

Pleasanton, September 29, 2016

## **FDA Grants Roche Label Extension for the cobas® EGFR Mutation Test v2 for use with Plasma as a Companion Diagnostic for TAGRISSO™**

*Test utilizes either plasma or tumor tissue, as a companion diagnostic for non-small cell lung cancer therapies*

Roche (SIX: RO, ROG; OTCQX, RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has approved a label extension of the **cobas®** EGFR Mutation Test v2 for use with plasma samples as a companion diagnostic for Astra Zeneca's non-small cell lung cancer (NSCLC) therapy TAGRISSO™ (osimertinib).

"The label extension for the **cobas®** EGFR Mutation Test v2 to include another TKI (tyrosine-kinase inhibitor) therapy shows our continued commitment to helping healthcare providers make the best diagnosis for their NSCLC patients at multiple stages of their treatment pathway," said Uwe Oberlaender, Head of Roche Molecular Diagnostics.

On June 1<sup>st</sup>, 2016, the FDA granted approval of the **cobas®** EGFR Mutation Test v2, making it the first FDA-approved liquid biopsy test for use in clinical decisions. The test is 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, and patients who have the resistance mutation T790M are candidates for TAGRISSO™ in subsequent lines of treatment.

Current clinical guidelines, including those from 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.

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

The **cobas**<sup>®</sup> EGFR Mutation Test v2 is based upon the **cobas**<sup>®</sup> 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**<sup>®</sup> 4800 System, which offers high-performance polymerase chain reaction (PCR) amplification and detection coupled with software that automates results interpretation and reporting. The **cobas**<sup>®</sup> 4800 System menu for diagnostic use in oncology includes the **cobas**<sup>®</sup> EGFR Mutation Test v2, the **cobas**<sup>®</sup> KRAS Mutation Test, and the **cobas**<sup>®</sup> 4800 BRAF V600 Mutation Test.

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### **About TAGRISSO**

TAGRISSO™ (osimertinib) 80mg once-daily tablet is the first medicine indicated for the treatment of metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive NSCLC, as detected by an FDA-approved test, who have progressed on or after EGFR TKI therapy.

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### **About Roche**

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

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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