Media Release

Pleasanton, 29, August 2016

Roche receives FDA Emergency Use Authorization for Zika PCR test

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 LightMix® Zika rRT-PCR Test. The product is for use in patients meeting CDC Zika virus clinical criteria and/or CDC Zika virus epidemiological criteria. The test is used for the detection of Zika virus in EDTA plasma or serum samples using Roche's LightCycler® 480 Instrument II or **cobas z** 480 Analyzer.

"The LightMix Zika test is an easy-to-use molecular diagnostic test that enables healthcare professionals to quickly detect the virus," said Uwe Oberlaender, Head of Roche Molecular Diagnostics. "As a leader in diagnostics, Roche is committed to providing testing solutions for the world's most challenging healthcare emergencies. The FDA's granting of this EUA supports our commitment to help healthcare professionals who are working to combat this serious disease."

In addition to the LightMix® Zika rRT-PCR Test, Roche has also developed the cobas® Zika Test for use with the cobas® 6800/8800 Systems. This test is available under an Investigational New Drug Application (IND) protocol to initiate collection and testing of blood samples for screening. It is currently being utilized in blood centres in the United States.

About the LightMix® Zika rRT-PCR Test

Manufactured by TIB MOLBIOL GmbH and exclusively distributed by Roche, the LightMix® Zika rRT-PCR Test is an assay for the qualitative detection of Zika viral RNA in combination with a full process RNA control that monitors all steps from extraction to PCR result. Nucleic acid extraction is authorised to be performed with Roche's MagNA Pure Compact Instrument (and Isolation Kit I – Large Volume) or, for laboratories wanting to process a higher number of samples, the MagNA Pure 96 Instrument (and DNA and Viral NA Large Volume Kit) for high-throughput automated extraction. The test was developed to run on the LightCycler® 480 Instrument II or **cobas z** 480 Analyzer, allowing the utilization of a broad installed instrument base. The end-to-end automated process from sample preparation to results for up to 96 samples can be performed in just 2.5 hours.

About Emergency Use Authorization Status

The LightMix® Zika rRT-PCR 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 high complexity tests, or by similarly qualified non-U.S. laboratories. The test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens. It is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Zika virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

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 front-runner in diabetes management. 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.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine 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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 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.

About TIB MOLBIOL, GmbH

Since 1990, TIB MOLBIOL has been providing high quality products used in the fields of life science research, medical diagnostics, product quality assessment and environmental analysis. Head Quartered in Berlin, Germany, TIB Molbiol has offices and production facilities in the USA, Italy, Spain and Poland. The company's presence in several countries has facilitated the support and cooperation with its customers and increased its potential to quickly respond to critical biological threats such as Ebola, SARS, Anthrax, Avian Influenza H5N1 and the novel Influenza H1N1 swine. For more information, please visit www.tib-molbiol.com.

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