FDA approves new Roche test to evaluate response to hepatitis C therapy

Viral load test uses a novel dual-probe approach designed to manage patients being treated with antiviral therapies

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received approval from the US Food and Drug Administration (FDA) for a next-generation viral load test to be used in the management of patients with chronic hepatitis C virus (HCV) infection. The COBAS AmpliPrep/COBAS TaqMan HCV Test, v2.0 provides a novel dual-probe approach, for an extra layer of protection in detecting and quantifying the virus. The test is designed to accurately determine the amount of hepatitis C virus ribonucleic acid (RNA) in order to assess a patient’s response to antiviral therapy.

“The rapidly changing hepatitis C treatment landscape requires tests with an additional layer of protection in detecting and accurately quantifying hepatitis C RNA across genotypes,” stated Roland Diggelmann, Chief Operating Officer of Roche’s Diagnostics Division. “This test can play a valuable role in response-guided therapy, helping physicians and patients better manage the disease and optimise treatment choices and duration.”

Furthermore, Roche tests have been used in the development of recently FDA-approved direct-acting antiviral treatment regimens. With this launch Roche Molecular Diagnostics continues its long heritage of providing innovative viral load testing solutions for establishing treatment efficacy for new therapeutic regimens.

The new HCV viral load test is part of Roche’s complete portfolio of diagnostic tests to diagnose, confirm and manage hepatitis C infection. Roche expects to begin shipping the new HCV viral load test kit in the US shortly.

About the test
The COBAS AmpliPrep/COBAS TaqMan HCV Test, v2.0 is intended for use in the management of patients with chronic HCV, in conjunction with clinical and laboratory markers of infection. It is an in vitro nucleic acid amplification test for the quantitation of hepatitis C virus RNA genotypes 1 to 6 in human EDTA.
plasma or serum. The test can be used to predict the probability of sustained virologic response (SVR) early during a course of antiviral therapy and to assess viral response to antiviral treatment (response-guided therapy), as measured by changes of HCV RNA levels.

The real-time polymerase chain reaction (PCR)-based HCV test is designed for use on Roche’s fully automated COBAS AmpliPrep/COBAS TaqMan System, an established platform for viral load monitoring of multiple infectious diseases that improves workflow in testing laboratories. The system can be combined with the cobas p 630 instrument, which provides an integrated pre-analytical primary tube handling solution.

**Personalised healthcare in hepatitis C**
Response-guided therapy in hepatitis C is a good example of personalised healthcare and delivering real benefit to patients by combining pharmaceuticals and diagnostics.

Viral load assays, which are a measure of treatment response, help to individualise treatment by indicating when a course of treatment will be successful or therapy should be discontinued. Physicians can tailor treatment to the appropriate specific groups of patients based on the genotype and quantity of virus present in the blood.

In addition to the heterogeneity of HCV, patient characteristics also impact treatment outcomes. Based on changes in blood viral load in response to the treatment, patients can be categorised into several groups, such as rapid responders, slow responders, or relapers. By monitoring viral load at specific points during treatment, physicians can optimise treatment duration and thus exposure of patients to treatment.

**About hepatitis C**
According to the World Health Organization, HCV affects some 200 million people globally. Approximately 170 million people are chronic carriers of the hepatitis C virus, and most do not know they are infected. According to the Centers for Disease Control and Prevention, in the US there are about 5 million people living with hepatitis C. The disease can ultimately result in cirrhosis, liver failure and hepatocellular carcinoma, which together are responsible for hundreds of thousands of deaths each year.

**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, infectious diseases, inflammation, metabolism and neuroscience. Roche
is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit [http://www.roche.com/](http://www.roche.com/)

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For further information please also see the following publication:
[http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3553902/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3553902/)

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