Media & Investor Release

European Commission approves Roche's Alecensa as the first and only targeted adjuvant treatment for people with ALK-positive early-stage lung cancer

- **Alecensa reduced the risk of disease recurrence or death by an unprecedented 76% in people with ALK-positive resected non-small cell lung cancer, as demonstrated in the Phase III ALINA study[1]**
- **Alecensa's approval addresses an urgent unmet need in the early-stage setting where about half of all people experience disease recurrence following surgery, despite adjuvant chemotherapy[2]**
- **Early diagnosis and treatment of lung cancer can reduce the burden associated with progressive disease and give people the best possible chance of cure[3-6]**

Basel, 10 June 2024 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Commission has approved Alecensa® (alectinib) monotherapy, as adjuvant treatment following tumour resection for adult patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) at high risk of recurrence (Stage IB [≥4 cm]–IIIA NSCLC [7th edition UICC/AJCC]). Data from the Phase III ALINA trial, where Alecensa demonstrated an unprecedented 76% reduction in the risk of disease recurrence or death in people with resected ALK-positive NSCLC, supported the marketing authorisation application.[1]

"For the first time, people in Europe who have undergone surgical resection of ALK-positive NSCLC can be treated with an ALK inhibitor, which can significantly reduce the risk of disease recurrence or death," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "This is a landmark approval for people who have historically faced a high risk of their cancer returning after surgery. We are now able to bring the transformational benefits of Alecensa to even more people with ALK-positive lung cancer."

"When it comes to early stage ALK-positive NSCLC, surgery is not always enough as there remains a high risk of recurrence that leaves patients concerned about what's to come," said Professor Fabrice Barlesi, thoracic oncologist, Paris Saclay University and chief executive officer of Gustave Roussy Institute. "The magnitude of disease-free survival benefit observed in the ALINA study was unprecedented and consistent across all disease stages. The use of early ALK testing will help to identify all patients that could benefit from this important new treatment option."

In the ALINA study, Alecensa reduced the risk of disease recurrence or death by 76% (hazard ratio [HR]=0.24, 95% CI: 0.13-0.43, p<0.0001) compared with platinum-based chemotherapy in people with completely resected IB (tumour ≥ 4 cm) to IIIA (UICC/AJCC 7th edition) ALK-

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

positive NSCLC.[1] In an exploratory analysis, an improvement of central nervous system disease-free survival was observed (HR=0.22; 95% CI: 0.08-0.58).[1] This is of particular importance for people with ALK-positive NSCLC, who are at greater risk of developing brain metastases than those with other types of NSCLC.[7] The safety and tolerability of Alecensa in the ALINA trial were generally consistent with previous trials in the metastatic setting and no unexpected safety findings were observed.[1] These data were published in the *New England Journal of Medicine* in April 2024.

Alecensa is the preferred treatment option for patients with advanced ALK-positive NSCLC and has transformed outcomes for people with this disease. Approved in more than 100 countries as a first- and second-line treatment, more than 94,000 patients with advanced disease have been treated with Alecensa in clinical practice. Following its approval in the adjuvant treatment setting, Alecensa could for the first time play a pivotal role in ALK-positive resectable disease, where there is a significant unmet medical need. Today's approval in Europe follows the April 2024 U.S. Food and Drug Administration (FDA) approval of Alecensa as adjuvant treatment following tumour resection for patients with ALK-positive NSCLC (tumours ≥ 4 cm or node positive), as detected by an FDA-approved test. Submissions to additional health authorities worldwide are ongoing to bring this much-needed new treatment option to as many patients as possible.

To support clinicians' decision-making, routine testing of resected surgical tissue or biopsy for ALK, EGFR and PD-L1 biomarkers in patients with stage IB to IIIA and select IIIB (UICC/AJCC 8th edition) NSCLC, in addition to in the advanced setting, is recommended by international guidelines, including the National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology (NCCN Guidelines®).

About the ALINA study

The ALINA study [NCT03456076] is a Phase III, randomised, active-controlled, multicentre, open-label study evaluating the efficacy and safety of adjuvant Alecensa® (alectinib) compared with platinum-based chemotherapy in people with resected Stage IB (tumour ≥ 4 cm) to IIIA (UICC/AJCC 7th edition) anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer. The study included 257 patients who were randomly assigned to either the Alecensa or chemotherapy treatment arm. The primary endpoint is disease-free survival. Secondary outcome measures include overall survival and percentage of patients with adverse events.

About lung cancer

Lung cancer is one of the leading causes of cancer death globally.[8] Each year 1.8 million people die as a result of the disease; this translates into more than 4,900 deaths worldwide every day.[8] Lung cancer can be broadly divided into two major types: non-small cell lung cancer (NSCLC) and small-cell lung cancer. NSCLC is the most prevalent type, accounting for around 85% of all cases.[9] Today, about half of all people with early lung cancer (45-76%,

depending on disease stage) still experience a cancer recurrence following surgery, despite adjuvant chemotherapy.[2] Treating lung cancer early, before it has spread, may help prevent the disease from returning and provide people with the best opportunity for a cure.[10]

About Alecensa® (alectinib)

Alecensa is a highly selective, central nervous system-active, oral medicine created at Chugai, a member of the Roche Group, Kamakura Research Laboratories for people with non-small cell lung cancer (NSCLC) whose tumours are identified as anaplastic lymphoma kinase (ALK)-positive. Alecensa is already approved in over 100 countries as an initial (first-line) and second-line treatment for ALK-positive, metastatic NSCLC, including in the United States, Europe, Japan and China. Alecensa was approved by the U.S. Food and Drug Administration (FDA) in April 2024 as adjuvant treatment following tumour resection for patients with ALK-positive NSCLC (tumours ≥ 4 cm or node positive), as detected by an FDA-approved test, and in June 2024 by the European Commission, as a monotherapy for adjuvant treatment following tumour resection for adult patients with ALK-positive NSCLC at high risk of recurrence (Stage IB [≥4 cm]–IIIA NSCLC [7th edition UICC/AJCC]).

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 six 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. Roche is committed to improving treatment of early-stage lung cancers to help increase the chance of cure for more people.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavour to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the fifteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

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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Roche Global Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD
Phone: +41 79 407 72 58

Nathalie Altermatt
Phone: +41 79 771 05 25

Karsten Kleine
Phone: +41 79 461 86 83

Kirti Pandey
Phone: +49 172 6367262

Dr. Rebekka Schnell
Phone: +41 79 205 27 03

Sileia Urech
Phone: +41 79 935 81 48

Simon Goldsborough
Phone: +44 797 32 72 915

Nina Mählitz
Phone: +41 79 327 54 74

Yvette Petillon
Phone: +41 79 961 92 50

Roche Investor Relations

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com