Media Release

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Roche submits filing to FDA for companion diagnostic for non-small cell lung cancer drug therapy

The cobas® EGFR Mutation Test v2 is designed for expanded EGFR mutation detection in non-small cell lung cancer patients

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced it has submitted the **cobas®** EGFR Mutation Test v2 for Premarket Approval (PMA) to the U.S. Food and Drug Administration (FDA), as a companion diagnostic test for AZD9291, an AstraZeneca investigational therapy for non-small cell lung cancer patients with an acquired resistant mutation.

Patients with non-small cell lung cancer who have adenocarcinoma with tumor containing an EGFR sensitizing mutation show significant benefit from currently available EGFR TKI therapies. However, approximately two-thirds of these patients will relapse and develop drug resistance. In many cases, this resistance is caused by an acquired mutation called T790M. The **cobas®** EGFR v2 test can aid clinicians to appropriately select NSCLC patients who have acquired the T790M mutation and are most likely to benefit from AstraZeneca's novel therapy.

"The collaboration with AstraZeneca to be the companion diagnostic for their third generation EGFR drug therapy is a testament to the innovation and quality of Roche oncology assays and demonstrates the value of molecular testing in patients," said Paul Brown, Head of Roche Molecular Diagnostics (RMD). "At Roche Molecular Diagnostics, we have one of the broadest portfolios of FDA-approved tests for Oncology that enable clinicians to make informed treatment decisions for their patients."

"At AstraZeneca, we are focused on developing novel treatments that address the genetic drivers underlying lung cancer disease progression and resistance mechanisms. AZD9291 was designed to inhibit both the activating sensitising EGFRm and the resistance mutation, T790M. The partnership with Roche on developing a companion diagnostics test for AZD9291, ensures that physicians will be able to identify the patients most likely to benefit from the treatment," said Antoine Yver, Head of Oncology, Global Medicines Development at AstraZeneca.

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About the cobas® EGFR Mutation Test v2

The **cobas®** EGFR Mutation Test v2 is built upon the existing FDA-approved **cobas®** EGFR Mutation Test, developed by Roche. It is intended to identify a broad spectrum of EGFR mutations for patients with non-small cell lung cancer, including the T790M acquired resistant mutation.

About AZD9291

AZD9291 is a once daily, selective, irreversible EGFR TKI designed to target both the activating sensitising mutation, EGFRm, and T790M, the genetic mutation responsible for EGFR TKI treatment resistance in up to approximately two-thirds of cases of EGFRm advanced NSCLC. AZD9291 has been granted Breakthrough Therapy designation, Orphan Drug and Fast Track status by the US Food and Drug Administration (FDA).

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. 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 chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. 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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