

Statement



Roche statement on the preliminary phase III data from UK University of Oxford-led RECOVERY trial for casirivimab and imdevimab

Basel, 16 June 2021

On 16 June, The University of Oxford announced results from the phase III Randomised Evaluation of COVID-19 Therapy (RECOVERY) trial in the United Kingdom, an open-label trial in patients hospitalised with COVID-19. The data demonstrated that the investigational antibody cocktail of casirivimab and imdevimab reduced the risk of death when given to patients hospitalised with severe COVID-19 who had not mounted a natural antibody response of their own (seronegative). The trial also showed that the antibody combination shortened the time until patients were discharged from hospital and reduced their risk of progressing to mechanical ventilation or death. These benefits were not seen in the overall study population, which combined patients who had and who had not mounted a natural antibody response (seropositive and seronegative, respectively), and those whose serostatus could not be determined. The data are an important addition to the evolving body of evidence regarding the efficacy and safety of casirivimab and imdevimab for the treatment of people hospitalised with severe COVID-19.

We look forward to reviewing the preliminary data from this evaluation of casirivimab and imdevimab when the University of Oxford makes them available as a pre-print on medRxiv shortly.

In addition to RECOVERY, the investigational antibody cocktail continues to be evaluated in clinical trials in multiple settings for COVID-19, including non-hospitalised patients, in the preventive setting, as well as in hospitalised patients.

Although emergency authorisations have been granted in some countries, casirivimab and imdevimab remains an investigational medicine and has not been approved by the European Medicines Agency (EMA), United States (U.S.) Food and Drug Administration (FDA), or in any other country for use in any setting.

As the pandemic continues to have a major impact on public and individual health globally, the need for effective treatments remains urgent. There are still only a limited number of authorised medications for the treatment of COVID-19 available. Together with our partner Regeneron, we're working to report additional data from trials on an ongoing basis in both the therapeutic and preventive settings, and will continue working with global regulatory bodies on the next steps to bring the antibody cocktail to as many people as possible, if approved.

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

About the investigational antibody cocktail casirivimab and imdevimab

Based on available data, casirivimab and imdevimab is undergoing a rolling review from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP). Separately, and in parallel, in February 2021, the EMA's CHMP issued a scientific opinion under Article 5(3) supporting the use of the investigational antibody cocktail as a treatment option for patients with confirmed COVID-19 who do not require oxygen supplementation and who are at high risk of progressing to severe COVID-19. Casirivimab and imdevimab has also been authorised for emergency use in multiple countries for the treatment of defined non-hospitalised patients with COVID-19.

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 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 *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 US 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 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/RoActemra (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/RoActemra 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/RoActemra 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/RoActemra on top of usual care may provide a favourable benefit risk profile.

Roche remains committed to continuing the Actemra/RoActemra clinical trial programme in COVID-19 to further explore Actemra/RoActemra 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, 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, Roche 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 Pharmaceuticals 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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