Media Release

Pleasanton, July 5, 2012

Roche receives FDA approval for Cytomegalovirus viral load test

First FDA-approved laboratory test for quantifying DNA of potentially deadly virus helps physicians manage organ transplant patients on antiviral therapy

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received premarket approval (PMA) from the U.S. Food and Drug Administration (FDA) for a new test to assess a patient's viral load of cytomegalovirus (CMV). The fully automated COBAS® AmpliPrep / COBAS® TaqMan® CMV Test is the first FDA-approved laboratory test for use in quantifying CMV DNA in human plasma specimens. Physicians use CMV DNA viral load information from the test to help manage patients who have been diagnosed with CMV disease, specifically patients whose immune system has been suppressed for solid organ transplantation.

"We are pleased to offer this innovative test to address a key medical need for immunosuppressed solid organ transplant patients," said Paul Brown, Ph.D., head of Roche Molecular Diagnostics. "With this test, laboratories now have an FDA-approved option for standardized and automated CMV viral load testing that improves the laboratory's workflow. It provides physicians with clinically useful information to aid in the management of solid organ transplant patients with CMV disease."

Roche's new real-time polymerase chain reaction (PCR)-based CMV test is designed for use on the fully automated COBAS® AmpliPrep/COBAS® TaqMan® System, an established platform for viral load monitoring of multiple infectious diseases. The system can be combined with the **cobas p** 630 Instrument, which provides an integrated pre-analytical primary tube handling solution.

Roche expects to begin shipping the new CMV test kit in the U.S. in August 2012.

About the test

The COBAS® AmpliPrep / COBAS® TaqMan® CMV Test is intended for use as an aid in the management of solid-organ transplant patients who are undergoing anti-CMV therapy. In this population, the test can be used to assess virological response to antiviral treatment. The

test is traceable to the first WHO International Standard for Human Cytomegalovirus for Nucleic Acid Amplification Techniques (NIBSC 09/162) and reliably monitors cytomegalovirus (CMV) infections.

About the COBAS AmpliPrep/COBAS TaqMan System

Roche's fully automated COBAS® AmpliPrep/COBAS TaqMan® System combines the COBAS AmpliPrep Instrument for automated sample preparation and the COBAS® TaqMan® Analyzer or the smaller COBAS TaqMan 48 Analyzer for automated real-time PCR amplification and detection. The COBAS AmpliPrep/COBAS TaqMan® System has parallel processing with other key molecular diagnostics assays targeting medically relevant diseases (Hepatitis B virus, Hepatitis C virus, and Human Immunodeficiency Virus). Roche's AmpErase enzyme is also included in each test and is designed to prevent cross-contamination of samples and labs.

About Cytomegalovirus

CMV is the most common and important viral infection in solid organ transplant (SOT) recipients. The virus can be transmitted through the donor organ, resulting in CMV infection and leading to the development of CMV disease, or can occur by reactivation of the virus in transplant recipients with previous CMV infection. CMV disease in transplant recipients may be similar to infectious mononucleosis with fever, malaise and mild laboratory abnormalities, or can be more serious with inv olvement of the lung or gastrointestinal tract. Between 50 – 80% of all people in the US become infected with CMV. Although healthy persons usually have few symptoms at the time of initial infection, after infection the virus remains in a latent state in the body for the rest of a person's life. The virus can then be transmitted and cause infection through organ donation, or latent virus in the transplant recipient can become reactivated and cause symptomatic disease.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2011, Roche had over 80,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted

sales of 42.5 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.