Media Release

FDA approves Roche's Actemra for the treatment of COVID-19 in hospitalised adults

- **Actemra is the first FDA-approved monoclonal antibody to treat COVID-19**
- **Since the beginning of the pandemic, more than one million people hospitalised with COVID-19 have been treated with Actemra worldwide**
- **Actemra is approved for this use in more than 30 countries for the treatment of COVID-19**

Basel, 21 December 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has approved Actemra® (tocilizumab) intravenous (IV) for the treatment of COVID-19 in hospitalised adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Actemra is the first FDA-approved monoclonal antibody to treat COVID-19 and is recommended for use as a single 60-minute IV infusion.

"With new variants emerging, FDA-approved treatments including Actemra remain essential to the continued fight against COVID-19," said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development. "Actemra is the first FDA-approved monoclonal antibody for treating patients with severe COVID-19, providing an important option for hospitalised patients and their healthcare providers who continue to be on the frontlines treating COVID-19."

Four randomised, controlled studies evaluated Actemra for the treatment of COVID-19 in more than 5,500 hospitalised patients. Altogether, the results of these four studies (the University of Oxford-led RECOVERY trial, along with the Roche-sponsored global trials, EMPACTA, COVACTA and REMDACTA) showed that Actemra may improve outcomes in patients receiving corticosteroids and requiring supplemental oxygen or breathing support. The FDA approval is based on the results from the RECOVERY trial, as well as the EMPACTA trial, the first global, Phase III study in COVID-19 to focus on patients from underrepresented racial and ethnic groups. No new warnings and precautions related to Actemra in COVID-19 studies have been identified.

The FDA approval follows the FDA's Emergency Use Authorization (EUA) for Actemra in hospitalised adults and children (ages 2 and older) with COVID-19, which was granted in June 2021. The use of Actemra to treat hospitalised people ages 2 to less than 18 years old is not FDA approved, however the EUA for this age group currently remains in place after the FDA approval for hospitalised adult patients.

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More than one million people hospitalised with COVID-19 have been treated with Actemra worldwide, since the beginning of the pandemic. Around the world, Actemra is approved for use in more than 30 countries for patients hospitalised with severe COVID-19. In the United States, this is the seventh FDA approved indication for Actemra since the medicine was launched in 2010.

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 in COVID-19

Actemra®/RoActemra® is approved for use in multiple territories including the United States, European Union, Japan, the United Kingdom, New Zealand, Russia and Brazil, provisionally approved in Australia, and authorised for emergency use in Ghana, Mexico and Korea for defined patients hospitalised with severe or critical COVID-19. It has also been recommended and prequalified by the World Health Organization.

About Actemra/Roactemra

Actemra®/RoActemra® was the first humanised interleukin-6 (IL-6) receptor antagonist approved for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have used one or more disease-modifying antirheumatic drugs (DMARDs), such as methotrexate (MTX), that did not provide enough relief. The extensive Actemra 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 RA subcutaneous clinical development program included two Phase III clinical studies and enrolled more than 1,800 people with RA in 33 countries. Actemra subcutaneous injection is also approved for the treatment of adult patients with giant cell arteritis (GCA), for the treatment of patients two years of age and older with active polyarticular juvenile idiopathic arthritis (PJIA) or active systemic juvenile idiopathic arthritis (SJIA), and for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD). In addition, Actemra is also approved in the IV formulation for patients two years of age and older with active PJIA, SJIA, GCA or CAR T cell-induced cytokine release syndrome (CRS). Actemra is not approved for subcutaneous use in people with CRS. Actemra IV is approved for the treatment of COVID-19 in hospitalised adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). It is not known if Actemra is safe and effective in children with PJIA, SJIA or CRS under two years of age or in children with conditions other than PJIA, SJIA or CRS.

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. That is why we are working with governments, policy makers, healthcare professionals and others to help contain the COVID-19 pandemic and make sure patients continue to receive the tests, treatment and care they need.

The pandemic has profoundly raised awareness of the role diagnostics play in COVID-19 diagnosis, treatment development and disease management. Roche has developed and launched more than 20 COVID-19 diagnostics solutions, including polymerase chain reaction (PCR) and rapid antigen and antibody tests. Our solutions serve the entire diagnostic continuum, from high-throughput laboratories to point-of-care and home self-testing, and cover all currently known variants. To help meet global demand, we have supplied more than 1.5 billion tests for COVID-19 since March 2020.

Roche continues to evaluate its existing therapeutic portfolio and is researching future options to help benefit patients with COVID-19. Our IL-6 inhibitor Actemra®/RoActemra® (tocilizumab) has been approved for patients hospitalised with severe COVID-19 in more than 30 countries including the European Union and the United States. The World Health Organization has prequalified Actemra for use in patients with severe COVID-19, facilitating its availability in low- and middle-income countries. In addition, we have been improving access to Actemra by introducing an international differentiated pricing strategy, providing the medicine at cost for use in low- and middle-income countries and non asserting patents in these regions during the pandemic.

We have also been partnering with Regeneron to jointly develop the antibody combination Ronapreve™ (casirivimab and imdevimab, known as REGEN-COV™ in the US). It has been approved in multiple territories including the European Union, Japan, and Switzerland and authorised for emergency or temporary pandemic use in many countries including the US. We are constantly monitoring and assessing Ronapreve's neutralising activity against emerging variants of concern and entered a dialogue with regulators and industry representatives to discuss the efficacy of monoclonal antibodies in the context of rapidly evolving SARS-CoV-2 variants.

Our utmost goal remains to be a trusted partner who acts with urgency to save and improve the lives of patients with COVID-19 and to reduce its burden on society. For more information please visit our COVID-19 response page.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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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