Media Release

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KRAS Diagnostic Test that assists with personalized treatment of colorectal cancer receives CE Mark

cobas KRAS Mutation Test identifies colorectal cancer patients not likely to respond to anti-EGFR antibody therapies

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the cobas KRAS Mutation Test is now commercially available in Europe for use in colorectal cancer.

The cobas KRAS Mutation Test identifies mutations in the KRAS gene of colorectal cancer tissue that are predictive of individual response to therapy with anti-epidermal growth factor receptor (EGFR) antibody therapies.

"By quickly and reliably detecting KRAS mutations, the cobas KRAS Mutation Test provides oncology professionals with a new, validated tool to help guide and personalize treatment of colorectal cancer," said Paul Brown, head of Roche Molecular Systems (RMS), the business area of Roche that developed the test.

KRAS mutations occur in 35 to 45 percent of colorectal cancers. The remaining tumors (approximately 60 percent) have no KRAS mutations, and are referred to as KRAS wild type. The cobas KRAS Mutation Test was designed to detect KRAS mutations with high sensitivity, which is important because of the safety issues of treating mutation positive patients with anti-EGFR

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monoclonal antibody therapies. The test detects mutations in codons 12, 13 and 61 of the KRAS gene.

There is strong evidence that tumor KRAS status is a predictive biomarker of efficacy for EGFR-targeted monoclonal antibodies. Treatment with EGFR-targeted monoclonal antibodies is beneficial in patients with KRAS wild-type colorectal cancer, whereas it is not effective, or may even be detrimental, in patients with KRAS mutations.

International oncology organizations such as the American Society of Clinical Oncology (ASCO),[1] the National Comprehensive Cancer Network (NCCN)[2] and the European Society for Medical Oncology (ESMO) recommend KRAS mutation testing for the selection of patients to receive anti-EGFR antibody therapy. [3] United States and European regulatory authorities have restricted the use of these agents to patients with KRAS wild-type tumors.

About the cobas KRAS Mutation Test and the cobas 4800 System, v2.0

The cobas KRAS Mutation Test is a TaqMelt™, polymerase chain reaction-based diagnostic test intended for the detection of mutations in codons 12, 13 and 61 of the KRAS gene. The cobas KRAS Mutation Test is now commercially available in countries that recognize the CE mark.

The cobas 4800 System v2.0 offers high-performance amplification and detection coupled with software that automates thermal cycling conditions, results interpretation, analysis and reporting. The cobas 4800 System v1.1 was recently approved in the US and all countries accepting a CE mark.

About Roche

[1] Allegra CJ, Jessup JM, Somerfield MR, et al. American Society of Clinical Oncology provisional clinical opinion: testing for KRAS gene mutations in patients with metastatic colorectal carcinoma to predict response to anti-epidermal growth factor receptor monoclonal antibody therapy. J Clin Oncol 2009 Apr 20;27(12):2091-6.
[2] National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Colon cancer, 2010, v.2.
[3] Van Cutsem E, Oliveira J; ESMO Guidelines Working Group. Advanced colorectal cancer: ESMO clinical recommendations for diagnosis, treatment and follow-up. Ann Oncol 2009 May;20 Suppl 4:61-3.

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.