Roche receives FDA clearance for BK virus quantitative test on cobas 6800/8800 Systems to support better care for transplant patients

- **Immunocompromised transplant patients are at risk of major complications when infected with BK virus**
- **cobas BKV test addresses critical need for hospitals and laboratories to have standardised and comparable results across institutions**
- **New Breakthrough Device test expands Roche molecular test menu for transplant patients, enabling simultaneous testing of BK virus with Cytomegalovirus and Epstein-Barr virus**

Basel, 8 September 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced U.S. Food and Drug Administration (FDA) 510k clearance for the cobas® BKV Test on the cobas® 6800 and 8800 Systems. The test was previously granted FDA Breakthrough Device designation demonstrating the improved treatment or diagnosis of life-threatening diseases or conditions for transplant patients. The test provides standardised, high-quality results that can help healthcare professionals better assess the risk of complications caused by the BK virus in transplant patients and identify effective treatment options.

BK virus (BKV) is a member of the polyomavirus family that can cause severe transplant-associated complications. Infection can occur without symptoms and happen early in life. After primary infection, the virus can remain inactive, only to possibly reactivate in immunocompromised individuals such as transplant recipients.

“Our diagnostic tests can help clinicians greatly improve patient treatment plans and make quick adjustments for personalised healthcare,” said Thomas Schinecker, CEO Roche Diagnostics. “This FDA clearance allows Roche to offer healthcare professionals a transplant testing portfolio that includes Cytomegalovirus, Epstein-Barr virus and BK virus so they can simultaneously monitor and improve care for transplant patients who are at risk for these common infections or viral reactivations which can cause further illness or death.”

The cobas BKV Test is a polymerase chain reaction (PCR) viral load test that runs on the fully automated and widely available cobas® 6800 and cobas® 8800 Systems. Along with the previously approved cobas® EBV and CMV Tests, the cobas BKV Test has been calibrated to the World Health Organization (WHO) International Standard. This means that test results are reported in international units, making it possible for laboratories anywhere in the U.S. to obtain comparable results when measuring levels of BKV DNA.

About the cobas BKV Test
The cobas BKV Test was previously granted Breakthrough Device Designation by the FDA, together with the cobas EBV Test.

The cobas BKV Test is a real-time polymerase chain reaction (PCR) test with dual-target technology that

provides quantitative accuracy and guards against the risk of sequence variations that may be present in the BK virus. The cobas BKV Test has robust coverage with a limit of detection of 21.5 IU/mL and an expanded linear range from 21.5 IU/mL to 1E+08 IU/mL in EDTA plasma.

The test offers an alternative to lab-developed tests (LDTs) or Analyte Specific Reagent (ASR) combinations, potentially minimising variability and complexity in testing, reducing workload and alleviating risk for laboratories. The test supports the goal of result standardisation across institutions by providing reproducible, high-quality results for clinical decision-making.

The fully automated cobas BKV Test and the cobas CMV and cobas EBV Tests can run on the cobas 6800/8800 Systems simultaneously, providing absolute automation with proven performance and flexibility, leading to time savings and increased efficiency.

About BK polyomavirus
BK polyomavirus (BKV) is a member of the polyomavirus family that can cause transplant-associated complications including nephropathy in kidney transplantation and hemorrhagic cystitis in hematopoietic stem cell transplantation. Infection can occur early in life, often with no symptoms. After primary infection, the virus can remain inactive throughout life, only to possibly reactivate in immunocompromised individuals, such as patients who receive solid-organ transplants. For kidney transplant patients, BKV infection is considered the most common viral complication, causing polyomavirus nephropathy (PVN) in up to 10 percent of kidney transplant recipients, and about 50 percent of PVN-affected patients will experience transplant graft failure.[1] BKV is also associated with hemorrhagic cystitis after allogeneic hematopoietic stem cell transplantation.[2]

About the cobas 6800/8800 Systems
When every moment matters, the fully automated cobas 6800/8800 Systems offer the fastest time to results with the highest throughput and the longest walk-away time available among automated molecular platforms. The systems provide up to 96 results in about three hours and 384 results for the cobas 6800 System and 1,056 results for the cobas 8800 System in an eight hour shift.*

Both systems 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.*

These real-time PCR systems serve the areas of infectious disease, donor screening, sexual health, transplant, respiratory and antimicrobial stewardship.

Through an ever-increasing worldwide install base of cobas 6800/8800 Systems, labs are quickly and easily processing millions of tests per month to meet the changing demands of their communities, their customers,

and the patients relying on the results of each assay. Globally, labs know and trust that a Roche assay guarantees high precision, accuracy, and traceability to World Health Organization standards.

Today, rapid advancements in healthcare technology, a shortage of skilled workers, industry-wide consolidation, and the proven need to be ready for the next outbreak have health systems looking to lay a reliable foundation for the future. With proven performance, absolute automation, and unmatched flexibility delivering unparalleled throughput 24/7—cobas 6800/8800 Systems are designed to ensure a lab's long-term sustainability and success … now, more than ever.

Learn more now: www.cobas68008800.com or http://diagnostics.roche.com.
*May vary based on workflow demands

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.

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