

Pleasanton, June 1, 2016

## **FDA Grants First Liquid Biopsy Approval to the Roche cobas®EGFR Mutation Test v2**

***Test can be used with either plasma or tumor tissue, as a companion diagnostic for non-small cell lung cancer therapy***

Roche (SIX: RO, ROG; OTCQX, RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has approved the **cobas®** EGFR Mutation Test v2 for use with plasma samples, as a companion diagnostic for the non-small cell lung cancer (NSCLC) therapy, Tarceva®. This is the first FDA approval of a liquid biopsy test as an aid in clinical decisions, and makes the **cobas®** EGFR Mutation Test v2 the only companion diagnostic that is FDA-approved for the detection of the epidermal growth factor receptor (EGFR) gene in DNA derived from plasma or tumor tissue. NSCLC patients who have EGFR exon 19 deletions or L858R mutations are candidates for the EGFR-targeted therapy Tarceva® (erlotinib), in first-line treatment.

“The FDA approval of the **cobas®** EGFR Mutation Test v2 for liquid biopsy for diagnostic use sets a standard in testing for NSCLC patients,” said Uwe Oberlaender, Head of Roche Molecular Diagnostics. “The approval of the test for use with plasma samples means patients who previously could not be tested now have a testing option for personalized healthcare.”

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<sup>1,2</sup>. Currently, many patients do not have the opportunity to be selected for targeted therapies as surgical procedures can be too invasive for very sick patients, travel to surgical locations can be challenging and tumor tissue can be difficult to obtain in sufficient quantity for molecular testing. The FDA approval of the **cobas®** EGFR Mutation Test v2 for use with plasma or tumor tissue will help alleviate barriers to molecular testing by giving clinicians more options for their patients.

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<sup>1</sup> 2015 European Lung Cancer Conference (ELCC): Abstract LBA2\_PR. Presented April 17, 2015

<sup>2</sup> Davenport, Liam, "EGFR Testing Not Done in 25% of Lung Cancer Patients." Medscape Medical News, April 17, 2015

Current clinical guidelines, including the National Comprehensive Cancer Network (NCCN) in the U.S., and the European Society for Medical Oncology (ESMO), recommend EGFR mutation testing in patients with advanced NSCLC, prior to administering targeted therapies.

“The advent of liquid diagnostic platforms in non-small cell lung cancer is truly a game changer in the diagnostic workup of advanced stage patients. The ability to both isolate and genetically interrogate tumor DNA from a simple, minimally invasive test that can subsequently inform treatment decisions is a win for both physician and patient,” said Dr. Benjamin Levy, MD, Director of Thoracic Medical Oncology, Mount Sinai Health Systems and Hospital. “These platforms have the potential to expedite care and potentially circumvent an otherwise cumbersome process of procuring tissue (biopsy) often fraught with complications and complexity.”

### **About the cobas®EGFR Mutation Test v2**

The **cobas**® EGFR Mutation Test v2 is built upon the success of the **cobas**® EGFR Mutation Test available globally today, with expanded mutation coverage that identifies 42 EGFR mutations in exons 18-21, including L858R, exon 19 deletions, and T790M. The test is performed on the **cobas**® 4800 System, which offers high-performance polymerase chain reaction (PCR) amplification and detection coupled with software that automates results interpretation and reporting. The **cobas**® 4800 System menu for diagnostic use in oncology includes the **cobas**® EGFR Mutation Test v2, the **cobas**® EGFR Mutation Test, the **cobas**® KRAS Mutation Test, and the **cobas**® 4800 BRAF V600 Mutation Test. Tarceva is developed and commercialized by Astellas Pharma US in partnership with Genentech in the United States, Chugai in Japan and Roche in the rest of the world.

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### **About Roche**

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Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in *in vitro* diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. 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 cancer medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 billion. 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](http://www.roche.com).

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