Roche's cobas EGFR Mutation Test For Personalized Treatment Of Non-Small Cell Lung Cancer Receives CE Mark

New Test allows identification of lung cancer patients who may benefit from early treatment with EGFR inhibitors

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the cobas EGFR Mutation Test is now CE marked for commercial availability in Europe and other countries that recognize CE mark. The cobas EGFR Mutation Test is a companion diagnostic to identify patients with non-small cell lung cancer (NSCLC) who harbor mutations in the EGFR (epidermal growth factor receptor) gene and who may benefit from treatment with anti-EGFR tyrosine kinase inhibitors such as Roche’s Tarceva (erlotinib). Tarceva, an oral EGFR inhibitor, was approved by the European Commission in September as first-line monotherapy in people with locally advanced or metastatic NSCLC with EGFR activating mutations.

“Our new EGFR test will help physicians to directly determine the appropriate course of treatment for the individual patient,” said Daniel O’Day, COO of Roche Diagnostics. “Patients with this genetically distinct form of lung cancer derive great benefit when EGFR inhibitors are used as initial treatment. The cobas EGFR test together with other companion tests already launched this year greatly illustrates our strength to enable and support personalised treatment approaches.”

It is estimated that 10-30 percent of patients with NSCLC have tumors with EGFR activating mutations which are highly responsive to EGFR inhibitors such as Tarceva. Treatment with this medicine has been shown to more than triple the number of patients whose tumours shrink (response rate) and to nearly double the time patients live without their disease progressing (progression free survival – PFS) compared to chemotherapy.

International oncology organizations such as the European Society for Medical Oncology (ESMO), the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) recommend EGFR mutation testing for people with metastatic NSCLC.
The cobas EGFR Mutation Test rapidly detects 41 mutations across four different exons of the EGFR gene from a single section of the patient’s tumor. It provides automated analysis and reporting, accurate and reliable mutation detection with a higher degree of sensitivity compared to Sanger sequencing, the most commonly used method for mutation detection and delivers test results within an 8 hour period. The Cobas EGFR Mutation Test marks the third cobas diagnostic test to receive the CE mark approval in the Roche oncology portfolio this year. Other tests include the cobas BRAF Mutation Test for metastatic melanoma and the cobas KRAS Mutation Test for advanced colorectal cancer. The tests run on the cobas 4800 System, v2.0, which standardizes mutation testing across tumor types, and is the only commercial system offering automated result analysis, interpretation and reporting of results.

**About the cobas EGFR Mutation Test and cobas 4800 System**

The cobas EGFR Mutation Test is a real-time polymerase chain reaction-based diagnostic test that identifies 41 mutations across exons 18, 19, 20 and 21 of the EGFR gene using multiplex PCR chemistry. It is now available in all countries that recognize the CE mark. 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 Tarceva**

Tarceva is a once-daily, oral, non-chemotherapy treatment for the treatment of advanced or metastatic NSCLC. It has been shown to potently inhibit EGFR, a protein involved in the growth and development of cancers. Tarceva is a trademark of OSI Pharmaceuticals, LLC, a wholly owned subsidiary of Astellas Holding US Inc. a holding company owned by Astellas Pharma Inc.

**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 2010, Roche had over 80’000 employees worldwide and invested over 9 billion Swiss francs in R&D. The Group posted sales of 47.5 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.

All trademarks used or mentioned in this release are protected by law.

Roche Group Media Relations
Phone: +41 -61 688 8888 / e-mail: basel.mediaoffice@roche.com
- Alexander Klauser (Head)
- Silvia Dobry
- Daniel Grotzky
- Claudia Schmitt

---

\(^2\) Rosell R et al. J Clin Oncol. 2011;29; Abstract 7503.