Media Release

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Roche receives approval in Japan for the cobas® EGFR Mutation Test v2

New test includes expanded mutation coverage to detect EGFR mutations in non-small cell lung cancer patients

Roche (SIX: RO, ROG; OTCQX, RHHBY) today announced that the Ministry of Health, Labour and Welfare (MHLW) in Japan has approved the **cobas®** EGFR Mutation Test v2 for diagnostic use. The test from Roche includes expanded mutation coverage of the epidermal growth factor receptor (EGFR) gene in DNA derived from tumour tissue, designed to detect both sensitising and resistant mutations in non-small cell lung cancer (NSCLC) patients. NSCLC patients who harbor an EGFR mutation are candidates for EGFR-targeted therapies such as Tarceva® (erlotinib), Gilotrif® (afatinib), and IRESSA® (gefitinib) in first-line treatment, and TAGRISSO™ (osimertinib) in subsequent lines of treatment.

"The approval in Japan for the **cobas®** EGFR Mutation Test v2 is a testament to the importance of molecular testing for targeted therapies," said Uwe Oberlaender, Head of Roche Molecular Diagnostics. "With more than half of Asian patients with advanced NSCLC having an EGFR mutation, knowing the specific mutation can inform the clinician about what treatment regimen to prescribe and, more importantly, who is eligible for the targeted therapy."

A recent study published in the *Journal of Thoracic Oncology* found that 51.4 percent of Asian patients with NSCLC have EGFR mutations. 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.

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 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**® BRAF V600 Mutation Test.

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.

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