Phase II/III trial shows Ronapreve™ (casirivimab and imdevimab) significantly reduces viral load within seven days of treatment in patients hospitalised with COVID-19

- **Trial met primary endpoint, showing Ronapreve significantly reduced viral load in seronegative patients hospitalised with COVID-19 who did not require high-flow oxygen or mechanical ventilation at baseline**
- **Clinical data complement previous findings in hospitalised setting, including from United Kingdom (UK) University of Oxford-led RECOVERY trial**

Basel, 30 September 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today confirmed positive data from the phase II/III 2066 study, investigating Ronapreve™ (casirivimab and imdevimab) in patients hospitalised with COVID-19. The trial met its primary endpoint, showing that Ronapreve significantly reduced viral load within seven days of treatment in patients who had not mounted a natural antibody response of their own (seronegative) and who required low-flow or no supplemental oxygen (p=0.0172). Full results of the study will be presented at ID Week 2021 today.

"COVID-19 continues to devastate communities with over 4.7 million recorded deaths worldwide[1], the majority of which were in hospitalised patients. While vaccines are effective in preventing hospitalisations, a significant unmet need remains in many who still get infected, and whose disease requires hospital care," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "These data add to previous findings that support the potential of Ronapreve in hospitalised patients, which may also help to ease pressure on healthcare systems."

The study also reported clinical results supportive of the much larger UK RECOVERY trial in hospitalised patients showing that patients who received Ronapreve (2,400 mg or 8,000 mg) in addition to standard-of-care treatment experienced numeric improvements across all clinical endpoints assessed, compared to standard of care alone (placebo). Comparable clinical outcomes were recorded with both 2,400 mg and 8,000 mg doses. No new safety signals were identified.

The efficacy and safety of Ronapreve have been studied across multiple phase III clinical trials in non-hospitalised and hospitalised COVID-19 patients, and in the preventive setting. Ronapreve is currently not authorised in patients who are hospitalised due to COVID-19 infection. Earlier this year, the European Medicines Agency's Committee for Medicinal Products for Human Use issued a scientific opinion supporting the use of Ronapreve as a treatment option for non-hospitalised patients with confirmed COVID-19. Outside the European Union, Ronapreve has been approved for use in different patient populations in Japan and conditionally in the UK, and is authorised for emergency or temporary pandemic use in numerous territories including the United States, India and Canada. In addition, the World Health Organization recently issued guidance regarding the use of Ronapreve for the treatment of certain patients with COVID-

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19. So far, Ronapreve has been made available to patients in more than 40 countries via bilateral purchase agreements across many geographies and economies, including lower middle-income countries.

In these exceptional times, Roche stands together with society, governments, healthcare providers and all those working towards the common goal of overcoming the COVID-19 pandemic.

About the REGN-COV 2066 study
The phase II/III, randomised, double-blind, placebo-controlled trial evaluated Ronapreve™ (casirivimab and imdevimab) in hospitalised adult patients with COVID-19. Of the 1,197 patients included in the efficacy analysis, 530 entered the trial with no supplemental oxygen and 667 were on low-flow oxygen. The safety analysis included results from all patients in the efficacy analysis plus additional patients from earlier stages of the clinical program who were on low-flow oxygen at baseline.

Patients were randomised 1:1:1 to receive a one-time infusion of Ronapreve 8,000 mg, Ronapreve 2,400 mg or placebo. All patients entering the trial were hospitalised with laboratory-confirmed COVID-19, and all received other background standard-of-care as required including corticosteroids (75%) and remdesivir (55%).

On average, patients included in the efficacy analysis had experienced symptoms for 6 days prior to entering the trial, and nearly half (43%) were seronegative. Approximately 30% were Hispanic and 12% were African American. Patients were on average 62 years of age, 54% were male and 46% were female.

No serious or dose-dependent safety signals in Ronapreve treated patients were observed. In a safety analysis involving 2,007 patients (Ronapreve=1,340, placebo=667) serious adverse events occurred in 21% Ronapreve patients (n=285) and 26% placebo patients (n=174). Infusion-related reactions and hypersensitivity reactions that were grade >2 occurred more commonly among Ronapreve patients (2% and 1% respectively) than placebo patients (1% and <0.5% respectively). The trial originally assessed a larger group of patients; however in late 2020 the trial was adjusted to exclude patients who were on mechanical ventilation or high-flow oxygen at baseline, based on a potential safety signal identified by an Independent Data Monitoring Committee in 199 patients on mechanical ventilation or high flow-oxygen, a finding that was not replicated in the much larger RECOVERY trial that enrolled hospitalized patients with a broad range of severe COVID-19, including these patient groups.

About Ronapreve™ (casirivimab and imdevimab)
Ronapreve™ (casirivimab and imdevimab) is being jointly developed by Roche and Regeneron. It is a combination of two monoclonal antibodies, casirivimab and imdevimab (also known as REGN10933 and REGN10987), and was designed to block infectivity of SARS-CoV-2, the virus that causes COVID-19. The

two potent, virus-neutralising antibodies 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. In addition, data from preclinical studies showed that Ronapreve retained neutralisation activity against key emerging variants, as referenced in publications in Cell and Nature.

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

The impact of COVID-19 goes beyond those who contract it. That is why we are working with healthcare providers, laboratories, authorities and organisations to help make sure patients continue to receive the tests, treatment and care they need during these challenging times. Building on a longstanding tradition of partnerships, we are working together with governments and others to make healthcare stronger and more sustainable in the future.

Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic and Roche has so far launched 16 diagnostics solutions to help minimise the impact of COVID-19. As soon as the novel SARS-CoV-2 virus was sequenced in early 2020, we got to work. On 13 March 2020 we became the first company to receive U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for a high-volume molecular test to detect the virus. Since then, we have continued to add a range of diagnostics solutions to our global portfolio to help in the fight against COVID-19. In addition to the gold standard PCR test, we have developed antigen tests to; help diagnose the virus in settings where there is limited molecular laboratory infrastructure, rapid antigen tests where the virus can be detected on the spot, tests that can test for both flu and COVID-19 at the same time, both high throughput and at the point of care, and tests that can detect virus antibodies that can help monitor the spread of the virus and can also support in vaccine development. On 16 March 2021 the SARS-CoV-2 variant test was launched, designed to detect key spike mutations.

Aside from these tests we have also looked at how we can support care for patients who have COVID-19, receiving 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, a digital algorithm that could help simplify the screening, diagnosis and monitoring of respiratory-compromised patients with COVID-19. Roche is working closely with governments and health authorities around the world, and has significantly increased production to support availability of tests globally.

Roche is actively involved in understanding the potential of the existing portfolio and is researching options for the future. In 2020, Roche entered into a number of new partnerships, including with Regeneron, Atea and Gilead to develop, manufacture and distribute molecules that can potentially both treat and prevent COVID-19.

In February 2021, the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) initiated a rolling review of our partner Regeneron's Ronapreve™ (casirivimab and imdevimab). In parallel, the CHMP issued a scientific opinion (under Article 5(3) of Regulation 726/2004) supporting the use of the 2,400 mg dose of Ronapreve as a treatment option for non-hospitalised patients with confirmed COVID-19 who do not require oxygen supplementation and who are at high risk for progressing to severe COVID-19, which can be used by European Union member states to support national decision making before a formal authorisation is issued. Ronapreve has been approved for use in Japan and conditionally in the United Kingdom, and is authorised for emergency or temporary pandemic use in additional territories such as the United States (US), India, Canada and several European countries. In addition, the World Health Organization issued guidance regarding the use of Ronapreve for the treatment of certain patients with COVID-19. The antibody combination has been studied in two phase I-III adaptive clinical trials for the treatment of COVID-19 and in a phase III trial for the prevention of the disease. As part of the global partnership with Regeneron, we are committing a significant amount of manufacturing capacity and are working to expand supply of this antibody combination beyond the US to as many people as possible.

In October 2020, Roche announced a partnership with Atea Pharmaceuticals to jointly develop the investigational compound AT-527. If approved, Atea will distribute AT-527 in the US and Roche will be responsible for global manufacturing and distribution outside the US. Atea's compound has the potential to be the first oral antiviral to treat COVID-19 patients outside the hospital setting as well as in the hospital. Its anticipated formulation (pill) may help to facilitate access to a broad patient population.

In addition, we have explored the potential of our existing medicine Actemra/RoActemra in three global phase III clinical trials investigating its safety and efficacy in COVID-19 associated pneumonia (COVACTA, EMPACTA and REMDACTA). In June 2021, Actemra/RoActemra received an EUA from the U.S. FDA for the intravenous treatment of COVID-19 in hospitalised adults and paediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation. ACTEMRA is not FDA-approved for this use. In addition, the World Health Organization issued guidance regarding the use of Actemra/RoActemra for the treatment of patients with COVID-19.

For more information on how Roche is responding to the global COVID-19 pandemic, please visit our COVID-19 response page.

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.

References

[1] World Health Organisation: Coronavirus (COVID-19) Dashboard. [Internet cited; September 2021] Available from: https://covid19.who.int/

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