CHMP recommends EU approval of Ronapreve to treat non-hospitalised COVID-19 patients and for prophylaxis of the disease

- **Recommendation 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**
- **Ronapreve's combination approach continues to retain neutralisation activity against variants of concern**

Basel, 11 November 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 the approval of the antibody combination, 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). A final decision regarding the approval of Ronapreve is expected from the European Commission in the near future.

"With cases in Europe surging, it is vital that people have access to different approaches, in addition to vaccines, that reduce the disease burden, and Ronapreve has demonstrated efficacy in treating and preventing COVID-19 and against variants of concern," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "People with COVID-19 across Europe are already being treated with Ronapreve based on emergency authorisations that followed the CHMP's scientific opinion earlier this year, and we're pleased that the committee has now recommended the approval of the antibody combination."

In February, the EMA's CHMP initiated a rolling review of Ronapreve, one of the regulatory tools used to speed up the assessment of a promising medicine during a public health emergency. Today's recommendation is based on 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.

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)
Ronapreve™ (casirivimab and imdevimab, known as REGEN-COV®in the United States), which is jointly developed by Roche and Regeneron, has been approved for use in Japan and conditionally in Australia and the United Kingdom, and is authorised for emergency or temporary pandemic use in additional territories

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such as the United States, India and Canada. It has also been conditionally recommended by WHO. Currently, Ronapreve is available in nearly 50 countries via bilateral purchase agreements, including upper-middle-income and lower-middle-income countries.

In parallel to the EMA's rolling review, the CHMP issued a scientific opinion (under Article 5(3) of Regulation 726/2004) in February 2021, supporting the use of Ronapreve as a treatment option for patients with confirmed COVID-19 who do not require oxygen supplementation and who are at high risk for progressing to severe COVID-19. The scientific opinion can be used by EU member states to support national decision making before a formal authorisation is issued.

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. 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 CHMP's decision 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 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 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. On 16 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 Pharmaceuticals 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 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 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 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.

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