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Roche Diagnostics Distributes K-RAS Mutation Test Throughout Asia Pacific

Test identifies colorectal cancer patients with genetic mutations who are unlikely to benefit from certain cancer drugs

New Zealand July 2009 – Roche Diagnostics announced today that it has begun the distribution of the TheraScreen®: K-RAS Mutation Kit throughout Asia Pacific, in countries that accept IVD products with the CE Mark, following an exclusive distribution agreement with DxS. The TheraScreen®: K-RAS Mutation Kit is the first CE Mark certified test for K-RAS mutation status, which is intended to provide doctors with information that may guide them in making subsequent therapeutic decisions for their colorectal cancer patients who may not benefit from anti-EGFR therapy such as cetuximab or panitumumab.

Approximately 35 to 45 percent of colorectal cancer patients have a mutation in their K-RAS gene. A mutated K-RAS gene continues to send growth signals to a cell even in the absence of an external trigger. This leads to uncontrolled cell proliferation thereby promoting tumor growth.ⁱ

Recent studies have shown that efficacy of anti-EGFR monoclonal therapies such as panitumumab and cetuximab is limited to patients with wild-type K-RAS, while patients with K-RAS mutations do not derive benefit.

The American Society of Clinical Oncology (ASCO) Provisional Clinical Opinion published in February 2009 addresses the utility of K-RAS gene mutation testing in patients with metastatic colorectal carcinoma to predict response to anti-epidermal growth factor receptor (anti-EGFR) monoclonal antibody (MoAb) therapy with cetuximab or panitumumab. ASCO's provisional clinical opinions reflect expert consensus.

The Provisional Clinical Opinion is based on a systematic review of the relevant literature and states that all patients with metastatic colorectal carcinoma who are candidates for anti-EGFR monoclonal antibody therapy should have their tumor tested for KRAS mutations in a CLIA-accredited laboratory. If KRAS mutation in codon 12 or 13 is detected, then patients with metastatic colorectal carcinoma should not receive anti-EGFR monoclonal antibody therapy as part of their treatment.ⁱⁱ

The TheraScreen®: K-RAS Mutation Kit detects not only low level mutations that may be missed by sequencing methods, but can also deliver qualitative and accurate detection of the seven mutations in the K-RAS geneⁱⁱⁱ that account for more than 96% of all mutations.ⁱⁱ The test is highly sensitive, being able to detect 1% of mutant in a background of wild-type genomic DNA.ⁱⁱⁱ

Colorectal cancer is a growing issue throughout Asia, and is estimated to have the fourth highest incidence, after lung, breast and uterine cancers. According to Roland Diggelmann, Managing Director of Roche Diagnostics Asia Pacific, the use of diagnostics tests such as the TheraScreen®: K-RAS Mutation Kit, benefits the whole community. “Being able to identify which patients will not benefit from a particular drug has the potential to improve treatment outcome, save time and reduce the costs often associated with cancer therapy,” he said.

About DxS

DxS is a UK-based personalized medicine company providing molecular diagnostics to aid doctors and drug companies in selecting therapies for patients. DxS offers products, technology and services to the healthcare industry to enable the delivery of safe and effective medicines. Working predominantly in the field of cancer, DxS has a range of companion diagnostic and research kits that detect mutations in oncogenes associated with cancer drug response. The TheraScreen® range of CE Mark certified diagnostic products includes kits that detect mutations in the EGFR and K-RAS genes. Tumor mutation products are available for research use for EGFR, RAS, RAF, BCR-ABL and other genes that show a correlation between patient mutation status and drug response. DxS also provides a genetic analysis service to support clinical development. For more information, visit www.dxsdiagnostics.com.

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 2008, Roche had over 80,000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 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.

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ⁱ Ciardiello, F. et al. EGFR antagonists in cancer treatment. *New England Journal of Medicine*. 2008 Mar 13; **358**(11):1160-74

ⁱⁱ Allegra CJ, Jessup JM, Somerfield MR, et al. *Journal of Clinical Oncology*, 27:2009. 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.

ⁱⁱⁱ National Comprehensive Cancer Network. *Practive Guidelines in Oncology*. 2008 v.3