Media Release

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Roche receives FDA approval for cobas EGFR Mutation Test v2 as companion diagnostic with IRESSA (gefitinib) in first-line treatment of patients with non-small cell lung cancer (NSCLC)

- **New indication approval for cobas EGFR Mutation Test v2 as companion diagnostic, follows previous approvals with Tarceva (erlotinib) and TAGRISSO (osimertinib)**
- **Results for EGFR mutations can be available in less than one day with the cobas EGFR Mutation Test v2 to determine if patients can benefit from IRESSA**
- **Approval for use of either tumour tissue or plasma biopsy provides patients and clinicians a non-invasive sample collection option**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced approval from the U.S. Food and Drug Administration (FDA) for the **cobas**® EGFR Mutation Test v2 as a companion diagnostic test (CDx) with IRESSA®. A CDx test provides information that is essential for the safe and effective use of a corresponding therapeutic product. Clinical studies have demonstrated that patients diagnosed with NSCLC who test positive for defined mutations of the epidermal growth factor receptor (EGFR) gene benefit from tyrosine kinase inhibitor (TKI) therapies.

"The **cobas**® EGFR Mutation Test v2 is a companion diagnostic test that supports IRESSA® as an additional therapeutic option for patients and gives physicians greater flexibility to make appropriate treatment decisions," said Uwe Oberlaender, Head of Roche Molecular Diagnostics. "Additionally, the ability to provide reliable patient test results in less than one day from sample preparation to report, eliminates delays and provides patients with the ability to begin therapy regimens earlier."

The **cobas**® EGFR Mutation Test v2 is currently the only FDA-approved diagnostic test for NSCLC using liquid biopsy. EGFR testing in plasma offers a non-invasive option for patients using a simple blood draw for those who are not eligible for a tissue biopsy.

About the cobas EGFR Mutation Test v2

The **cobas**® EGFR Mutation Test v2 is a real-time polymerase chain reaction (PCR) test for the qualitative detection of 42 defined mutations of the EGFR gene in exons 18-21, including L858R, exon 19 deletions, and T790M mutations. This *in-vitro* diagnostic (IVD) test is the first and currently the only FDA-approved EGFR test to include both tissue and liquid biopsy (plasma) as patient sample types for testing. A number of well-published clinical studies such as AURA, AURA2, FLAURA, ENSURE, EURTAC, and FASTACT2, have now demonstrated that the **cobas**® EGFR Mutation Test v2 is a robust and reliable diagnostic test for the detection of defined mutations of the EGFR gene from a tumour tissue biopsy or from plasma and is able to identify those patients most likely to respond to EGFR tyrosine kinase inhibitor (TKI) therapies. The test is performed on the **cobas**® 4800 System, which offers high-performance PCR amplification and detection coupled with software that automates result interpretation and reporting.

About IRESSA
IRESSA® (gefitinib) is a targeted monotherapy for the treatment of patients with advanced or metastatic epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutation-positive NSCLC. IRESSA® acts by inhibiting the tyrosine kinase enzyme in the EGFR, thus inhibiting the transmission of signals involved in the growth and spread of tumors.

About Roche
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalized healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

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.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, anti-malarials and cancer medicines. Roche has been recognized as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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.

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