Roche provides update on the phase III REMDACTA trial of Actemra/RoActemra plus Veklury in patients with severe COVID-19 pneumonia

- **The REMDACTA clinical trial of Actemra/RoActemra plus Veklury did not meet its primary endpoint of improved time to hospital discharge for patients with severe COVID-19 pneumonia or its key secondary endpoints compared to Veklury alone**
- **Roche will submit the REMDACTA results to a peer-reviewed journal**

Basel, 11 March 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the global phase III randomised, double-blind, multicentre REMDACTA study of Actemra®/RoActemra® (tocilizumab) plus Veklury® (remdesivir), versus placebo plus Veklury, did not meet its primary endpoint. This was measured by improved time to hospital discharge up to day 28 in patients with severe COVID-19 pneumonia receiving standard of care. No new safety signals were identified for Actemra/RoActemra in the REMDACTA trial. The study was conducted in collaboration with Gilead Sciences, Inc.

Roche will continue to evaluate data from the REMDACTA, COVACTA and EMPACTA studies as well as other studies of Actemra/RoActemra in COVID-19 pneumonia. The EMPACTA study met its primary endpoint, while COVACTA did not meet its primary endpoint. Both were recently published in the New England Journal of Medicine.

“Given the global impact of COVID-19 pneumonia on patients, we are disappointed that the REMDACTA study did not meet its endpoints,” said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development. “We continue to believe that the totality of data suggests a potential role for Actemra in treating certain patients with COVID-19, and will discuss the results with health authorities. We thank our partners at Gilead, and all the patients, investigators and healthcare professionals for their participation.”

REMDACTA did not meet key secondary endpoints, which included likelihood of death, likelihood of progression to mechanical ventilation or death, and clinical status. The full results of the trial will be submitted for publication in a peer-reviewed journal later this year.

Actemra/RoActemra is not approved for the treatment of COVID-19 pneumonia.

The antiviral medication Veklury was invented and developed by Gilead Sciences and is approved or authorized for temporary use for the treatment of COVID-19 in approximately 50 countries worldwide.

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

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About the REMDACTA Trial
REMDACTA is a two-armed global phase III, randomised, double-blind, multicentre study (REMDACTA, NCT04409262) to evaluate the efficacy and safety of Actemra/RoActemra plus Veklury, versus placebo plus Veklury in hospitalised patients with severe COVID-19 pneumonia receiving standard of care. Veklury is an antiviral medicine that works to stop replication of SARS-CoV-2, the virus that causes COVID-19. The REMDACTA trial is being conducted in collaboration with Gilead Sciences, Inc. The primary endpoint of the study is improvement in time to hospital discharge by Day 28. Key secondary endpoints include likelihood of death, likelihood of progression to mechanical ventilation or death, and clinical status. Clinical status is measured by the 7-category ordinal scale, which tracks patients' clinical status based on the need for intensive care and/or ventilator use, as well as supplemental oxygen requirements. Patients will be followed for 60 days post-randomisation.

About the COVACTA Trial
COVACTA is a global, randomised, double-blind, placebo-controlled phase III study (COVACTA, NCT04320615) which evaluated the safety and efficacy of intravenous Actemra/RoActemra added to standard of care in adult patients hospitalised with severe COVID-19 pneumonia compared to placebo plus standard of care. The primary and secondary endpoints included clinical status, mortality, mechanical ventilation and intensive care unit (ICU) variables. Patients were followed for 60 days post-randomisation.

About the EMPACTA Trial
EMPACTA (Evaluating Minority Patients with Actemra) is a phase III, randomised, double-blind, placebo-controlled multicentre study (EMPACTA, NCT04372186) which evaluated the efficacy and safety of Actemra/RoActemra in the treatment of hospitalised COVID-19 pneumonia among patients that are often underrepresented in clinical trials.

The primary endpoint was the cumulative proportion of participants dying or requiring mechanical ventilation by Day 28. Secondary endpoints included: time to clinical failure, defined as the time to death, mechanical ventilation, ICU admission, or withdrawal (whichever occurs first); mortality rate by Day 28; and time to hospital discharge or "ready for discharge."

About Actemra/RoActemra
Actemra/RoActemra was the first approved anti-IL-6 receptor biologic, and is 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 also approved globally for polyarticular juvenile idiopathic arthritis (pJIA) and systemic juvenile idiopathic arthritis (sJIA) in children two years of age and older. Actemra/RoActemra SC is approved globally for giant cell arteritis (GCA), and Actemra/RoActemra IV 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 sJIA, GCA and CRS. Actemra SC is now approved in the U.S. for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD). In addition to the above-mentioned indications, in Japan Actemra IV is also approved for the treatment of Castleman's disease and adult Still's disease, and the Actemra SC formulation is approved for 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

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 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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