Roche’s Actemra approved in Switzerland for patients with giant cell arteritis
• Actemra is the first targeted treatment approved for giant cell arteritis (GCA)
• Over half of the patients who received Actemra during the pivotal study showed no new GCA symptoms even six months after ending the co-medication with steroids

Basel, 27. June 2018 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the Swiss regulatory and supervisory authority responsible for therapeutic products (Swissmedic) has approved Actemra® (tocilizumab) for the treatment of giant cell arteritis in adult patients. Actemra is the first nonsteroidal medicine to be approved for this disease.

This approval was based on positive data from the Phase III GiACTA trial. The trial satisfied the criteria for both its primary endpoint and for an important secondary endpoint.

The criteria for the primary endpoint were met with Actemra – initially combined with a six-month steroid taper regimen – significantly increasing the proportion of patients achieving sustained disease remission at one year (56% [weekly administration, p<0.0001] and 53.1% [administration every two weeks, p<0.0001] versus 14% with a six-month steroid-only taper regimen).[1]

The criteria for an important secondary endpoint were met in that it was shown that the total dosage of steroids that had to be administered to patients for a year in order to control the GCA could be significantly reduced by combination therapy with Actemra [1862 mg weekly (95% CI, 1582 to 1942) or 1862 mg two-weekly (95% CI, 1568 to 2240), compared to 3296 mg (95% CI, 2730 to 4024) with a steroid-only regimen over 26 weeks].

“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 Professor Peter M. Villiger, Head of the Rheumatology Department at Inselspital Bern and one of the world’s acknowledged authorities on GCA, who carried out the Phase II trial in this indication at Inselspital. [2] “However, steroid therapy often fails to control the disease in the long term. The approval of Actemra has the potential to fundamentally change the way people with GCA are treated.”

No new safety signals were observed. [1] The safety profile of Actemra in GCA is consistent with Actemra’s documented safety profile in rheumatoid arthritis.

About the GiACTA trial
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.
About Giant Cell Arteritis

Giant cell arteritis – also known as temporal arteritis – 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.[3] GCA is often difficult to diagnose because of the wide and variable spectrum of signs and symptoms. The disease can cause severe headaches, jaw pain and visual symptoms and, if left untreated, can lead to blindness, aortic aneurysm or stroke.[3] Treatment to date has been limited to high-dose steroids that play a role as an effective “emergency” treatment option to prevent damage such as vision loss.[4] However, steroids do not always maintain long-term disease control (flare-free remission). [3], [6], [7]

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 (known in the EU under its trade name 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 in combination with methotrexate (MTX) in adults who are intolerant to, or have failed to respond to, other anti-rheumatic medications known as DMARDs and TNF inhibitors. In the most recent update to the European League Against Rheumatism (EULAR) rheumatoid arthritis 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 anti-rheumatic drugs.[8] The extensive Actemra/RoActemra RA IV clinical development programme included five Phase III clinical studies and enrolled more than 4,000 people with rheumatoid arthritis 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 rheumatoid arthritis in 33 countries.

The intravenous formulation of Actemra/RoActemra is also approved in most major countries for the treatment of 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 and in Switzerland since 2008.

About Roche in immunology

The Roche Group’s immunology medicines currently include Actemra/RoActemra (tocilizumab) for rheumatoid arthritis and juvenile idiopathic arthritis and Rituxan/MabThera (rituximab) for rheumatoid arthritis. 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 and obinutuzumab for lupus nephritis.
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 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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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