolizumab for ulcerative colitis and Crohn’s disease; and lebrikizumab in a number of respiratory conditions and atopic dermatitis.
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 eight 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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References

1 Stone, J et al. Efficacy and Safety of Tocilizumab in Patients with Giant Cell Arteritis: Primary and Secondary Outcomes from a Phase 3, Randomised, Double-Blind, Placebo-Controlled Trial. Presented at the 2016 American College of Rheumatology (ACR) and Association for Rheumatology Health Professionals (ARHP) Annual Meeting on Sun 13th Nov, abstract ID: 911.