Roche response to COVID-19 pandemic

- Roche accelerates delivery and production of Actemra
- Roche is working around the clock to increase availability of COVID-19 tests
- Roche calls on governments across the world to work closely with industry to keep manufacturing and supply running

Basel, 24 March 2020 - Roche Group (SIX: RO, ROG; OTCQX: RHHBY), today provided an update on the various actions the company is taking to address the COVID-19 pandemic.

Roche initiates global phase III study and collects data on Actemra’s potential utility in severe COVID-19 pneumonia patients

On March 19, 2020, Roche confirmed initiation of 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). The study, COVACTA, will evaluate the safety and efficacy of intravenous Actemra®/RoActemra® (tocilizumab) on top of standard of care in hospitalised adult patients with severe COVID-19 pneumonia compared to placebo on top of standard of care.

This is the first global study of Actemra/RoActemra in this setting. In addition to the Roche trial, Roche is also carefully following independently-led clinical trials, on multiple medicines including Actemra, that are taking place around the world.

At the moment, there are no robust, well-controlled studies showing safety and efficacy of Actemra in clinical treatment of COVID-19 pneumonia, and Actemra is not currently approved for this use.

Actemra Manufacturing and Supply

Despite some of the supply and logistics challenges due to COVID-19, Roche has been able to continue to deliver life-saving medicines to patients around the world, thanks to the resilience of its global network. Currently, we continue to see limited disruption, and are continually monitoring the situation.

With the announcement of new clinical trials, and a potential increase in demand for Actemra, Roche is working urgently to accelerate manufacturing capacity to maximize production of Actemra wherever possible with the goal of increasing available supply globally.

While Roche is ensuring a coordinated, global overview of additional supply requests, provision of medicines is managed on a country level according to local rules and regulations and in close collaboration with the authorities.
**Cobas® SARS-CoV-2 Test to detect the novel virus that causes COVID-19 disease**

As a leader in diagnostics, Roche is committed to providing testing solutions for the world’s most challenging healthcare emergencies. On March 12, 2020, Roche received FDA Emergency Use Authorization for the cobas® SARS-CoV-2 Test to detect the novel virus that causes COVID-19 disease. The test is also available in markets accepting the CE mark.

Roche is committed to delivering as many tests as possible within the limits of supply and delivering its coronavirus tests to areas where they can be immediately effective. Tests will be shipped from Roche’s production sites to locations where appropriate infrastructure is in place and testing can begin without delay. At the current maximum production rate, Roche can supply millions of tests per month on the cobas 6800/8800 instruments and on the MagnaPure / Lightcycler solution. Roche is working around the clock to increase that quantity as the company recognises the importance of patients having access to these critical tests.

To safeguard supply, Roche strongly advises to focus COVID-19 testing on patients with signs and symptoms of the disease, not broad testing of the healthy population.

**Industry, governments and society must work together to tackle this pandemic**

Roche is committed to doing all we can to ensure adequate supply of our medicines and tests during this pandemic, but we cannot do it alone. Roche is calling on governments across the world to work closely with industry to keep manufacturing and supply running, and to help us meet demand across the globe.

- Ensure the free flow of vital goods across national borders to keep manufacturing and supply running;
- Consider pragmatic temporary adjustments to regulations on packaging, reviews, customs etc, to expedite delivery of urgently needed medical supplies;
- Work together across governments internationally, in order to balance global needs.

**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.

All trademarks used or mentioned in this release are protected by law.

Roche Group Media Relations
Phone: +41 61 688 8888 / e-mail: media.relations@roche.com
- Nicolas Dunant (Head)
- Patrick Barth
- Daniel Grotzky
- Karsten Kleine
- Nathalie Meetz
- Barbara von Schnurbein