Ronapreve approved by European Commission to treat non-hospitalised COVID-19 patients and for prophylaxis of the disease

- **EU marketing authorisation follows approvals in Japan, the United Kingdom and Australia**
- **Approval based on data demonstrating Ronapreve reduced risk of hospitalisation in certain patients with mild to moderate disease and reduced risk of symptomatic COVID-19 infections in people exposed to the virus**

Basel, 12 November 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the European Commission has granted a marketing authorisation for Ronapreve™ (casirivimab and imdevimab), for treating COVID-19 in adults and adolescents (from 12 years of age and weighing at least 40 kilograms) who do not require supplemental oxygen and who are at increased risk of their disease becoming severe, and for preventing COVID-19 in people aged 12 years and older weighing at least 40 kilograms (pre- or post-exposure prophylaxis). This decision follows one day after the positive opinion by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP), reflecting the EMA and the European Commission's priority to shorten review timelines for safe, effective and high-quality therapeutics during the COVID-19 public health emergency.

"We welcome this quick approval from the European Commission, which adds to the growing number of health authorities that recognize Ronapreve as an important therapy for the treatment and prevention of COVID-19," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Although vaccinations are increasing globally, Europe is entering a fourth wave of rising cases and treatment options for the full range of disease severity and variants of concern are still needed. We look forward to working with additional global regulatory bodies as we continue to tackle COVID-19 together."

Today's decision from the European Commission is based on the EMA's CHMP's review of positive data from the REGN-COV 2067 treatment study in non-hospitalised patients and the REGN-COV 2069 prophylaxis study in people exposed to SARS-CoV-2 virus. Roche will continue to work with the EMA to potentially extend the marketing authorisation of Ronapreve to treat hospitalised patients with COVID-19.

Outside of the European Union, Ronapreve has been approved for use in Japan and conditionally in the United Kingdom and Australia, and is authorised for emergency or temporary pandemic use in additional territories, including the United States, India and Canada. Ronapreve, being jointly developed by Roche and Regeneron, is currently available in nearly 50 countries via bilateral purchase agreements across many geographies and economies, including lower middle-income countries. In addition, the World Health Organization recommended the use of Ronapreve for the treatment of patients with COVID-19.

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COVID-19 remains prevalent across the world, partly due to the multiple SARS-CoV-2 variants in circulation. In the past two months, new cases in Europe have reached >180,000 per day consistently. Currently, the region reports the highest weekly case incidence rates worldwide and cases are on the rise as we enter the winter season.[1] 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 Ronapreve™ (casirivimab and imdevimab)
The efficacy and safety of Ronapreve™ (casirivimab and imdevimab, known as REGEN-COV®in the United States) have been studied across multiple phase III clinical trials in non-hospitalised and hospitalised COVID-19 patients, and in the preventive setting. In addition, data from preclinical studies showed that Ronapreve retained neutralisation activity against key emerging variants, as referenced in publications in *Cell* and *Nature*.

The decision from the European Commission is based on data from multiple studies, including:

- the REGN-COV 2067 study, showing that Ronapreve reduced hospitalisation or death by 70% and symptom duration by four days.
- the REGN-COV 2069 study, showing that the administration of Ronapreve reduced the risk of symptomatic infections by 81% in those who were not infected when they entered the trial.

There have been no new safety signals identified for Ronapreve in these studies.

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 potential 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 16 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 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 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 actively involved in understanding the potential of the existing portfolio and is researching options for the future. In 2020, Roche entered into a number of new partnerships, including with Regeneron, Atea and Gilead to develop, manufacture and distribute molecules that can potentially both treat and prevent COVID-19.

In October 2020, Roche announced a partnership with Atea Pharmaceuticals to jointly develop the investigational compound AT-527. AT-527 is still being evaluated in clinical trials, across non-hospitalised and hospitalised COVID-19 patients and is not currently approved or authorised for the treatment of COVID-19 by any health authority.

In addition, we have explored the potential of our existing medicine Actemra/RoActemra in three global phase III clinical trials investigating its safety and efficacy in COVID-19 associated pneumonia (COVACTA, EMPACTA and REMDACTA). In June 2021, Actemra/RoActemra received an Emergency Use Authorization 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 twelfth 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.

References

[1] World Health Organisation: Coronavirus (COVID-19) Dashboard. [Internet cited; October 2021] Available from: https://covid19.who.int/

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