

Pleasanton, 18 April 2018

## **Roche expands indication for cobas® EGFR Mutation Test v2 as a companion diagnostic with TAGRISSO®**

- New indication as a companion diagnostic with AstraZeneca's TAGRISSO® (osimertinib) in first line treatment of patients with non-small cell lung cancer (NSCLC)
- 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 TAGRISSO®
- Approval for use of either tumour tissue or plasma biopsy enables patients and clinicians a non-invasive option to collect sample

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced it has received approval from the U.S. Food and Drug Administration (FDA) of its Premarket Approval (PMA) supplement for the **cobas®** EGFR Mutation Test v2 to be used as a companion diagnostic test (CDx) with TAGRISSO® for first line treatment of patients diagnosed with metastatic NSCLC whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations. A companion diagnostic test is a medical device which 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 was previously FDA-approved as a companion diagnostic test with TAGRISSO® for second line treatment and beyond in NSCLC patients who test positive for the EGFR T790M mutation. The test is also a companion diagnostic test with Tarceva® (erlotinib) for NSCLC patients who test positive for the EGFR exon 19 deletion or L858R sensitizing mutations.

Approvals thus far are for both tissue and liquid (patient blood plasma) 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. In addition, the workflow for **cobas®** EGFR Mutation Test v2 enables patients and clinicians to obtain results in as little as one day.

“The ability to provide confident patient test results in less than one day from sample preparation to report, provides clinicians the information necessary to choose the optimal

therapy and avoid delays in getting their patients started on treatment,” said Sid Scudder, MD, Senior Director, Clinical Research, Genomics & Oncology, Roche Molecular Diagnostics.

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

The **cobas®** EGFR Mutation Test v2 is a real-time 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). 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 TAGRISSO® (osimertinib)**

TAGRISSO® (osimertinib) is a third-generation, irreversible EGFR-TKI designed to inhibit both EGFR-sensitizing and EGFR T790M-resistance mutations, with clinical activity against CNS metastases. TAGRISSO 40mg and 80mg once-daily oral tablets have been approved for 1st-line EGFRm advanced NSCLC, and for patients with EGFR T790M mutation-positive advanced non-small cell lung cancer.

### **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 personalised 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, antimalarials and cancer medicines. Roche has been recognised 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](http://www.roche.com).

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