Investor Update

CHMP recommends EU approval of Roche's Alecensa as the first adjuvant treatment for resected ALK-positive early-stage lung cancer

- **If approved, Alecensa will be the first and only ALK inhibitor approved for people with resected ALK-positive early-stage non-small cell lung cancer (NSCLC)**
- **The positive recommendation is based on results from the Phase III ALINA study where Alecensa showed an unprecedented 76% reduction in the risk of disease recurrence or death, compared to adjuvant chemotherapy[1]**
- **With about half of people living with early-stage NSCLC experiencing disease recurrence or death following surgery, Alecensa could minimise the risk by treating NSCLC before it has spread[2]**

Basel, 26 April 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of Alecensa® (alectinib) monotherapy, as adjuvant treatment following complete tumour resection for adult patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) at high risk of recurrence*. Cancer recurrence affects approximately half of all people with early-stage NSCLC following surgery, despite adjuvant chemotherapy, at which point the disease often becomes incurable.[2-8] By treating NSCLC before it has spread to other parts of the body and reducing the chance of a person's cancer returning, Alecensa has the potential to change the current standard of care for people with resected ALK-positive early-stage NSCLC. A final decision is expected from the European Commission in the near future.

"Minimising the risk of disease recurrence or death by an unprecedented 76% for people with ALK-positive NSCLC could have a profound impact on patients and their families by providing the best chance for cure," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "The CHMP's recommendation for adjuvant Alecensa marks an important step towards providing a new, effective therapy for people with early-stage NSCLC that could improve outcomes through a targeted and biomarker-driven treatment approach."

The CHMP recommendation is based on positive results from the Phase III ALINA study that demonstrated 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-positive early-stage NSCLC.[1]

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An exploratory analysis also showed improvement of central nervous system disease-free survival (HR=0.22; 95% CI: 0.08-0.58).[1] The safety and tolerability of Alecensa in this trial were consistent with previous trials in the metastatic setting and no unexpected safety findings were observed.[1] These data were presented as a late-breaking oral presentation at the European Society of Medical Oncology Congress 2023 Presidential Symposium in October 2023 and were also recently published in the *New England Journal of Medicine* in April 2024.

In April 2024, the U.S. Food and Drug Administration (FDA) granted approval to 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. The FDA reviewed and approved the supplemental application under its Real-Time Oncology Review (RTOR) programme, which aims to explore a more efficient review process to ensure safe and effective treatments are available to patients as early as possible. Submissions to additional health authorities worldwide are ongoing with the aim of bringing this much-needed new treatment option to as many patients as possible.

Alecensa has transformed outcomes for people with ALK-positive advanced NSCLC as evidenced by its approval as a first- and second-line treatment in this setting. Following this positive recommendation, Alecensa could for the first time play a pivotal role in resectable disease, where there is a significant unmet medical need. 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® (NCCN®) Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Alecensa is also recommended by NCCN Guidelines® as a category 1 preferred treatment option for people with completely resected stage II-IIIA or select stage IIIB (UICC/AJCC 8th edition) NSCLC, whose tumours harbour ALK rearrangements.

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 (DFS). Secondary outcome measures include overall survival, central nervous system DFS, and percentage of patients with adverse events.

About lung cancer

Lung cancer is one of the leading causes of cancer death globally.[9] Each year 1.8 million people die as a result of the disease; this translates into more than 4,900 deaths worldwide every day.[9] 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.[10] 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.[11]

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.

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.

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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*Stage IB (tumours ≥ 4 cm) - IIIA non-small cell lung cancer (UICC/AJCC 7th edition)

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