Media & Investor Release

WHO grants prequalification of Actemra/RoActemra for patients with severe or critical COVID-19

- **WHO's prequalification adds to several mechanisms already in place to improve access to Actemra/RoActemra for people with COVID-19 in low- and middle-income countries**
- **Since the beginning of the pandemic, more than one million patients with severe COVID-19 have been treated with Actemra/RoActemra, as recommended in global treatment guidelines**
- **Twelfth Roche medicine or test to be prequalified**

Basel, 11 February 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that Actemra®/RoActemra® (tocilizumab) intravenous (IV) has been granted World Health Organization (WHO) prequalification. Prequalification is a confirmation by WHO that Actemra/RoActemra meets the WHO standards for quality, safety and efficacy for the treatment of COVID-19 in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation.[1] It helps procurers in low- and middle-income countries identify priority medicines to improve access to care and support better health.

"People from many low- and middle-income countries continue to feel the devastating impact of COVID-19, and care needs remain unprecedented," said Bill Anderson, Chief Executive Officer of Roche Pharmaceuticals. "We've partnered with WHO and others throughout the last year to ensure that our COVID-19 medicines and tests can potentially reach more than 100 low- and middle-income countries, and WHO's prequalification of Actemra/RoActemra is just one of the paths taken together to achieve this. We will keep working tirelessly so that our COVID-19 care options reach as many people in need as possible."

Actemra/RoActemra and Ronapreve™ (casirivimab and imdevimab, known as REGEN-COV® in the United States) were recommended in WHO's Therapeutics and COVID-19 Living Guideline last year.[2] Roche has established a comprehensive access approach to improve availability of both medicines around the world. This includes:

- Providing Actemra/RoActemra at cost to WHO and partners of the Access to COVID-19 Tools Accelerator (ACT-A) Initiative, to distribute to low- and middle-income countries in line with public health needs, thereby 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.[3]
- Working with ACT-A partners/UNICEF to donate Ronapreve, together with Regeneron, to support the most vulnerable communities in low-and middle-income countries in the event of future variants for which Ronapreve might have utility.[3]

- Not asserting any patents against the use of Actemra/RoActemra in COVID-19 in low- and middle-income countries during the current pandemic (alongside Chugai), to provide legal certainty for biologic manufacturers who are ready and able to produce the medicine.[3]
- Implementing an international differentiated pricing strategy specifically designed to address needs during this pandemic and improve affordability across upper-middle-, lower-middle- and low-income countries.[3]
- Overcoming industry-wide supply challenges as the pandemic has evolved, including dedicating our largest manufacturing facility exclusively to producing COVID-19 medicines and working with partners to transfer technologies to maximise production.[3]

In addition to the supply of its medicines, Roche has enabled more than 1.2 billion COVID-19 tests since the start of the pandemic, informing healthcare decisions around the world.[3] The Roche **cobas**® SARS-CoV-2 Test on the **cobas**® 6800/8800 Systems is also included in Roche's Global Access Programme for low- and middle-income countries, reinforcing Roche's continued commitment to further improve access to reliable and vital diagnostics at affordable prices, which is crucial to combat this global pandemic.[3]

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

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

Multiple studies have evaluated the efficacy and safety of Actemra/RoActemra, including the Roche-led COVACTA, EMPACTA and REMDACTA trials, and the University of Oxford-led RECOVERY study. WHO has also reported that IL-6 receptor blockers, such as Actemra/RoActemra, are expected to still be effective against the SARS-CoV-2 variant of concern, Omicron (B.1.1.529).

Actemra/RoActemra is a first-in-class anti-interleukin-6 receptor (aIL-6R) therapy for the treatment of rheumatoid arthritis, systemic juvenile idiopathic arthritis, polyarticular juvenile idiopathic arthritis, giant cell arteritis and chimeric antigen receptor T-cell induced severe or life-threatening cytokine release syndrome, in addition to COVID-19. It is approved in more than 110 countries.

About Ronapreve™ (casirivimab and imdevimab)

Ronapreve (known as REGEN-COV™ in the United States [US] and invented by Regeneron) is 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 (WHO) for the treatment of patients with COVID-19.

Ronapreve is available to COVID-19 patients in more than 50 countries, including upper-middle- and lower-middle-income countries.

The efficacy and safety of Ronapreve have been studied across multiple phase III clinical trials in non-hospitalised and hospitalised COVID-19 patients, and in the preventive setting.

Recent *in vitro* analyses and structural modelling have shown that Ronapreve has diminished potency versus the SARS-CoV-2 variant of concern, Omicron (B.1.1.529). Ronapreve has shown to retain its activity against all other main variants of concern, including Delta (B.1.617.2).

Ronapreve is being jointly developed by Roche and Regeneron. It is a combination of two monoclonal antibodies, casirivimab and imdevimab, and was designed to block infectivity of SARS-CoV-2, the virus that causes COVID-19.

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, 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 (WHO) for the treatment of patients with COVID-19. 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. In December 2021, Actemra/RoActemra was approved by the European Commission to treat patients with severe 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 in1896 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

[1] World Health Organization. Prequalification of medicines by WHO. [Internet; cited 31 Jan 2022]. Available https://www.who.int/news-room/fact-sheets/detail/prequalification-of-medicines-by-who
[2] World Health Organization. Therapeutics and COVID-19. [Internet; cited 31 Jan 2021]. Available from: https://apps.who.int/iris/bitstream/handle/10665/351006/WHO-2019-nCoV-therapeutics-2022.1-eng.pdf
[3] Roche data on file

Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Dr. Nicolas Dunant
Phone: +41 61 687 05 17

Dr. Barbara von Schnurbein
Phone: +41 61 687 89 67

Nina Mählitz
Phone: +41 79 327 54 74

Sileia Urech
Phone: +41 79 935 81 48

Karsten Kleine
Phone: +41 61 682 28 31

Nathalie Meetz
Phone: +41 61 687 43 05

Roche Investor Relations

Dr. Karl Mahler
Phone: +41 61 68-78503
e-mail: karl.mahler@roche.com

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com