Media Release

Pleasanton, California / December 2, 2009

FDA approves use of Roche test to screen source plasma for HIV, hepatitis B virus and hepatitis C virus

cobas® TaqScreen MPX Test is the most comprehensive – detects multiple viruses for increased plasma product safety

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the United States Food and Drug Administration (FDA) approved an additional intended use for its licensed nucleic acid test, to screen source plasma in pools comprised of up to 96 individual donations. The test, called the cobas® TaqScreen MPX Test for use on the **cobas s** 201 system, is a qualitative, in-vitro test for the simultaneous, direct detection of the human immunodeficiency virus (HIV-1 Group M RNA, HIV-1 Group O RNA , HIV-2 RNA), hepatitis C virus RNA and hepatitis B virus DNA in human plasma. The test was approved in the US last year for screening plasma specimens from blood donors and, earlier this year, received the CE Mark for screening source plasma.

"Roche is committed to providing the broadest coverage and an easy-to-use menu of screening tests to ensure the highest safety of blood and plasma products," said Daniel O'Day, head of Roche Molecular Diagnostics, the business area of Roche Diagnostics that developed the test. "The expanded use of our multiplex test, which has been widely adopted and has demonstrated excellent performance worldwide, is one more step toward that goal. We are pleased to introduce this new use of the cobas® TaqScreen MPX Test in the US as we continue to further invest in solutions for this critical industry."

Human plasma is fractionated into its components, such as immunoglobulins, albumin, and clotting factors, which have many therapeutic uses. These include treatment of chronic and hereditary diseases and disorders such as hemophilia and primary immunodeficiency diseases. Plasma is also used to treat patients who have suffered severe burns or trauma, and during major surgery.

Many countries have implemented Nucleic Acid Technology (NAT) testing in order to further ensure the safety of blood and blood products. In Western Europe and North America, routine NAT testing, which can detect HIV-1 and HCV in the early stages of infection, has reduced the risk of transfusion-transmitted HIV-1 and HCV infections to negligible levels. The importance of hepatitis B virus in transfusion-transmitted diseases is increasingly being recognized and NAT screening for HBV is being implemented in some countries.

The cobas® TaqScreen MPX Test runs on the fully automated, real-time PCR **cobas s** 201 system, designed to increase processing efficiency with a unique modular design and ready-to-use reagents.

The **cobas s** 201 system has the capability of running multiple channels using multi-dye technology, enabling simultaneous detection of several viruses. Roche is developing another multi-dye assay on the same platform, the cobas® TaqScreen DPX test, that is designed to simultaneously provide a quantitative result for B19 virus and a qualitative result for hepatitis A virus.

"As a stand-alone PCR system the **cobas s** 201 system and cobas® TaqScreen MPX Test for HBV, HIV and HCV, provides a simple user interface while improving process control and lab efficiencies," said Douglas Lee, PhD, Sr. Director Pathogen Safety and Research, Talecris Biotherapeutics, one of the largest fractionators in the US and a clinical trial site for the cobas® TaqScreen MPX Test.

About Roche Blood Screening

Roche Diagnostics is the leading provider of real-time PCR-based nucleic acid tests for the international blood bank market. Nucleic acid-based tests enable earlier detection of active HIV, hepatitis C and hepatitis B infections than conventional antibody or antigen assays. Roche assays have been used since 1999 to screen blood and plasma products. Roche launched the automated **cobas s** 201 system and the cobas® TaqScreen MPX Test outside the United States in 2006 for the most comprehensive single-assay detection of HIV-1 Groups M & O, HIV-2, and hepatitis B and C in donated blood and plasma. The West Nile Virus test for this platform was launched in the US in 2007.

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 2008, Roche had over 80,000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 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.