Basel, 28 September 2015

Roche launches the cobas EGFR Mutation Test v2 for use with either plasma or tumour tissue samples

New test is the first to be validated for use of either sample type in a single test

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the commercial availability in countries that accept the CE mark\(^1\) of the cobas® EGFR Mutation Test v2, the first oncology assay from Roche that utilises either plasma or tumour tissue as a sample. The test identifies 42 mutations in the epidermal growth factor receptor (EGFR) gene, the most of any In-vitro Diagnostic (IVD) on the market, and can also be used as an aid in selecting eligible patients with non-small cell lung cancer (NSCLC) for therapy with an EGFR tyrosine kinase inhibitor (TKI).

“As more targeted therapies become available, it is critical that we provide innovative molecular testing methods that make it easier for patients to get tested, regardless of the surgery risks or tumour tissue availability,” said Roland Diggelmann, COO, Roche Diagnostics. “By investing in liquid biopsy research and developing the cobas EGFR Mutation Test v2 for use with either plasma or tissue samples, Roche is helping to remove these common barriers from molecular testing.”

According to a recent survey of more than 550 oncologists, EGFR genetic testing is not being conducted in about 25 percent of patients with NSCLC\(^2,3\). Some of the reasons for not testing included lack of diagnostic material and cases where a patient was deemed unfit to undergo biopsy. With the cobas® EGFR Mutation Test v2 being validated with both tissue and plasma sample types, patients who previously did not qualify for biopsy now have the opportunity to receive a result from a simple plasma test to guide the corresponding therapy.

The cobas EGFR Mutation Test v2 is available now in countries that accept the CE mark\(^1\). For more information, please visit www.cobas-egfrtestv2.com.
About the cobas EGFR Mutation Test v2
The cobas EGFR Mutation Test v2 is a real-time PCR test that identifies 42 mutations in exons 18-21, including L858R, exon 19 deletions, L861Q and the TKI-resistance mutation, T790M. It is designed to enable testing of either tissue or plasma specimens with one kit, and allows labs to mix-batch tissue and plasma on the same plate. Additionally, Roche has developed a cell-free DNA (cfDNA) sample preparation kit that is optimised for extracting the DNA from plasma.

When testing plasma with the cobas EGFR Mutation Test v2, a new feature called the Semi-Quantitative Index (SQI) is included in the report. This number is designed to reflect a trend in the amount of mutant cfDNA in the sample. When frequently testing for the EGFR mutation using the test, tracking the SQI value and identifying a trend may lead to understanding tumour progression.

The cobas® EGFR Mutation Test v2 is designed to run on the cobas 4800 System, v2.1 or higher. The system can also be used for the detection of mutations in the KRAS and BRAF gene of tumour samples.

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 personalised 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-nine 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 www.roche.com.

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References
1 Local product availability may vary independently from CE Mark approval.
2 2015 European Lung Cancer Conference (ELCC): Abstract LBA2_PR. Presented April 17, 2015
3 Davenport, Liam, "EGFR Testing Not Done in 25% of Lung Cancer Patients." Medscape Medical News, April 17, 2015