Roche SARS-CoV-2 Rapid Antigen Test receives special approval for at-home patient self-testing using nasal swabs in Germany

- **Special approval from German Federal Institute for Drugs and Medical Devices (BfArM) enables home use of a SARS-CoV-2 Rapid Antigen Test using a simple nasal swab**
- **The test will be widely available in pharmacies across Germany**

Basel, 26 February 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced it has been granted special approval by the German Federal Institute for Drugs and Medical Devices (BfArM) to offer the SARS-CoV-2 Rapid Antigen Test using a simple nasal swab for patient self-testing in Germany.

The test is a reliable rapid test for the qualitative detection of a specific SARS-CoV-2 antigen in nasal swab samples.This rapid antigen test collects the sample from the front area of the nose instead of the nasopharynx, resulting in a simplified and more comfortable sampling procedure. By following simple instructions, patients can perform the test at home with results ready after only 15 minutes. The test will be made available in pharmacies and requires no prescription.

The German Federal Institute for Drugs and Medical Devices' special approval of our test provides people in Germany with a reliable option to test themselves in the comfort of their own home," said Thomas Schinecker, CEO Roche Diagnostics. "Regular self-testing at home can reduce pressure on healthcare systems. It can quickly identify people with the highest potential to be infectious so they can take immediate action to manage their infection, seek medical advice and protect others."

This test is part of a partnership with SD Biosensor Inc., with whom Roche has also launched a SARS-CoV-2 Rapid Antibody Test in July and two SARS-CoV-2 Rapid Antigen Tests for professional use in September 2020 and February 2021. Those tests will continue to play an important role in this pandemic and remain available for healthcare professional testing.

Roche continues to expand its comprehensive COVID-19 portfolio to support healthcare systems in diagnosing SARS-CoV-2 infection.

About the SARS-CoV-2 Rapid Antigen Test for at-home patient self-testing
The SARS-CoV-2 Rapid Antigen Test for self testing is a rapid chromatographic immunoassay for the qualitative detection of the nucleocapsid protein of SARS-CoV-2 present in human nasal specimens. In a self-testing clinical study, the SARS-CoV-2 Rapid Antigen Test showed a sensitivity of 82.5% and a specificity of 100.0% when compared to RT-PCR testing. The relative sensitivity was 91.2% for samples with a high viral load (Ct ≤30). Patients suspected of COVID-19 followed written and illustrated instructions to sample and test themselves[1]. Most study participants considered the procedures easy to perform.

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About antigen testing
An antigen test detects proteins which are structural or functional components of a pathogen and are very specific to that pathogen[2]. In this case, the test would provide a qualitative "yes/no" answer on the presence of the antigen in the patient sample and can be offered as a rapid strip test that is performed at the point of care. If the target antigen (nucleocapsid protein) is present in sufficient concentrations in the sample, it will bind to specific antibodies and generate a visually detectable signal on the test strip, typically with results ready in 15 minutes. A rapid antigen test can reliably detect individuals with a high viral load allowing healthcare professionals to quickly identify those patients at the greatest risk of spreading the infection.[3]

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. This new test is an additional step in Roche's fight against the COVID-19 pandemic, which has already included:

- Launching COVID-19 diagnostic tests for active infection and the detection of antibodies in patients who have been exposed to the virus,
- Investigating treatments from our existing portfolio to better understand their potential to treat patients with COVID-19,
- Increasing manufacturing and supply chain capacity to meet product demand across our portfolio within the wider context of COVID-19 treatment, and
- Ensuring the supply of our existing medicines and diagnostics to patients around the world under exceptional conditions.

Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic. On 13 March 2020 we received FDA Emergency Use Authorization 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 2020, Roche announced that its COVID-19 antibody test, aimed at detecting the presence of antibodies in the blood, also received FDA Emergency Use Authorization and is available in markets accepting the CE mark. Also in June of last year we received 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, which could help simplify the screening, diagnosis and monitoring of patients with respiratory compromise in the current COVID-19 pandemic. In July of 2020, we added a Rapid Antibody Test, with SD Biosensor as manufacturing partner, to the portfolio, that allows the detection of antibodies against COVID-19 at the point of care, a Rapid Antigen Test in September and a lab-based Antigen Test in December. Roche is working closely with governments and health authorities around the world, and has significantly increased production to help ensure availability of tests globally.

Roche is actively involved in understanding the potential of the existing portfolio and is researching options for the future. Roche has an ongoing clinical trial program evaluating the role of Actemra©/RoActemra©

(tocilizumab) in COVID-19 pneumonia. On 29 July 2020 Roche announced that the COVACTA trial did not meet its primary endpoint of improved clinical status in patients with COVID-19 associated pneumonia, or the key secondary endpoint of reduced patient mortality. The study was the first global, randomised, double-blind, placebo-controlled phase III trial investigating Actemra/RoActemra in this setting. Roche remains committed to continuing the Actemra/RoActemra clinical trial programme in COVID-19 to further explore Actemra/RoActemra in other treatment settings, including in combination with an antiviral. In addition to COVACTA, Roche has initiated several studies to further investigate Actemra/RoActemra as a potential treatment for patients with COVID-19 associated pneumonia, including two phase III clinical trials, REMDACTA and EMPACTA, as well as the phase II MARIPOSA trial. Roche has further initiated an internal early research programme focused on the development of medicines for COVID-19 and is engaged in multiple research collaborations. On 19 August 2020, Roche announced a partnership with Regeneron to develop, manufacture and distribute REGN-COV2, Regeneron's investigational antiviral antibody combination, to people around the globe. On 18 October 2020, Roche announced a collaboration with Atea Pharmaceuticals to develop a potential oral treatment for COVID-19 patients.

In these exceptional times, Roche stands together with governments, healthcare providers and all those working to overcome the pandemic.

About SD Biosensor
SD Biosensor is a global in-vitro diagnostic company focused on the development of immunoassay and molecular diagnostic products at the POC. Founded in 2010, SD Biosensor has continued to research and develop products that can aid in the fast and accurate diagnosis of patients across the testing journey. Through these innovative products, they are striving to become a leading global in vitro diagnostics company.

For more information, please visit www.sdbiosensor.com.

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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