Statement

Roche statement on follow-up analysis of Ronapreve phase III prevention trial

Basel, 8 November 2021

Roche announced today that additional positive results from a follow-up analysis of the phase III 2069 prevention trial assessing the use of a single administration of Ronapreve™ (1,200 mg subcutaneous) to prevent COVID-19 in uninfected individuals have been published. The results show that Ronapreve reduced the risk of contracting COVID-19 (i.e., laboratory-confirmed symptomatic SARS-CoV-2 infections) by 81.6% during the follow-up period (months 2-8).

Earlier this year, Roche had announced results from the primary analysis of the 2069 prevention trial that assessed the ability of Ronapreve to reduce the risk and burden of COVID-19 infection among household contacts of SARS-CoV-2 infected individuals. The results showed that the subcutaneous administration of Ronapreve reduced the risk of symptomatic infections by 81.4% within one month in those who were not infected when they entered the trial.

The new phase III analyses announced today add to the increasing body of evidence supporting the use of Ronapreve to prevent COVID-19. We are encouraged by the preliminary results of this follow-up analysis and its potential benefit for patients.

Although vaccinations are increasing globally, there remains a critical unmet need to prevent infections and provide protection from COVID-19 between close household contacts and for people being exposed to the virus in community settings. By providing long-term immunity, Ronapreve may in particular represent an important preventive approach for people who do not adequately respond to vaccines and who face an ongoing risk of encountering the virus during their daily lives.

We are looking forward to further analysing the data with our partner Regeneron and discussing them with health authorities with the goal of making Ronapreve available to more people in the preventive setting as soon as possible.

In results published in *The New England Journal of Medicine*, the 2069 prevention trial met its primary endpoint, reducing the risk of COVID-19 (i.e., laboratory-confirmed symptomatic SARS-CoV-2 infections) by 81.4% within one month of receiving Ronapreve ($p<0.001$). The new results describe a pre-specified analysis for the following seven months. As demonstrated by this analysis, Ronapreve provides extended protection for the following seven months without requiring additional doses. No new safety signals were identified for Ronapreve during the follow-up period of the trial.

Roche stands together with society, governments, healthcare providers and all those working towards the common goal of overcoming the COVID-19 pandemic.

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About Ronapreve
Ronapreve™ (casirivimab and imdevimab, known as REGN-COV™ in the United States) has been approved for use in Japan, Australia and conditionally in the United Kingdom, and is authorised for emergency or temporary pandemic use in additional territories such as the US, India and Canada. It has also been conditionally recommended by the World Health Organisation.

Currently, Ronapreve is available to COVID-19 patients in nearly 50 countries via bilateral purchase agreements, including upper-middle-income 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. In addition, data from preclinical studies showed that Ronapreve retained neutralisation activity against key emerging variants, as referenced in publications in Cell and Nature.

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
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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