Media Release

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

- **In the fight against the Coronavirus, Ronapreve marks an additional treatment option**
- **Approval based on data demonstrating Ronapreve reduced risk of hospitalisation or death in certain patients with mild to moderate disease and reduced risk of COVID-19 infections in people exposed to the virus**

Basel, 27 December 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Swiss agency for therapeutic products (Swissmedic) has approved Ronapreve™ (casirivimab and imdevimab), for the treatment of confirmed COVID-19 in adult and in adolescent patients (12 years of age or older and weighing at least 40 kg) who do not require supplemental oxygen or hospitalisation for COVID-19 and who are at high risk of progressing to severe COVID-19. Ronapreve is also indicated for the prevention of COVID-19 in adult and in adolescent patients (12 years of age and older and weighing at least 40kg) who are not able to mount an appropriate immune response to the SARS-CoV-2 vaccination.

“It is good news that Ronapreve is now fully authorised in Switzerland and that we were able to complete the rolling authorisation process together with Swissmedic in a joint effort”, said Jean-Marc Häusler, M.D., Roche's Country Medical Director in Switzerland.

The decision from Swissmedic is based on the 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 Swissmedic to potentially extend the marketing authorisation of Ronapreve to treat hospitalised patients with COVID-19.

Ronapreve has already been available to patients in Switzerland since mid-May 2021 under the so-called declaratory order by Swissmedic following the listing of the antibody combination of casirivimab and imdevimab on Annex 5 of Covid-19 Regulation 3 by the Federal Council on 14 April 2021. More than 2500 patients were already treated with Ronapreve in Switzerland under this declaratory order.

Ronapreve has shown[1] to retain its activity against all other main variants of concern, including Delta (B.1.617.2), however, it does not retain efficacy against Omicron. Together with Regeneron, Roche will continue to constantly monitor and rapidly assess its neutralising activity against future emerging variants of concern and respond accordingly.

Outside of Switzerland, Ronapreve has been approved for use in the EU, 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.

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.

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 thirteenth 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] https://www.cell.com/cell/fulltext/S0092-8674(21)00367-6 and https://www.nature.com/articles/s41586-021-03777-9

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