Media Release

Roche's cobas SARS-CoV-2 Test to detect novel coronavirus receives FDA Emergency Use Authorization and is available in markets accepting the CE mark

- **First commercial test for SARS-CoV-2 will enable expedited coronavirus testing to meet urgent medical needs**
- **Testing on widely available, high-volume cobas 6800/8800 will significantly increase available testing capacity**
- **Roche expedites test development to support urgent need for patient testing during pandemic outbreak to avoid a further spread of the virus at an early stage of infection**

Basel, 13 March 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the cobas® SARS-CoV-2 Test. It is intended for the qualitative detection of SARS-CoV-2, the virus that causes COVID-19 disease, in nasopharyngeal and oropharyngeal swab samples from patients who meet COVID-19 clinical and/or epidemiological criteria for testing. Hospitals and reference laboratories can run the test on Roche's fully automated cobas® 6800 and cobas® 8800 Systems, which are widely available in the U.S. and around the world.

The CE-IVD test is also available in markets accepting the CE mark for patients with signs and symptoms of COVID-19 disease and living in affected areas where the SARS-CoV-2 virus is known to be present.

"Providing quality, high-volume testing capabilities will allow us to respond effectively to what the World Health Organization has characterized as a pandemic. It is important to quickly and reliably detect whether a patient is infected with SARS-CoV-2," said Thomas Schinecker, CEO of Roche Diagnostics. "Over the last weeks, our emergency response teams have been working hard to bring this test to the patients. CE-mark certification and the FDA's granting of EUA supports our commitment to give more patients access to reliable diagnostics which are crucial to combat this serious disease."

The widely available Roche's cobas 6800/8800 Systems, which are used to perform the cobas SARS-CoV-2 Test, provide test results in three and half hours and offer improved operating efficiency, flexibility, and fastest time-to-results with the highest throughput providing up to 96 results in about three hours and a total of 1,440 results for the cobas 6800 System and 4,128 results for the cobas 8800 System in 24 hours. The test can be run simultaneously with other assays provided by Roche for use on the cobas 6800/8800 Systems.

Upon authorisation Roche will have millions of tests a month available for use on the cobas 6800 and 8800 systems. Roche is committed to delivering as many tests as possible and is going to the limits of our production capacity.

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About Emergency Use Authorization Status
The cobas SARS-CoV-2 Test has not been FDA cleared or approved. It has been authorized by the FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform moderate and high complexity tests. The test has been authorised only for the detection of RNA from SARS-CoV-2 virus and diagnosis of SARS-CoV-2 virus infection, not for any other viruses or pathogens. It is only authorised for the duration of the declaration that circumstances exist justifying the authorisation of the emergency use of in vitro diagnostics for detection of SARS-CoV-2 virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the authorisation is terminated or revoked sooner.

About SARS-CoV-2 (coronavirus)
Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). The novel coronavirus (SARS-CoV-2) is a new strain which has not previously been identified in humans.[1]

Signs of infection include respiratory symptoms such as cough, shortness of breath, difficulty breathing, and fever. In more severe cases, pneumonia, severe acute respiratory syndrome, kidney failure and death can occur.

To control the spread of the infection, WHO recommends regular hand washing, covering mouth and nose when coughing and sneezing, thoroughly cooking meat and eggs and avoiding close contact with anyone showing symptoms of respiratory illness.

About cobas SARS-CoV-2 Assay
The cobas SARS-CoV-2 Test is a single-well dual target assay, which includes both specific detection of SARS-CoV-2 and pan-sarbecovirus detection for the sarbecovirus subgenus family that includes SARS-CoV-2. The test is a real-time RT-PCR test intended for the qualitative detection of nucleic acids from SARS-CoV-2 in nasopharyngeal and oropharyngeal swab samples from patients who meet the CDC SARS-CoV-2 clinical criteria.The test runs on the cobas 6800/8800 Systems and has a full-process negative control, positive control and internal control.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The cobas SARS-CoV-2 is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. In the United States, the cobas SARS-CoV-2 is only for use under the FDA's Emergency Use Authorization.

About the cobas 6800/8800 Systems
Since 2014, the cobas 6800 and cobas 8800 Systems have established the new standard for routine molecular

testing by delivering fully integrated, automated solutions that serve the areas of viral load monitoring, donor screening, sexual health and microbiology. Based on Nobel prize-winning PCR technology, the systems deliver proven performance with full automation, increased throughput, fast turnaround time and complete track connectivity validated for molecular testing, providing users with greater flexibility to consolidate their IVD and LDT testing to a single system while increasing overall workflow efficiencies.

Our global install base for the cobas 6800 and 8800 Systems is 695 and 132 respectively. The systems provide up to 96 results in about three hours and a total of 1,440 results for the cobas 6800 System and 4,128 results for the cobas 8800 System in 24 hours. Both make it possible for labs to perform up to three tests in the same run with no pre-sorting required. The systems also enable up to eight hours (cobas 6800 System) and four hours (cobas 8800 System) of walk-away time with minimal user interaction. cobas 6800 and cobas 8800 Systems are the only fully automated molecular systems designated as moderately complex by the Clinical Laboratory Improvement Amendments (CLIA).

For more information about the tests and system, please visit www.diagnostics.roche.com

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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.

References

[1] https://www.who.int/health-topics/coronavirus. Accessed 23Jan2020

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