# *Statement*

## Roche statement on FDA acceptance of casirivimab and imdevimab (REGN-COV2) EUA in the US

## Basel, 22 November 2020

On 21 November 2020, our partner Regeneron announced that its investigational COVID-19 antibody cocktail of casirivimab and imdevimab, known as REGN-COV2, received Food and Drug Administration (FDA) Emergency Use Authorization (EUA) in the US for the treatment of mild-to-moderate COVID-19 in adults, as well as in paediatric patients at least 12 years of age and weighing at least 40 kg, who have received positive results of direct SARS-CoV-2 viral testing and are at high risk for progressing to severe COVID-19 and/or hospitalisation.

“The Emergency Use Authorization for casirivimab and imdevimab provides an important treatment option for non-hospitalised patients in the US with COVID-19. We are pleased to have partnered with Regeneron to increase global supply, and although manufacturing efforts are already underway, there will be limitations in meeting anticipated demand,” said Bill Anderson, Chief Executive Officer of Roche Pharmaceuticals. “We continue to work closely with Regeneron, governments, health authorities and global health institutions on the approvals and distribution of supply for casirivimab and imdevimab.”

In August, Roche and Regeneron announced a collaboration in the fight against COVID-19 to develop, manufacture and distribute casirivimab and imdevimab to people around the globe. Recent initial data from the phase II portion of an ongoing casirivimab and imdevimab study showed a reduction in viral load and a decrease in medically-attended visits in non-hospitalised patients with COVID-19. These data were from two analyses of 799 symptomatic patients who received casirivimab and imdevimab or placebo added to standard of care. The data also showed that casirivimab and imdevimab were generally well-tolerated.

Casirivimab and imdevimab have the potential to provide an important treatment option for infected individuals already experiencing symptoms of COVID-19, and may be able to prevent disease in people exposed to the virus, to hopefully help slow the spread of the global pandemic.

**About casirivimab and imdevimab**
Casirivimab and imdevimab were 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. These two potent, virus-neutralising antibodies, administered together, bind non-competitively to the critical receptor binding domain of the virus's spike protein, which may help diminish 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.

**About Emergency Use Authorization status**
The United States FDA has made casirivimab and imdevimab available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

Casirivimab and imdevimab have not undergone the same type of review as an FDA-approved or cleared product. The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labelling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for casirivimab and imdevimab is in effect for the duration of the COVID-19 declaration – section 564(b)(1) of the Act, 21 U.S.C. § 360bbb- 3(b)(1) – justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

**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 manage, detect and diagnose current and/or previous infection in patients, as well as providing digital support to healthcare systems. 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 qualitative antibody test, aimed at detecting the presence of antibodies in the blood targeting the nucleocapsid protein (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 (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.

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 or the key secondary endpoint of reduced mortality.

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 plus standard of care reduced the likelihood of progression to mechanical ventilation or death in hospitalised patients with COVID-19 associated pneumonia compared to placebo plus standard of care. 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 October we signed an agreement with Atea to jointly develop AT-527, an orally administered direct-acting antiviral (DAA) currently in Phase 2 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.

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.

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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