Statement

Ronapreve does not retain neutralising activity against the Omicron variant

Basel, 16 December 2021

Today, Regeneron issued a statement on Ronapreve's (casirivimab and imdevimab) diminished potency versus Omicron. This announcement follows Regeneron's initial analyses that indicated a reduced neutralisation activity of the antibody combination against selected mutations of the Omicron variant.

Ronapreve has shown* to retain its activity against all other main variants of concern, including Delta (B.1.617.2), which currently remains the predominant strain in most countries. Together with Regeneron, Roche will continue to constantly monitor and rapidly assess its neutralising activity against future emerging variants of concern and respond accordingly.

Throughout the pandemic, Ronapreve has demonstrated efficacy and been used as a medicine for COVID-19 across multiple indications and disease stages. We will continue to work tirelessly with our partners to ensure as many people as possible who could benefit from Ronapreve receive the medicine.

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

*(as demonstrated in in vitro analyses that have been published in Cell and Nature)

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 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

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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. In December 2021, Roche announced that it has developed additional testing options to differentiate mutations in the Omicron SARS-CoV-2 variant, which can help manage the evolving COVID-19 pandemic by assessing the spread of circulating variants. It can also help monitor the potential impact of therapeutics, vaccines, and public health interventions.

Roche is 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 the partnership with Regeneron to jointly develop Ronapreve™ (casirivimab and imdevimab, known as REGEN-COV™ in the United States [US]). The antibody combination has been approved for use in the European Union and Japan, and conditionally in the United Kingdom and Australia, and is authorised for emergency or temporary pandemic use in additional territories such as the US and Canada. In addition, the World Health Organization recommended the use of Ronapreve for the treatment of patients with COVID-19.

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 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.

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