Media Release

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

Basel, 19 March 2020- Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced we are working with the Food & Drug Administration (FDA) to initiate a randomised, double-blind, placebo-controlled Phase III clinical trial in collaboration with 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), to evaluate the safety and efficacy of Actemra®/RoActemra® (tocilizumab) plus standard of care in hospitalised adult patients with severe COVID-19 pneumonia compared to placebo plus standard of care.

This is the first global study of Actemra/RoActemra in this setting and is expected to begin enrolling as soon as possible in early April with a target of approximately 330 patients globally, including the US. The primary and secondary endpoints include clinical status, mortality, mechanical ventilation and intensive care unit (ICU) variables.

"We are initiating a clinical trial to study Actemra/RoActemra for the treatment of people hospitalised with COVID-19 pneumonia, so that we can better establish the potential role for Actemra/RoActemra in fighting this disease," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "In these unprecedented times, today's announcement is an important example of how industry and regulators can collaborate quickly to address the COVID-19 pandemic, and we will share the results as soon as possible."

To date, there are several independent clinical trials exploring the efficacy and safety of Actemra/RoActemra for the treatment of patients with COVID-19 pneumonia. Actemra/RoActemra has been included in the 7th updated diagnosis and treatment plan for COVID-19 issued by China's National Health Commission (NHC) on March 3, 2020.

However, this new trial is vital because there are no well-controlled studies and limited published evidence on the safety or efficacy of Actemra/RoActemra in the treatment of patients suffering from COVID-19. In addition, Actemra/RoActemra is not currently approved for this use by any health authorities, including the US Food and Drug Administration (FDA).

In addition to initiating this trial, Roche received FDA Emergency Use Authorisation for the cobas® SARS-CoV-2 Test on March 13, 2020, to detect the novel virus that causes COVID-19 disease. Learn more here.

About the Clinical Trial
Roche is initiating a randomised, double-blind, placebo-controlled Phase III study (COVACTA) to evaluate 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 include clinical status, mortality, mechanical ventilation and intensive care unit (ICU)

variables. Patients will be followed for 60 days post-randomisation, and an interim analysis will be conducted to look for early evidence of efficacy.

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 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
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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