Media Release

Pleasanton, CA 11 May 2015

Roche Receives FDA Approval for cobas® KRAS Mutation Test

Molecular PCR test identifies KRAS mutations to aid in determining therapy for metastatic colorectal cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has approved the **cobas®** KRAS Mutation Test for diagnostic use. The real-time PCR test is designed to identify KRAS mutations in tumor samples from metastatic colorectal cancer (mCRC) patients and aid clinicians in determining a therapeutic path for them.

"As more targeted treatment options for cancer patients become available, the importance of identifying the right molecular information to define their disease becomes critical," said Paul Brown, Head of Roche Molecular Diagnostics. "The **cobas®** KRAS Mutation Test gives clinicians actionable insights that enable them to make informed decisions about treatment for their patient. With this approval, Roche now offers the most comprehensive companion diagnostic FDA approved portfolio for oncology in the U.S., including tests for BRAF (melanoma), EGFR (lung cancer) and KRAS (mCRC) mutations."

According to the Centers for Disease Control and Prevention, colorectal cancer is the second leading cause of cancer-related deaths in the United States and the third most common cancer in men and women. The **cobas®** KRAS Mutation Test is intended to be used as an aid in the identification of mCRC patients for whom treatment with Erbitux® (cetuximab) or Vectibix® (panitumumab) may be effective if no KRAS mutation is present.

About the cobas® KRAS Mutation Test and the cobas® 4800 System

The **cobas®** KRAS Mutation Test is a TaqMelt™ assay; a polymerase chain reaction (PCR)-based diagnostic test intended for the detection of mutations in codons 12 and 13 of the KRAS gene. The test

can be performed in less than eight hours, so physicians can make treatment decisions quickly and confidently.

The test is performed on the **cobas**® 4800 System, which offers high-performance amplification and detection coupled with software that automates results interpretation and reporting. The **cobas**® 4800 System menu for oncology in the U.S. includes the **cobas**® KRAS Mutation Test, the **cobas**® BRAF V600 Mutation Test and the **cobas**® EGFR Mutation Test.

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, immunology, infectious diseases, ophthalmology 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 personalized healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 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 roche.com.

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