# *Media & Investor Release*

## CHMP recommends EU approval of Actemra/RoActemra to treat patients with severe COVID-19

- **Actemra/RoActemra reduced the risk of death in patients with severe COVID-19, as evidenced by a review of four phase III studies**
- **The European Commission is expected to make a final decision regarding approval in the near future**

Basel, 06 December 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended extending the marketing authorisation for Actemra®/RoActemra® (tocilizumab) to include the treatment of COVID-19 in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation. A final decision regarding the approval of Actemra/RoActemra is expected from the European Commission in the near future.

"As COVID-19 cases in Europe rise and with pressure on hospitals likely to increase, the need for effective treatments for those suffering most severely with COVID-19 could intensify," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We are proud that the CHMP has recognised the potential of Actemra/RoActemra as we continue our efforts to bring treatment options to those most in need."

In August 2021, the EMA's CHMP began an accelerated assessment of Actemra/RoActemra – this rapid analysis is reserved for medicines that may offer significant benefit to public health. The assessment reviewed results from four studies in over 5,500 patients with severe or critical COVID-19. These include the Roche-led phase III COVACTA, EMPACTA and REMDACTA trials, and the University of Oxford's Randomised Evaluation of COVID-19 Therapy (RECOVERY) study, which was supported by Roche. The totality of this clinical evidence demonstrated that Actemra/RoActemra reduced the risk of death in patients with severe or critical COVID-19.[1]

Actemra/RoActemra has been provisionally approved in Australia, authorised for emergency use in the United States and Ghana, and recommended by the World Health Organization (WHO) for the treatment of COVID-19. [1,2,3,4] Roche is working closely with regulatory bodies and other partners around the world on the next steps to bring this medicine to as many people as possible.

Following the recent emergence of the new SARS-CoV-2 variant of concern, Omicron (B.1.1.529), WHO has reported that interleukin 6 receptor blockers, such as Actemra/RoActemra, are expected to still be effective for managing patients with severe COVID-19.[5]

In these exceptional times, Roche stands together with society, governments, healthcare providers and all those working towards the common goal of overcoming the COVID-19 pandemic.

### About Actemra®/RoActemra® (tocilizumab) in COVID-19 clinical trials

Roche has evaluated Actemra/RoActemra in COVID-19 in three phase III randomised studies: COVACTA, EMPACTA and REMDACTA.

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COVACTA was a global, randomised, double-blind, placebo-controlled phase III study (COVACTA, NCT04320615), which evaluated the safety and efficacy of intravenous Actemra/RoActemra plus standard of care in adult patients hospitalised with severe COVID-19 pneumonia compared to placebo plus standard of care. The primary and secondary endpoints included clinical status, mortality, mechanical ventilation and intensive care unit (ICU) variables. Patients were followed for 60 days post-randomisation.

EMPACTA (Evaluating Minority Patients with Actemra) was a phase III, randomised, double-blind, placebo-controlled multicentre study (EMPACTA, NCT04372186) which evaluated the efficacy and safety of Actemra/RoActemra in the treatment of COVID-19 pneumonia among hospitalised patients that are often underrepresented in clinical trials. The primary endpoint was the cumulative proportion of participants dying or requiring mechanical ventilation by Day 28. Secondary endpoints included: time to clinical failure (defined as the time to death), mechanical ventilation, ICU admission, or withdrawal (whichever occured first); mortality rate by Day 28; and time to hospital discharge or "ready for discharge."

REMDACTA was a two-armed global phase III, randomised, double-blind, multicentre study (REMDACTA, NCT04409262) to evaluate the efficacy and safety of Actemra/RoActemra plus Veklury® (remdesivir), versus placebo plus Veklury in hospitalised patients with severe COVID-19 pneumonia receiving standard of care. Veklury is an antiviral medicine that works to stop replication of SARS-CoV-2, the virus that causes COVID-19. The REMDACTA trial was conducted in collaboration with Gilead Sciences, Inc. The primary endpoint was improvement in time to hospital discharge by Day 28. Key secondary endpoints included likelihood of death, likelihood of progression to mechanical ventilation or death, and clinical status. Clinical status was measured by the 7-category ordinal scale, which tracks patients' clinical status based on the need for intensive care and/or ventilator use, as well as supplemental oxygen requirements. Patients were followed for 60 days post-randomisation.

There have also been a number of clinical trials with an external third party as the sponsor exploring the efficacy and safety of Actemra/RoActemra for the treatment of patients hospitalised with COVID-19, including the University of Oxford's RECOVERY study, which was supported by Roche. RECOVERY was a phase III, randomised trial (NCT04381936), which evaluated whether multiple potential treatments, including Actemra/RoActemra, prevent death in hospitalised adult patients with severe COVID-19.

Results of a prospective meta-analysis of almost 11,000 patients across 27 clinical trials, published by researchers from the World Health Organization in The Journal of the American Medical Association, found that treatment of hospitalised patients with severe or critical COVID-19 with IL-6 receptor blockers, including Actemra/RoActemra, was associated with improved mortality and reduced progression to invasive mechanical ventilation or death compared with usual care or placebo. The prospective meta-analysis included data on Actemra/RoActemra in COVID-19 from COVACTA, EMPACTA and REMDACTA, along with 16 additional third-party studies.

## About Actemra®/RoActemra® (tocilizumab)

Actemra/RoActemra was the first approved anti-IL-6 receptor biologic and is 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 disease-modifying anti-rheumatic drugs (DMARDs). In Europe, RoActemra IV and SC are also approved for use in adult patients with severe, active and progressive RA who previously have not been treated with MTX. Actemra/RoActemra IV and SC are also approved globally for polyarticular juvenile idiopathic arthritis (pJIA) and systemic juvenile idiopathic arthritis (sJIA) in children two years of age and older. Actemra/RoActemra SC is approved globally for giant cell arteritis (GCA), and Actemra/RoActemra IV is approved for the treatment of chimeric antigen receptor (CAR) T-cell-induced severe or life-threatening cytokine release syndrome (CRS) in people two years of age and older. Actemra/RoActemra was the first approved treatment for sJIA, GCA and CRS. Actemra SC is now approved in the United States for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD). In addition to the above-mentioned indications, in Japan Actemra IV is also approved for the treatment of Castleman's disease and adult Still's disease, and the Actemra SC formulation is approved for Takayasu arteritis.

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 110 countries worldwide.

## About Roche's response to the COVID-19 pandemic

As a leading healthcare company, we are doing all we can to support countries in their fight against COVID-19 and minimising its impact. We have developed a growing number of diagnostic solutions that help to detect and diagnose the infection, as well as providing digital support to healthcare systems. We also continue to identify, develop, and support therapies which can play a role in treating the disease.

The impact of COVID-19 goes beyond those who contract it. That is why we are working with healthcare providers, laboratories, authorities, and organisations to help make sure patients continue to receive the tests, treatment and care they need during these challenging times. Building on a longstanding tradition of partnerships, we are working together with governments and others to make healthcare stronger and more sustainable in the future.

Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic and Roche has so far launched 21 diagnostics solutions to help minimise the impact of COVID-19. As soon as the novel SARS-CoV-2 virus was sequenced in early 2020, we got to work. On 13 March 2020 we became the first company to receive United States (U.S.) Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for a high-volume molecular test to detect the virus. Since then, we have continued to add a range of diagnostics solutions to our global portfolio to help in the fight against COVID-19. In addition to the gold standard PCR test, we have developed antigen tests to help diagnose the virus in settings where there is limited molecular laboratory infrastructure, rapid antigen tests where the virus can be detected on the spot, tests that can test for both flu and COVID-19 at the same time, both high

throughput and at the point of care, and tests that can detect virus antibodies that can help monitor the spread of the virus and can also support in vaccine development. In March 2021 the SARS-CoV-2 variant test was launched, designed to detect key spike mutations.

Aside from these tests we have also looked at how we can support care for patients who have COVID-19, receiving an U.S. FDA EUA for the Elecsys® IL-6 test to assist in identifying severe inflammatory response in patients with confirmed COVID-19, as well as launching Roche v-TAC, a digital algorithm that could help simplify the screening, diagnosis, and monitoring of respiratory-compromised patients with COVID-19. Roche is working closely with governments and health authorities around the world and has significantly increased production to support availability of tests globally.

Roche is also actively involved in understanding the potential of the existing pharmaceuticals portfolio and is researching options for the future. In 2020, Roche entered into a number of new partnerships, including with Regeneron and Gilead to develop, manufacture and distribute molecules that can potentially both treat and prevent COVID-19.

Roche entered a partnership with Regeneron to jointly develop Ronapreve™ (casirivimab and imdevimab, known as REGEN-COV™ in the US. The antibody combination has been approved for use in the European Union and Japan, and conditionally in the United Kingdom and Australia, and is authorised for emergency or temporary pandemic use in additional territories such as the US and Canada. In addition, the World Health Organization recommended the use of Ronapreve for the treatment of patients with COVID-19.

In June 2021, Actemra/RoActemra received an EUA from the U.S. FDA for the intravenous treatment of COVID-19 in hospitalised adults and paediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation. In addition, the World Health Organization recommended the use of Actemra/RoActemra for the treatment of certain patients with COVID-19.

For more information on how Roche is responding to the global COVID-19 pandemic, please visit our COVID-19 response page.

## 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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, the company has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

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. More than 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. Moreover, for the thirteenth consecutive year, Roche has been recognised as one of the most sustainable companies in the pharmaceutical industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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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