Media Release

Roche to present results of first prospective trial using blood-based next generation sequencing which successfully identifies people for treatment with Alecensa

- **Efficacy of Alecensa® (alectinib) in people identified to have ALK-positive non-small cell lung cancer using liquid biopsy is consistent with efficacy in those identified by tissue analysis in the pivotal Phase III ALEX study**

Basel, 30 September 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) will today announce positive results from a single-arm cohort of the Phase II/III Blood First Assay Screening Trial (BFAST), the first prospective study to use only blood-based next generation sequencing (NGS) to detect specific fusions with the aim of selecting treatment for people with advanced non-small cell lung cancer (NSCLC), without the need for tissue biopsy. Results from the anaplastic lymphoma kinase (ALK) cohort will be presented at the European Society for Medical Oncology (ESMO) 2019 Congress on Monday 30 September 2019, from 9:15 - 9:30 am CEST (Abstract LBA81 PR), and were also part of the official ESMO press programme.

"Obtaining tumour tissue for biomarker testing can be a challenge in many people with cancer and, as a result, some may not receive optimal treatment for their disease," said Sandra Horning, MD, chief medical officer and head of Global Product Development. "BFAST is the first trial to show that by using a blood-based next-generation diagnostic, it is possible to identify the ALK mutation in people with non-small cell lung cancer using a blood draw alone, which means that more people could potentially benefit from Alecensa."

"Foundation Medicine is pleased to partner with Roche on this study, a first-of-its-kind, pivotal trial that directly demonstrates the clinical utility of using our comprehensive blood-based assay, FoundationOne Liquid, to detect specific fusions and match NSCLC patients with first-line treatment," said Brian Alexander, MD, chief medical officer of Foundation Medicine. "Validated and comprehensive liquid biopsy tests are critical to help physicians find the best possible treatment approach for patients with advanced cancer and for whom tissue testing isn't feasible. Identifying ALK fusions can be particularly challenging and these data demonstrate that FoundationOne Liquid can accurately predict which patients can respond to therapy."

The BFAST study used FoundationOne® Liquid, Foundation Medicine's comprehensive liquid biopsy test, which detects the four main classes of genomic alterations, microsatellite instability (MSI) and select fusions including ALK in circulating tumour DNA (ctDNA) from a blood draw. These data demonstrate that the FoundationOne Liquid assay can help to test and identify a broader population of people with advanced NSCLC who may benefit from Alecensa® (alectinib), for whom current diagnostic tests are not suitable, such as for those who cannot provide tissue samples due to insufficient or absent tumour tissue or where tissue diagnostics are not available, and validate the clinical utility of blood-based NGS as an additional method to inform clinical decision-making in ALK-positive NSCLC.

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In the study, 87.4% (95% CI: 78.5-93.5) of people with advanced NSCLC who were identified by the FoundationOne Liquid biopsy assay to have ALK fusions had a confirmed response to treatment with Alecensa (overall response rate; ORR) as measured by the investigator per Response Evaluation Criteria in Solid Tumours (RECIST v1.1). This is consistent with the ORR for Alecensa observed in the pivotal Phase III ALEX trial, which identified people using tissue-based testing. When measured using an Independent Review Facility per RECIST v1.1, the confirmed ORR was numerically higher at 92.0% (95% CI: 84.1-96.7). Median progression free-survival (PFS) and duration of response (DoR) were not reached after a median follow-up of 12.6 months. The safety profile of Alecensa was consistent with prior clinical trials and post-marketing experience, with no new safety signals observed.

About the BFAST Study
BFAST (Blood First Assay Screening Trial; NCT03178552) is a Phase II/III global, multi-centre, open label, multi-cohort study evaluating the safety and efficacy of targeted therapies or immunotherapies as single agents or in combination in people with unresectable, advanced or metastatic NSCLC determined to harbour oncogenic somatic mutations or be tumour mutational burden (TMB) positive as identified by blood-based NGS ctDNA assays. The Alecensa ALK-positive cohort is the first to readout, with other cohorts due to follow. The primary endpoint for the Alecensa ALK-positive cohort of the BFAST study is confirmed investigator (INV)-assessed ORR. Secondary endpoints include: independent review facility (IRF)-assessed ORR, DoR (INV and IRF), PFS (INV and IRF), overall survival (OS) and safety.

About Alecensa
Alecensa (RG7853/AF-802/RO5424802/CH5424802) is a highly selective, CNS active, oral medicine created at Chugai Kamakura Research Laboratories and is being developed for people with NSCLC whose tumours are identified as ALK-positive. ALK-positive NSCLC is often found in younger people who have a light or non-smoking history. It is almost always found in people with a specific type of NSCLC called adenocarcinoma. Alecensa is now approved in 83 countries as an initial (first-line) treatment for ALK-positive, metastatic NSCLC, including in the US, Europe, Japan and China.

About Foundation Medicine
Foundation Medicine is a molecular information company dedicated to a transformation in cancer care in which treatment is informed by a deep understanding of the genomic changes that contribute to each patient's unique cancer. The company, a member of the Roche Group, offers a full suite of comprehensive genomic profiling tests to identify the molecular alterations in a patient's cancer and match them with relevant targeted therapies, immunotherapies and clinical trials. Foundation Medicine's molecular information platform aims to improve day-to-day care for patients by serving the needs of clinicians, academic researchers and drug developers to help advance the science of molecular medicine in cancer.

For more information, please visit http://www.foundationmedicine.com or follow Foundation Medicine on Twitter (@FoundationMedicineATCG).

About Roche in lung cancer
Lung cancer is a major area of focus and investment for Roche, and we are committed to developing new approaches, medicines and tests that can help people with this deadly disease. Our goal is to provide an effective treatment option for every person diagnosed with lung cancer. We currently have five approved medicines to treat certain kinds of lung cancer and more than ten medicines being developed to target the most common genetic drivers of lung cancer or to boost the immune system to combat the disease.

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. More than 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. Moreover, for the eleventh consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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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