

Roche confirms US government agreement to purchase additional doses of Regeneron's casirivimab and imdevimab

- **New agreement covers 1.25 million additional doses of the antibody cocktail, bringing the total potential US supply to over 1.5 million doses**
- **Casirivimab and imdevimab were granted U.S. FDA Emergency Use Authorization for recently-diagnosed, high-risk, mild to moderate COVID-19 patients**
- **Roche and Regeneron are collaborating on developing and manufacturing casirivimab and imdevimab; Regeneron is distributing the antibody cocktail in the US and Roche will be responsible for distribution outside the US**

Basel, 12 January 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today confirmed that the U.S. Department of Health and Human Services (HHS) and the Department of Defense (DOD) will purchase additional supply of Regeneron's casirivimab and imdevimab antibody cocktail for use in non-hospitalised COVID-19 patients as part of Operation Warp Speed. The US government said it will provide these additional doses at no cost to patients, though healthcare facilities may charge fees related to administration, and will continue to coordinate allocation of the antibody cocktail to state and territorial health departments.

Under the new agreement, the US government will purchase up to 1.25 million finished doses of casirivimab and imdevimab by 30 June 2021. Regeneron is already supplying doses to treat approximately 300,000 people, bringing the total potential purchase to over 1.5 million doses in the US.

"We are doing all we can to lessen the impact of the ongoing COVID-19 pandemic, and we remain committed to collaborating with Regeneron to increase supply of their antibody cocktail," said Bill Anderson, Chief Executive Officer of Roche Pharmaceuticals. "Casirivimab and imdevimab will be critically important to help address the pandemic if approved, and we will continue to work with regulators and governments across the globe to bring the medicine to as many people as possible."

The efficacy and safety of casirivimab and imdevimab continue to be evaluated in clinical trials for the treatment of COVID-19 in certain hospitalised and non-hospitalised patients, including the open-label RECOVERY trial of hospitalised patients in the UK, and a trial for the prevention of COVID-19 in household contacts of infected individuals. Lower doses of casirivimab and imdevimab are also being studied with the aim of increasing supply and offering the therapy to more patients. To date, nearly 15,000 people have participated in casirivimab and imdevimab clinical trials.

Roche is collaborating with Regeneron to increase global supply of casirivimab and imdevimab, with the aim of having more than 2 million treatment doses available annually. Regeneron is responsible for the development and distribution of the treatment in the US, and Roche is primarily responsible for the development and distribution outside the US. Roche is actively working with governments outside of the US on potential supply agreements. The companies share a commitment to making the antibody cocktail

available to COVID-19 patients around the globe if approved and will support access in low- and lower-middle-income countries through drug donations to be made in partnership with public health organisations.

About casirivimab and imdevimab

Casirivimab and imdevimab is a cocktail of two monoclonal antibodies (also known as REGN10933 and REGN10987, respectively) and was designed by Regeneron scientists to block infectivity of SARS-CoV-2, the virus that causes COVID-19. They evaluated thousands of fully-human antibodies produced by the company's proprietary VelocImmune® mice, which have been genetically-modified to have a human immune system, as well as antibodies identified from humans who have recovered from COVID-19.

The two potent, virus-neutralising antibodies that form casirivimab and imdevimab are believed to bind non-competitively to the critical receptor binding domain of the virus's spike protein, which is hypothesised to diminish the ability of mutant viruses to escape treatment and to protect against spike variants that may arise in the human population, as detailed in recent Science publications.

Casirivimab and imdevimab's development, manufacturing and clinical trials have been funded in part by the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services under OT number: HHSO100201700020C.

About Emergency Use Authorization status

Casirivimab and imdevimab have not been FDA cleared or approved. They have been authorised by the FDA under an Emergency Use Authorization (EUA) during the current public health emergency for the treatment of mild to moderate COVID-19 in adults and paediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalisation. Please see the Fact Sheet for Healthcare Providers for more information, including important safety information. The cocktail is only authorised for the duration of the declaration that circumstances exist justifying the authorisation of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorisation revoked sooner.

About Roche's response to the COVID-19 pandemic

As a leading healthcare company we are doing all we can to support countries in minimising the impact of COVID-19. We have developed a growing number of diagnostic solutions that help to detect and diagnose the infection in patients, as well as providing digital support to healthcare systems, and we continue to identify, develop and support potential therapies which can play a role in treating the disease.

We understand the impact of COVID-19 goes beyond those who contract it, which is why we are working with healthcare providers, laboratories, authorities and organisations to help make sure that patients

continue to receive the tests, treatment and care they need during these challenging times. As we learn from the pandemic, we are partnering with governments and others to make healthcare stronger and more sustainable in the future.

Our diagnostics solutions:

Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic. Our portfolio includes:

- a high-volume molecular test to detect SARS-CoV-2, the virus that causes COVID-19, (FDA Emergency Use Authorisation (EUA) and available in countries accepting the CE Mark)
- a SARS-CoV-2 laboratory-based antibody test, aimed at detecting the presence of antibodies in the blood targeting the nucleocapsid (FDA EUA and CE Mark)
- an IL-6 test to assist in identifying severe inflammatory response in patients with confirmed COVID-19 (FDA EUA and CE Mark)
- Roche v-TAC, which could help simplify the screening, diagnosis and monitoring of patients with respiratory compromise in the current COVID-19 pandemic
- a SARS-CoV-2 rapid antibody test to help determine at the point of care whether a person has been exposed to the virus (CE Mark)
- a rapid antigen test to support in the detection of SARS-CoV-2 at the point of care within 15 minutes (CE Mark)
- a high-volume molecular test to simultaneously detect and differentiate between SARS-CoV-2 and influenza A/B, as the symptoms are similar for both (FDA EUA and CE Mark)
- a second SARS-CoV-2 antibody test, aimed at measuring the spike protein to support vaccination development and complement our existing portfolio
- a point-of-care molecular PCR test that simultaneously detects and differentiates between SARS-CoV-2 and influenza A/B infections to support urgent triage and diagnosis (FDA EUA and CE Mark)

Our research into therapies:

Roche is committed to improving the treatment of COVID-19. We are actively involved in understanding the potential of our existing portfolio and are exploring the potential of our investigational molecules.

There have been/are a number of clinical trials with an external 3rd party as the sponsor exploring the efficacy and safety of Actemra (tocilizumab) for the treatment of COVID-19 associated pneumonia. COVACTA and EMPACTA, sponsored by Roche, are the first global phase III, multi-centre, randomised, placebo-controlled studies evaluating Actemra in this setting.

We continue to evaluate the data from the global COVACTA study, which did not meet its primary endpoint as announced on 29 July 2020, in conjunction with results from the global EMPACTA study of Actemra in

COVID-19 pneumonia, which met its primary endpoint as announced on 17 September 2020, as well as additional data sources that are in the public domain to determine whether a population can be defined based on patient and disease characteristics in which Actemra on top of usual care may provide a favourable benefit risk profile.

Roche remains committed to continuing the Actemra clinical trial programme in COVID-19 to further explore Actemra in other treatment settings, including in combination with an antiviral.

In August 2020 we signed a collaboration agreement with Regeneron on developing, manufacturing and significantly increasing global supply of an investigational antibody cocktail for COVID-19 if it proves safe and effective in clinical trials and regulatory approvals are granted.

In October 2020 we signed an agreement with Atea to jointly develop AT-527, an orally administered direct-acting antiviral (DAA) currently in phase II clinical trials. AT-527 has the potential to be the first novel oral antiviral to treat COVID-19 patients outside the hospital setting, as well as in the hospital, and may also be used in post-exposure prophylactic settings.

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 under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

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.

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 Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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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