

## **Roche and Regeneron collaborate to significantly increase global supply of REGN-COV2 investigational antibody combination for COVID-19**

- **REGN-COV2 is Regeneron's two-antibody combination currently in late-stage clinical trials for the treatment and prevention of COVID-19 infection.**
- **The companies will collaborate on developing and manufacturing REGN-COV2. Regeneron will distribute REGN-COV2 in the U.S. and Roche will be responsible for distribution outside the U.S.**
- **Under this collaboration, the overall capacity of REGN-COV2 is expected to increase by at least three and a half times, substantially increasing the number of doses available to patients in the U.S. and around the world.**

Basel, 19 August 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) and Regeneron (NASDAQ: REGN) announced today that they are joining forces in the fight against COVID-19 to develop, manufacture and distribute REGN-COV2, Regeneron's investigational antiviral antibody combination, to people around the globe. REGN-COV2 could provide a much-needed treatment option for people already experiencing symptoms of COVID-19, and also has the potential to prevent infection in people exposed to the virus, thus slowing the spread of the global pandemic. This collaboration is expected to increase supply of REGN-COV2 to at least three and a half times the current capacity, with the potential for even further expansion.

REGN-COV2 is currently being studied in two Phase 2/3 clinical trials for the treatment of COVID-19 and in a Phase 3 trial for the prevention of COVID-19 in household contacts of infected individuals. If it proves safe and effective in clinical trials and regulatory approvals are granted, Regeneron will distribute and record sales for REGN-COV2 in the U.S. and Roche will be responsible for distribution outside the U.S.

“We are excited about the potential for one medicine to serve both as a treatment for those infected as well as protection for people exposed to the virus. REGN-COV2 could be a critical line of defense against the COVID-19 pandemic,” said Bill Anderson, Chief Executive Officer of Roche Pharmaceuticals. “We're committing our manufacturing expertise and capacity, and our global distribution network to bring Regeneron's potential antibody combination to as many people around the world as we possibly can.”

“Regeneron has progressed the REGN-COV2 research and development program at record speed and worked tirelessly to maximize our in-house manufacturing capacity,” said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. “This major collaboration with Roche provides important scale and global expertise to bring REGN-COV2 to many more patients in the United States and around the globe.”

Under the terms of the agreement, each company has committed to dedicate a certain manufacturing capacity to REGN-COV2 each year, and the collaborators have already begun the technology transfer process. Each company will bear its own distribution expenses in their designated territories. The

collaborators will jointly fund and execute the ongoing Phase 3 prevention and Phase 1 healthy volunteers safety studies as well as additional global studies to evaluate further the potential for REGN-COV2 in treating or preventing COVID-19. Roche will be primarily responsible for securing regulatory approvals outside the U.S., following the initial European Medicines Agency (EMA) approval, and conducting any additional studies specifically required for approval by regulators outside the U.S.

### **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-neutralizing 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 have arisen 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**

The COVID-19 pandemic continues to evolve globally with varying developments from country to country and we are partnering with healthcare providers, laboratories, authorities and organisations to help make sure that patients receive the tests, treatment and care they need. This partnership is an additional step in Roche's fight against the COVID-19 pandemic, which has already included:

- Launching COVID-19 diagnostic tests for active infection and the detection of antibodies in patients who have been exposed to the virus,
- Investigating treatments from our existing portfolio to better understand their potential to treat patients with COVID-19,
- Increasing manufacturing and supply chain capacity to meet product demand across our portfolio within the wider context of COVID-19 treatment, and
- Ensuring the supply of our existing medicines and diagnostics to patients around the world under exceptional conditions.

Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic. On 13 March we received FDA Emergency Use Authorisation for a high-volume molecular test to detect SARS-CoV-2, the virus that causes COVID-19, which is also available in countries accepting the CE Mark. On 3 May, Roche announced that its COVID-19 antibody test, aimed at detecting the presence of antibodies in the blood, also received FDA Emergency Use Authorisation and is available in markets accepting the CE mark. Also in June we received an 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, which could help simplify the screening, diagnosis and monitoring of patients with respiratory compromise in the current COVID-19 pandemic. Roche is working closely with governments and health authorities around the world, and has significantly increased production to help ensure availability of tests globally.

We are actively involved in understanding the potential of our existing portfolio and are researching options for the future. Roche has an ongoing clinical trial program evaluating the role of Actemra®/RoActemra® (tocilizumab) in COVID-19 pneumonia. On 29 July we announced that the COVACTA trial did not meet its primary endpoint of improved clinical status in patients with COVID-19 associated pneumonia, or the key secondary endpoint of reduced patient mortality. The study was the first global, randomised, double-blind, placebo-controlled phase III trial investigating Actemra/RoActemra in this setting. 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 addition to COVACTA, Roche has initiated several studies to further investigate Actemra/RoActemra as a potential treatment for patients with COVID-19 associated pneumonia, including two phase III clinical trials, REMDACTA and EMPACTA, as well as the phase II MARIPOSA trial. 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 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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