



Pleasanton, California / August 23, 2011

## **Companion Diagnostic Test That Identifies Patients With Melanoma Tumor Mutation Available in Europe**

**cobas BRAF Mutation Test is used to identify patients with melanoma tumors that harbor a genetic mutation which can be treated with Zelboraf (vemurafenib)**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the cobas BRAF Mutation Test is now commercially available in Europe and in countries that recognize the CE-mark.

The cobas BRAF Mutation Test is a companion diagnostic developed by Roche to identify patients with melanoma tumors that carry a mutated form of the BRAF gene, and will be eligible for treatment with Zelboraf (vemurafenib), once it is commercially available. The test detects a specific BRAF mutation found in approximately 50 percent of malignant melanoma tumors. Zelboraf is currently under review in the EU and has just been approved in the United States together with the cobas BRAF test as a new treatment for BRAF V600 mutation-positive metastatic melanoma.

“Roche has led the way in the development of diagnostic products that enable targeted, individual cancer treatments,” said Paul Brown, Head of Roche Molecular Diagnostics (RMD), the business



area of Roche that developed the test. “The cobas BRAF test will play a critical role in improving treatment for metastatic melanoma, one of the most aggressive and deadly cancers.”

“Screening patients with this test, which was used to define the population studied in the Zelboraf development program and melanoma pivotal trials, is the best approach to ensure the right patients gain access to treatment with this novel drug once it is approved,” said Brown.

Clinical studies conducted in the metastatic melanoma setting demonstrate that the cobas test detects BRAF V600E mutations with a higher degree of sensitivity, accuracy, reliability and speed than other commonly used, unapproved detection methods.

### **About the cobas 4800 BRAF V600 Mutation Test and the cobas 4800 System**

The cobas BRAF Mutation Test is a real-time, polymerase chain reaction-based diagnostic test. The test allows doctors to know, based on tumor BRAF mutation status, whether a person with metastatic melanoma will be eligible for treatment with the BRAF inhibitor Zelboraf.

The cobas 4800 System is designed to deliver new standards in laboratory testing efficiency and medically relevant diagnostic information. The system is a consolidated and flexible PCR IVD platform designed to offer high performance, coupled with software that automates result interpretation, analysis and reporting.

### **About Metastatic Melanoma**

When melanoma is diagnosed early, it is generally a curable disease. However, when it spreads to other parts of the body, it is the deadliest and most aggressive form of skin cancer. A person with metastatic melanoma typically has a short life expectancy that is measured in months.

### **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 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.

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