Media Release

Roche initiates phase III clinical trial of Actemra/RoActemra plus remdesivir in hospitalised patients with severe COVID-19 pneumonia

- **Roche is also close to completing enrolment of a global randomised, double-blind, placebo-controlled phase III clinical trial of Actemra®/RoActemra® (tocilizumab) in hospitalised patients with severe COVID-19 pneumonia (COVACTA), with results expected this summer.**

Basel, 28 May 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the initiation of a global phase III, randomised, double-blind, multicentre study (REMDACTA) to evaluate the safety and efficacy of Actemra/RoActemra plus the investigational antiviral remdesivir, versus placebo plus remdesivir in hospitalised patients with severe COVID-19 pneumonia, in collaboration with Gilead Sciences, Inc.

“As more information about COVID-19 pneumonia becomes available in these unprecedented times, it is more important than ever to work together to fight this disease,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. "Based on our current understanding, we believe that combining an antiviral with an immune modulator could potentially be an effective approach to treating patients with severe disease. We're pleased to partner with Gilead to determine whether combining these medicines could potentially help more patients during this pandemic.”

The study is expected to begin enrolling in June with a target of approximately 450 patients globally, including the US, Canada and Europe.

In addition to REMDACTA, Roche is close to completing enrolment of the global randomised, double-blind, placebo-controlled phase III clinical trial (COVACTA, NCT04320615) to evaluate the safety and efficacy of intravenous Actemra/RoActemra plus standard of care (SOC), versus placebo plus SOC in hospitalised adult patients with severe COVID-19 pneumonia. The first patient was randomised on April 3. In total, approximately 450 patients will be enrolled in COVACTA. This increase from the original target of 330 patients will allow for even more robust data, while minimally extending the recruitment period. Roche is committed to sharing data from the COVACTA study as soon as possible this summer. In addition, the protocol for COVACTA allows the inclusion of patients who are being treated with antivirals, including investigational antivirals. Data from the REMDACTA trial are designed to supplement the COVACTA study.

The COVACTA study is conducted in collaboration with the US Food & Drug Administration (FDA) and the Biomedical Advanced Research and Development Authority (BARDA), a part of the US Health and Human Services Office of the Assistant Secretary for Preparedness and Response (ASPR). Roche is also a participant in the Accelerated COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, led by the National Institutes of Health (NIH) and the Foundation of the NIH.

Remdesivir has been issued an Emergency Use Authorisation by the US Food & Drug Administration (FDA) for the treatment of hospitalised patients with severe COVID-19. Remdesivir is an investigational antiviral

drug that is being studied in multiple ongoing international clinical trials, and the safety and efficacy of remdesivir for the treatment of COVID-19 are not yet established. Remdesivir has not been approved by the US FDA for any use. For information about the authorized use of remdesivir and mandatory requirements of the Emergency Use Authorisation in the US, please review the Fact Sheet for Healthcare Providers and FDA Letter of Authorisation available at www.gilead.com/remdesivir.

About the REMDACTA Clinical trial
REMDACTA is a two-armed global phase III, randomised, double-blind, multicentre study to evaluate the efficacy and safety of Actemra/RoActemra plus remdesivir, versus placebo plus remdesivir in hospitalised patients with severe COVID-19 pneumonia receiving standard of care (SOC). The primary and secondary endpoints include clinical status, mortality, mechanical ventilation, and intensive care variables. Patients will be followed for 60 days post-randomisation.

About the COVACTA Clinical Trial
COVACTA is a double-blind, placebo-controlled phase III study (COVACTA, NCT04320615) evaluating the safety and efficacy of intravenous Actemra/RoActemra added to standard of care in approximately 450 adult patients hospitalised with severe COVID-19 pneumonia compared to placebo plus standard of care. The primary endpoint is clinical status assessed using a 7-Category Ordinal Scale at day 28. The ordinal scale ranges from one (discharged from hospital) to seven (death), and covers different hospital locations such as non-intensive care unit (non-ICU) or ICU, and ventilation/treatment requirements, including not requiring supplemental oxygen, or requiring extracorporeal membrane oxygenation (ECMO) or mechanical ventilation and additional organ support. Key secondary endpoints include mortality, mechanical ventilation, clinical status at day 14, time to clinical improvement, and time to discharge.

About Actemra/RoActemra
Actemra/RoActemra was the first approved anti-IL-6 receptor biologic available in both intravenous (IV) and subcutaneous (SC) formulations for the treatment of adult patients with moderate-to-severe active rheumatoid arthritis (RA). Actemra/RoActemra can be used alone or with methotrexate (MTX) in adult RA patients who are intolerant to, or have failed to respond to, other disease-modifying anti-rheumatic drugs (DMARDs). In Europe, RoActemra IV and SC are also approved for use in adult patients with severe, active and progressive RA who previously have not been treated with MTX. Actemra/RoActemra IV and SC are approved globally for polyarticular juvenile idiopathic arthritis (pJIA) and in the US and Europe for systemic juvenile idiopathic arthritis (sJIA) in children two years of age and older. Actemra/RoActemra SC injection is also the first approved therapy for the treatment of giant cell arteritis (GCA) in more than 40 countries, including the US and Europe. In the US and Europe, Actemra/RoActemra IV injection is approved for the treatment of chimeric antigen receptor (CAR) T-cell-induced severe or life-threatening cytokine release syndrome (CRS) in people two years of age and older. Actemra/RoActemra was the first approved treatment for CRS in this setting. A prefilled autoinjector ACTPen has been approved in the US and Europe. In Japan, Actemra is also approved for the treatment of Castleman’s Disease, adult Still's disease and Takayasu Arteritis. Actemra/RoActemra is part of a co-development agreement with Chugai Pharmaceutical Co., Ltd and has been approved in Japan since April 2005. Actemra/RoActemra is approved in more than 110 countries worldwide.

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.

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. Our existing diagnostics portfolio for critical care has also been playing a significant role in supporting patient management during the COVID-19 crisis, with our blood gas and sepsis products being used to monitor patients in the acute setting. Roche is working closely with governments and health authorities around the world, and has significantly increased production to help ensure availability of tests globally.

While there are currently no approved medicines for the treatment of patients with COVID-19, we are actively involved in understanding the potential of our existing portfolio and are researching options for the future. 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. Roche has also initiated an internal early research programme focused on the development of medicines for COVID-19 and is evaluating a large number of potential 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.

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