Media & Investor Release

U.S. FDA grants priority review to Roche's Actemra/RoActemra for the treatment of COVID-19 in hospitalised adults

- **If approved, Actemra/RoActemra would be the first U.S. FDA-approved immunomodulator for the treatment of COVID-19 in hospitalised patients**
- **Since the beginning of the pandemic, more than one million people hospitalised with COVID-19 have been treated with Actemra/RoActemra worldwide[1]**
- **Actemra/RoActemra is approved for the treatment of COVID-19 in many territories including the European Union**
- **Roche has established a comprehensive access approach to improve availability of Actemra/RoActemra around the world**

Basel, 04 April 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's supplemental Biologics License Application (sBLA) and has granted Priority Review for Actemra®/RoActemra® (tocilizumab) intravenous for the treatment of COVID-19 in hospitalised adults who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation. A decision on U.S. FDA approval is expected in the second half of this year.

"The high rate of unvaccinated people will continue to put a strain on hospitals and healthcare systems around the world, furthering the need for effective treatments for patients hospitalised with COVID-19," said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development, Roche. "More than one million people with severe or critical COVID-19 have already been treated with Actemra/RoActemra worldwide, demonstrating the important role of this medicine in the fight against the pandemic."

The sBLA submission is based on results from four randomised, controlled studies that evaluated Actemra/RoActemra for the treatment of COVID-19 in more than 5,500 hospitalised patients. Altogether, the results of these four studies (EMPACTA, COVACTA, REMDACTA, and RECOVERY) suggest that Actemra/RoActemra may improve outcomes in patients receiving corticosteroids and requiring supplemental oxygen or breathing support.[2-5]

In June 2021, Actemra/RoActemra received Emergency Use Authorization from the U.S. FDA and is currently approved for use in 16 countries around the world for defined patients hospitalised with severe or critical COVID-19.[6,7] In February 2022, the World Health Organization (WHO) prequalified Actemra/RoActemra for patients with severe or critical COVID-19, supporting access to care in low- and middle-income countries.[8]

In addition to working with health authorities, Roche has established a comprehensive access approach to improve availability of its COVID-19 medicines around the world including:

- Providing Actemra/RoActemra at cost to WHO and partners of the Access to COVID-19 Tools Accelerator (ACT-A) Initiative, building on the significant portion of Actemra/RoActemra supply that Roche has provided to upper-middle- and lower-middle-income countries since the beginning of the pandemic.[7]
- Implementing an international differentiated pricing strategy specifically designed to address needs during this pandemic and improve affordability.[7]

Following the emergence of the SARS-CoV-2 variant of concern, Omicron (B.1.1.529), in December 2021 WHO reported that interleukin-6 receptor blockers, such as Actemra/RoActemra, are expected to still be effective for managing patients with severe COVID-19.[9]

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

Actemra/RoActemra is approved for use in multiple territories including the European Union, Japan, Bolivia, Chile, Guatemala, Ecuador, Honduras, Hong Kong, Myanmar, Peru, Philippines, the United Kingdom and Ukraine, provisionally approved in Australia, and authorised for emergency use in Ghana, Korea and the United States for defined patients hospitalised with severe or critical COVID-19. It has also been recommended and prequalified by the World Health Organization.

About the Actemra®/RoActemra® (tocilizumab) COVID-19 Clinical Trial Programme

Roche's clinical trial programme evaluated the safety and efficacy of Actemra/RoActemra in hospitalised patients with COVID-19. Actemra/RoActemra is not U.S. Food and Drug Administration (FDA)-approved for this use and there is limited information known about the safety or effectiveness of using Actemra/RoActemra to treat people in the hospital with COVID-19. COVACTA and EMPACTA were the first two global phase III, multicentre, randomised, placebo-controlled studies of Actemra/RoActemra in patients hospitalised with COVID-19 associated pneumonia. COVACTA was conducted in collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the United States Department of Health and Human Services (HHS). EMPACTA aimed to address research questions about the safety and efficacy of Actemra/RoActemra in underserved populations by emphasising enrollment from minority patients often underrepresented in clinical trials. Both studies were published in the New England Journal of Medicine. Roche also partnered with Gilead Sciences, Inc., on REMDACTA, a phase III, randomised, double-blind, multicentre study to evaluate the

safety and efficacy of Actemra/RoActemra plus Veklury® (remdesivir), versus placebo plus Veklury, in hospitalised patients with severe COVID-19 associated pneumonia.

About the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for Actemra®/RoActemra® (tocilizumab)

Actemra/RoActemra has not been approved by the U.S. FDA in this setting, but the FDA has made Actemra/RoActemra available under an emergency access mechanism called an EUA as a treatment for certain patients with COVID-19. There is limited information known about the safety or effectiveness of using Actemra/RoActemra to treat people in the hospital with COVID-19. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. The authorisation is temporary and does not replace the formal review and approval process, which is being pursued. Actemra/RoActemra is authorised under the EUA only for the duration of the declaration that circumstances exist justifying the authorisation of the emergency use of Actemra/RoActemra under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorisation is terminated or revoked sooner.

About Actemra®/RoActemra® (tocilizumab)

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/RoActemra RA intravenous (IV) clinical development programme included five phase III clinical studies and enrolled more than 4,000 people with RA in 41 countries. The Actemra/RoActemra RA subcutaneous clinical development programme included two phase III clinical studies and enrolled more than 1,800 people with RA in 33 countries. Actemra/RoActemra 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/RoActemra 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/RoActemra is not approved for subcutaneous use in people with CRS. It is not known if Actemra/RoActemra 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. 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 that 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, Japan, New Zealand and Switzerland, conditionally approved in Australia and the United Kingdom, and authorised for emergency or temporary pandemic use in additional territories such as Canada and the US. It has also been conditionally recommended by the World Health Organization for the treatment of 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

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 recognizing 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.

References

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