Media Release

Updated data demonstrate Roche's Alecensa increases overall survival rate for people with ALK-positive non-small cell lung cancer

- **ALEX study is the first global phase III study to show a clinically meaningful benefit in overall survival at five years (62.5% with Alecensa), compared with crizotinib (45.5%)**
- **Data confirm longer-term efficacy of Alecensa, both in patients with or without central nervous system metastases at baseline**

Basel, 29 May 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today presented updated data from the pivotal phase III ALEX study, showing an increased five-year survival rate with Alecensa® (alectinib), compared with crizotinib, in people living with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC). These data confirm the longer-term efficacy of Alecensa already demonstrated across three phase III clinical trials. Full findings were presented at the ASCO20 Virtual Scientific Programme, on 29 May 2020.

"These data further support Alecensa as the standard of care for people with metastatic ALK-positive NSCLC," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Importantly, these data show clinically meaningful benefit in people with or without central nervous system (CNS) metastases. These data, and our work in lung cancer more broadly, demonstrate our continued commitment to improving outcomes for people with this disease."

The updated results from the ALEX study show a five-year survival rate of 62.5% (95% CI: 54.3-70.8) in the Alecensa treatment group, versus 45.5% (95% CI: 33.6-57.4) with crizotinib.[1] Despite longer median treatment duration, the safety profile of Alecensa remains favourable and consistent with previous data, with no new safety signals identified.[1] The overall survival (OS) data, which are not yet mature, show a benefit in patients with CNS metastases at baseline (42% reduction in the risk of death versus crizotinib (95% CI: 0.34-1.00)), as well as in those without CNS metastases at baseline (24% reduction in the risk of death versus crizotinib (95% CI: 0.45-1.26)).[1] These data follow on from the final, mature progression-free survival data from the ALEX study, presented at the European Society for Medical Oncology (ESMO) congress in September 2019, which demonstrated a reduced risk of disease worsening or death by 57% (hazard ratio=0.43, 95% CI: 0.32–0.58) with Alecensa, versus crizotinib, in ALK-positive NSCLC.[2] The updated data confirm the superior efficacy and tolerability of Alecensa in comparison to crizotinib.

Approximately 85% of lung cancer cases are NSCLC and, of these people, about 5% are ALK-positive.[3,4] ALK-positive NSCLC is caused by a gene fusion or rearrangement that overactivates the ALK protein, driving cancer cell growth and survival.[5] The disease often affects those who least expect it; 50% of patients are younger than 50 years and approximately 70% have never smoked.[6,7,8]

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About the ALEX study[9]
ALEX (NCT02075840/B028984) is a randomised, multicentre, open-label, phase III study evaluating the efficacy and safety of Alecensa versus crizotinib in treatment-naïve patients with ALK-positive NSCLC whose tumours were characterised as ALK-positive by the VENTANA ALK (D5F3) CDx Assay, a companion immunohistochemistry (IHC) test developed by Roche Tissue Diagnostics. Patients were randomised (1:1) to receive either Alecensa or crizotinib. The primary endpoint of the ALEX study was progression-free survival (PFS) as assessed by the investigator, and secondary endpoints included: Independent Review Committee (IRC)-assessed PFS, time to CNS progression, objective response rate (ORR), duration of response (DOR) and OS. The multicentre study was conducted in 303 people across 161 sites in 31 countries. OS data continue to be considered immature.

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.[10] ALK-positive NSCLC is often found in younger people who have a light or non-smoking history.[6,7,8] It is almost always found in people with a specific type of NSCLC called adenocarcinoma.[11] Alecensa is now approved in 88 countries as an initial (first-line) treatment for ALK-positive, metastatic NSCLC, including in the US, Europe, Japan and China.[10]

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 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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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