Media & Investor Release

Roche receives FDA EUA for cobas SARS-CoV-2 Duo, the first PCR test to simultaneously detect COVID-19 and quantitatively measure viral load levels of COVID-19

- **The cobas SARS-CoV-2 Duo test combines the standard qualitative result of a traditional SARS-CoV-2 PCR test with a quantitative result, which measures the viral load of a patient suspected of COVID-19.**
- **Potential benefits of the cobas SARS-CoV-2 Duo test aim to help the healthcare community with contact tracing, patient triage and the approach to medical care.**
- **Since the start of pandemic, Roche has focused on bringing effective diagnostic solutions to healthcare communities worldwide in the fight against COVID-19**

Basel, 15 June 2022 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) for the cobas SARS-CoV-2 Duo for use on the fully automated cobas 6800/8800 Systems, expanding the Roche COVID-19 portfolio. This is the first automated, real-time RT-PCR assay for the in vitro qualitative and quantitative detection of SARS-CoV-2 RNA in nasal and nasopharyngeal swab specimens.

"With the SARS-CoV-2 Duo test, we are now able to detect the COVID-19 virus and simultaneously measure the viral load in an individual," said Thomas Schinecker, CEO Roche Diagnostics. "The test's performance suggests that, by earlier and more accurately identifying infected patients, the results may open the path for healthcare providers to more efficiently organise their therapeutic and monitoring interventions."

The quantitative result is traceable to the World Health Organization (WHO) International Standard for SARS-CoV-2 RNA. The potential benefits from reporting a standardized viral load along with the qualitative result may help clinicians in the assessment and monitoring of infected patients across laboratories and over time.

Roche continues to add a range of diagnostic solutions to our global portfolio to help in the fight against COVID-19. For more information on how Roche is responding to the global COVID-19 pandemic, please visit our COVID-19 response page.

The test will be available in the United States by Q2 2022.

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

About the cobas SARS-CoV-2 Duo test

The cobas SARS-CoV-2 Duo test received Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA) on June 14, 2022. The cobas SARS-CoV-2 Duo for use on the cobas® 6800/8800 Systems is an automated real-time RT-PCR assay for the qualitative detection of SARS-CoV-2 RNA in healthcare provider instructed self-collected nasal swab specimens (collected on site), and healthcare provider-collected nasal and nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider. This assay also performs quantitation of SARS-CoV-2 RNA levels in the collected specimen; however, only the qualitative result of cobas® SARS-CoV-2 Duo is intended for use as an aid in the diagnosis of SARS-CoV-2 infection in patients suspected of COVID-19 by their healthcare provider.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognizing our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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.

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD
Phone: +41 61 687 41 47

Karsten Kleine
Phone: +41 61 682 28 31

Nina Mählitz
Phone: +41 79 327 54 74

Nathalie Meetz
Phone: +41 79 771 05 25

Dr. Barbara von Schnurbein
Phone: +41 61 687 89 67

Sileia Urech
Phone: +41 79 935 81 48

Roche Investor Relations

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com