# Media Release



Pleasanton, March 31, 2011

## Roche's test for Cytomegalovirus is approved in Europe

## Test measures viral load of potentially deadly virus for transplant patients

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that its Cytomegalovirus (CMV) test<sup>1</sup> is now commercially available in Europe. CMV viral load testing helps physicians manage immunocompromised patients at risk of CMV disease, including those who have undergone solid organ and stem cell transplantation. This standardized and fully automated test monitors CMV infections using an easy-to-operate system capable of delivering accurate and reliable results to clinicians so that they can make critical treatment decisions.

"We are pleased to offer this innovative test to address a key medical need for immunosuppressed patients," said Paul Brown, Ph.D., Head of Roche Molecular Diagnostics. "With this test, Roche now enables rapid, standardized CMV testing while improving workflow for laboratories."

#### About this test

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 and the effect of antiviral therapy on viral activity.

## About COBAS<sup>®</sup> AmpliPrep / COBAS<sup>®</sup> TaqMan<sup>®</sup> System

This test is designed for use on Roche's fully automated COBAS<sup>®</sup> AmpliPrep/COBAS<sup>®</sup> TaqMan<sup>®</sup> System. The platform combines the COBAS<sup>®</sup> AmpliPrep Instrument for automated sample preparation and the COBAS<sup>®</sup> TaqMan<sup>®</sup> Analyzer or the smaller COBAS<sup>®</sup> TaqMan<sup>®</sup> 48 Analyzer for automated real-time PCR amplification and detection. The COBAS<sup>®</sup> AmpliPrep/COBAS<sup>®</sup> TaqMan<sup>®</sup> 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 proprietary AmpErase enzymes are also included in each test and are designed to prevent cross-contamination of samples and labs.

<sup>&</sup>lt;sup>1</sup> COBAS® AmpliPrep/COBAS® TaqMan®

\*The COBAS\* AmpliPrep/ COBAS\* TaqMan\* CMV Test is not approved or available for use in the US and is currently in development

#### About Cytomegalovirus

CMV is the most common and single most important viral infection in solid organ transplant (SOT) recipients. CMV can be transmitted through the donor organ resulting in CMV infection and leading to the development of CMV disease. Approximately 20-60% of all transplant recipients develop symptomatic CMV infection.<sup>2</sup> CMV infection usually develops during the first few months after transplantation. CMV disease is defined by evidence of CMV infection with attributable symptoms similar to infectious mononucleosis or glandular fever, prolonged fever, sore throat, and a mild hepatitis. Once infected, the virus remains latent in the body for the rest of the person's life.

#### 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 2010, Roche had over 80'000 employees worldwide and invested over 9 billion Swiss francs in R&D. The Group posted sales of 47.5 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.

All trademarks used or mentioned in this release are protected by law.

<sup>&</sup>lt;sup>2</sup> Emovon OE, Baillie GM, Rajagopalan PR, Chavin KD. Infections after kidney transplantation. CME Coverage, based on Renal Week 2002: American Society of Nephrology 35<sup>th</sup> Annual Meeting. Medscape Transplantation. 2002.