Media Release

Roche responds to WHO's declaration of a global health emergency due to the ongoing mpox outbreak

- **Roche is committed to supporting all those working to overcome the mpox outbreak by providing access to high-quality Polymerase Chain Reaction (PCR) testing**
- **Roche confirms that its cobas MPXV test, as well as the LightMix® research use only kits, detect the latest mpox virus variants**
- **It is actively working to enhance laboratory testing capacity for mpox worldwide**

Basel, 20 August 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it is supporting the international response to the mpox global health emergency with its diagnostic tests developed for mpox, formerly known as monkeypox. Mpox, a viral disease that can spread easily between people and from infected animals, was declared a Public Health Emergency of International Concern by the World Health Organization (WHO) (14 August 2024).

Globally, Roche is partnering with governments, healthcare providers and organisations dedicated to combating the mpox outbreak. More specifically, Roche is actively working with its partners to enhance mpox laboratory capacity worldwide. In addition, Roche provides training for laboratories across the African continent at the Roche Scientific Campus in South Africa, as well as locally.

"Our commitment to support the global response to mpox began in 2022 when we developed a suite of tests to enable global access to rapid and high-quality PCR testing," said Matt Sause, CEO of Roche Diagnostics. "Diagnostics are essential in addressing emerging public health challenges like mpox, as they enable healthcare providers to identify infected patients, devise effective treatment strategies and take appropriate actions."

To detect the mpox virus, Roche developed three unique LightMix® Modular Virus kits* for use on either a LightCycler®480 II Instrument*, LightCycler® PRO or cobas® z 480 Analyzer, as well as the cobas® MPXV test for use on the cobas® 6800/8800 Systems.

About the LightMix Modular Orthopox / MonkeypoxVirus Kits

In May 2022, Roche and its subsidiary TIB Molbiol rapidly developed a new suite of tests that detect the virus that causes mpox and aid in following its epidemiologic spread. The LightMix Modular Orthopox / Monkeypox Virus Kits are assays that detect Orthopoxviruses, including the virus that causes mpox, using a technology called quantitative PCR (qPCR). To do this, the test is performed with a patient sample that is first extracted using an established nucleic acid (NA) extraction method. The assay is then performed on either a LightCycler®480 II Instrument*, LightCycler® PRO or cobas® z 480 Analyzer.

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The LightMix Modular Orthopox / Monkeypox Virus kits are intended for use in confirmatory testing (evaluation and validation) in public health labs as Research Use Only, and are designed for research use in the majority of countries worldwide.

About the cobas MPXV test

In November 2022, the FDA granted Roche Emergency Use authorization (EUA) for the cobas MPXV test for use on the high-throughput cobas 6800/8800 Systems. The cobas MPXV test is an automated, real-time PCR test for the qualitative detection of DNA from the virus (MPXV) that causes mpox in human lesion swabs collected from individuals suspected of mpox infection by their healthcare provider and uses a dual-target approach. This approach ensures that cobas MPXV will continue to detect the virus even if a mutation occurs in one target region.

About the virus

MPXV was first detected in laboratory monkeys in 1958. The virus is, however, assumed to be transmitted from wild animals such as rodents to people – or from human to human. Symptoms of mpox include fever, chills, headaches, muscle aches, fatigue, swollen lymph nodes and a painful rash that characteristically appears as raised bumps on the skin and tends to be distributed on the face, extremities and genitals. As the disease progresses, these bumps fill with pus and fluid and become umbilicated. They will eventually ulcerate, scab and fall off. [1]

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 recognising our endeavour 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 fifteenth 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.

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* These products are for Research Use Only. Not for use in diagnostic procedures.

References

[1] World Health Organization factsheet monkeypox. Available at: https://www.who.int/news-room/fact-sheets/detail/monkeypox. Accessed 15 August 2024.

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