Media Release

Pleasanton, CA, 22 September 2010

Roche receives FDA approval for second-generation hepatitis B viral load test

Improved viral load testing with a sensitive and fully automated system

Roche Molecular Diagnostics (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food & Drug Administration (FDA) has approved the COBAS® AmpliPrep / COBAS® TaqMan® HBV Test v2.0 for use in the United States. The new Roche test provides a fully automated solution for the quantitative detection of hepatitis B virus (HBV) DNA in human plasma or serum for patients on HBV antiviral therapy.

"This new test enables clinicians to follow best practices in patient care with standardized viral load measurements, a broad range of detection, and high sensitivity," said Paul Brown, Ph.D., President and CEO of Roche Molecular Diagnostics. "The system is also carefully designed to protect the integrity of each patient result, so clinicians can make key medical decisions about therapy with confidence."

According to the Centers for Disease Control, an estimated 1.2 million people in the United States are living with chronic hepatitis B. Clinical practice guidelines for chronic HBV highlight the importance of monitoring the levels of circulating hepatitis B viral DNA as an indicator of when hepatitis B therapies should be started, and to measure response to treatment, including suppression of HBV replication.

"Viral load testing remains the gold-standard for the management of HBV antiviral therapy," said Teresa Wright, MD, Chief Medical Officer of Roche Molecular Diagnostics. "Roche's new HBV test provides accurate and reproducible results at the key medical decision points, allowing the clinician to optimize patient outcomes."

About the COBAS® AmpliPrep/COBAS® TaqMan® HBV Test v2.0

The Roche COBAS® AmpliPrep / COBAS® TaqMan® HBV Test v2.0 has been validated to quantify diverse samples from genotypes A-H and pre-core mutants across a broad linear dynamic range of 20 IU/mL to 1.7E+08 IU/mL. The new assay uses a reduced sample input volume of 650 uL of either serum or plasma specimens and is standardized against the World Health Organization (WHO) Standard for hepatitis B.

This test is designed for use on Roche's fully automated COBAS® AmpliPrep/COBAS® TaqMan® System that is used in more than 250 clinical laboratories across the U.S.

The platform 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.

"Sample in/results out" testing eliminates manual intervention between steps and configuration options allow for customizable solutions for throughput needs. For a flexible throughput solution, the test offers 72 tests per kit in self sealing, ready-to-use reagent cassettes. Roche's proprietary AmpErase enzymes are also included in each test and are designed to prevent cross-contamination of samples and labs.

About Hepatitis B

Approximately 4,500 cases of acute hepatitis B in the United States are reported to CDC each year and each year an estimated 43,000 persons are newly infected with HBV.[1] However, because many HBV infections are either asymptomatic or never reported, the actual number of new infections is estimated to be approximately tenfold higher.

The hepatitis B virus is spread through having unprotected sex, by sharing needles, or from an infected mother to her baby during child birth. Symptoms occur in about 70 percent of patients and include jaundice, fatigue, abdominal pain, loss of appetite, nausea and vomiting.

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 2009, Roche had over 80,000 employees worldwide and invested almost 10 billion Swiss francs in R&D. The Group posted sales of 49.1 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.

[1] Centers for Disease Control. http://cdc.gov/hepatitis/HBV

For further information please contact:

Jessica E. Brillant
Molecular Diagnostics Communication
925.730.8503