

## **Roche statement on REGN-COV2 US Emergency Use Authorization Request**

**Basel, 8 October 2020**

Following discussions with regulatory authorities, our partner Regeneron has submitted a request to the U.S. Food and Drug Administration (FDA) for an Emergency Use Authorization (EUA) for REGN-COV2, their investigational antibody cocktail against SARS-CoV-2, the virus that causes COVID-19. Regeneron has an agreement with the U.S. Government to supply initial doses of REGN-COV2 should an EUA be granted.

We will be working with governments, health authorities and global health institutions in a concerted, collective manner, with the aim of achieving broad approvals.

Roche and Regeneron will continue to work closely together on the next steps for REGN-COV2.

### **About Roche and Regeneron partnership**

In August, Roche and Regeneron announced a collaboration in the fight against COVID-19 to develop, manufacture and distribute REGN-COV2, Regeneron's investigational antiviral neutralising antibody cocktail, to people around the globe. REGN-COV2 could provide a much-needed treatment option for infected individuals already experiencing symptoms of COVID-19, and may be able to prevent infection in people exposed to the virus, and hopefully to help slow the spread of the global pandemic.

### **About REGN-COV2**

REGN-COV2 was designed specifically 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 REGN-COV2 bind non-competitively to the critical receptor binding domain of the virus's spike protein, which diminishes the ability of mutant viruses to escape treatment and protects against spike variants that may arise in the human population, as detailed in recent Science publications.

REGN-COV2'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 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 point of care molecular test to test for both SARS-CoV-2 and Flu A/B to help clinicians decide on the right treatment option for patients within 20 minutes at the point of care
- a second SARS-CoV-2 antibody test, aimed at measuring the spike protein to support

vaccination development and complement our existing portfolio

*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.

Specifically, on 19 March, we announced the initiation of COVACTA - a global Phase III randomised, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of intravenous Actemra®/RoActemra® (tocilizumab) plus standard of care in hospitalised adult patients with severe COVID-19 pneumonia compared to placebo plus standard of care. On 29 July we announced that COVACTA did not meet its primary endpoint of improved clinical status in patients with COVID-19 associated pneumonia

Separately, we have studied Actemra®/RoActemra® in the EMPACTA study in COVID-19 associated hospitalised pneumonia in patients that are often underrepresented in clinical trials. On 18 September we announced that the phase III EMPACTA study showed Actemra/RoActemra reduced the likelihood of needing mechanical ventilation or death in hospitalised patients with COVID-19 associated pneumonia. However, there was no statistical difference in mortality between patients who received Actemra/RoActemra or placebo

Actemra®/RoActemra® is also being studied in combination with the investigational antiviral remdesivir in hospitalised patients with severe COVID-19 pneumonia in the REMDACTA trial in partnership with Gilead, announced 28 May. Actemra®/RoActemra® is not approved by any health authority for use in COVID-19 pneumonia. Roche has further initiated an internal early research programme focused on the development of medicines for COVID-19 and is engaged in multiple research collaborations.

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

In these exceptional times, Roche stands together with governments, healthcare providers and all those working to overcome the pandemic.

## **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 eleventh 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](http://www.roche.com).

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