Media Release

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Roche receives FDA approval for Hepatitis C viral load test on its fully automated real-time PCR platform

Improved laboratory efficiencies and standardization to personalize patient care

Roche Molecular Diagnostics today announced that the U.S. Food & Drug Administration (FDA) has approved the COBAS® AmpliPrep / COBAS® TaqMan® HCV Test for use in the United States. The test uses Roche's proprietary real-time PCR technology to quantify the amount of Hepatitis C RNA in a patient's blood. Physicians use Hepatitis C viral load testing results to establish a baseline level of hepatitis C infection and to serially monitor viral load levels and treatment effectiveness in patients on therapy.

"This new Roche test enables laboratories to deliver reliable healthcare information with ease and allows physicians to more efficiently monitor their patients and improve treatment outcomes." said Daniel O'Day, President and CEO of Roche Molecular Diagnostics. "We are pleased to offer this new solution for laboratories and physicians to optimize their turnaround time, workflow and patient care with simultaneous processing of HIV and HCV patient samples."

The new test offers a broad dynamic range from high levels of virus in a patients blood to the "undetectable" low levels of viremia - the goal of therapy. To ensure accurate quantification, the test has been calibrated to World Health Organization (WHO) traceable standards and can detect down to 18 IU/mL with 100% certainty. In a 1,281 patient clinical trial, the COBAS® AmpliPrep / COBAS® TaqMan® HCV Test confirmed the importance of viral load testing to personalize Hepatitis C patient care by accurately predicting treatment response, from onset of therapy through end of treatment.

About the COBAS® AmpliPrep/COBAS® TaqMan® System

The COBAS® AmpliPrep / COBAS® TaqMan® HCV Viral Load Test is designed for use on the first fully automated, FDA approved, real-time PCR platform, providing sample-in/results-out capability. The platform is flexible and customizable to meet the space and workflow needs of

any laboratory. In the United States, more than 130 laboratories already utilize this fully automated platform for HIV testing.

The COBAS® AmpliPrep / COBAS® TaqMan® HCV Test is the third Roche COBAS® TaqMan® real-time PCR test approved by the FDA in the last eighteen months. The COBAS® AmpliPrep / COBAS® TaqMan® System menu includes an FDA approved HIV viral load test, with continuous loading of samples in addition to parallel processing of HIV and HCV tests. In September 2008, Roche received FDA approval of the COBAS® TaqMan® HBV Test to monitor Hepatitis B viral load in patients on therapy.

About Hepatitis C

According to the Centers for Disease Control and Prevention, each year in the U.S. approximately 8,000–10,000 people die from hepatitis C-related liver disease.

An estimated 3.2 million persons in the United States have chronic hepatitis C virus infection. Most people do not know they are infected because they don't look or feel sick. However, approximately 75%–85% of people who become infected with hepatitis C virus develop chronic infection.[1]

Hepatitis C infections can range in severity from a mild or "acute" illness lasting a few weeks to a serious, lifelong or "chronic" illness. For most people, acute infection leads to chronic infection. Chronic hepatitis C infection is a serious disease that can result in long-term health problems, including liver damage, liver failure, liver cancer, or even death. Hepatitis C is the leading cause of cirrhosis and liver cancer and the most common reason for liver transplantation in the United States.

Hepatitis C virus is passed from person to person when infected blood enters the body of someone who is not infected. Different ways people can be infected with the hepatitis C virus include sharing contaminated needles, high risk sex with an infected partner, and from an infected mother to her infant during pregnancy and childbirth.

About Roche and the Roche Diagnostics Division

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of

[1] U.S. Centers for Disease Control. http://www.cdc.gov

fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2007 sales by the Pharmaceuticals Division totaled 36.8 billion Swiss francs, and the Diagnostics Division posted sales of 9.3 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested over 8 billion Swiss francs in R&D in 2007. Worldwide, the Group employs about 80,000 people. Additional information is available on the Internet at www.roche.com.

For further information please contact:

Jessica E. Brillant
Molecular Diagnostics Communications
925.730.8503

Melinda Baker
Molecular Diagnostics Communications
925.730.8379