Media & Investor Release

Roche's Alecensa reduces the risk of disease recurrence or death by an unprecedented 76% in people with ALK-positive early-stage non-small cell lung cancer

- **These Phase III data are the first and only to show an improvement in disease-free survival in early-stage resected ALK-positive non-small cell lung cancer (NSCLC)**
- **With about one in two people with early-stage NSCLC experiencing disease recurrence following surgery, despite adjuvant chemotherapy,[1] more effective treatment options are urgently needed to provide the best chance for cure[2]**
- **Data are being presented as a late-breaking oral during the ESMO 2023 Presidential Symposium**

Basel, 18 October 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today results from the primary analysis of the Phase III ALINA study demonstrating a statistically significant and clinically meaningful improvement in disease-free survival (DFS; primary endpoint). The study results showed that Alecensa® (alectinib) reduces 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 stage IB (tumour ≥4cm) to IIIA (UICC/AJCC 7th edition) anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC).[3] A clinically meaningful improvement of central nervous system (CNS)-DFS was also observed (HR=0.22; 95% CI: 0.08-0.58).[3] 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.3 Overall survival data were immature at the time of this analysis and follow-up is ongoing to report a more mature estimate.[3]

The full results of ALINA are being presented as a late-breaking oral at the European Society of Medical Oncology (ESMO) Congress 2023 Presidential Symposium on Saturday 21 October 2023. These data will be submitted to global health authorities, including the U.S. Food and Drug Administration and the European Medicines Agency.

"By reducing the risk of recurrence or death of ALK-positive early-stage NSCLC by an unprecedented 76%, Alecensa can potentially alter the course of this disease as we aim to provide the best chance for cure," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We urgently need to do more to help people with lung cancer, as about half of patients with early-stage NSCLC experience disease recurrence. We're working with health authorities to bring Alecensa to patients in this setting as soon as possible."

"These potentially practice-changing data reinforce the potential of Alecensa as a new

standard of care in the ALK-positive early lung cancer setting where treatment options are currently extremely limited," said Professor Benjamin Solomon, Medical Oncologist, Peter MacCallum Cancer Centre, Australia. "The magnitude of disease-free survival observed in this study could represent a paradigm shift in the way we manage early-stage ALK-positive lung cancer."

Delaying disease progression is of particular importance for people with ALK-positive NSCLC, who are generally younger – usually around 55 – and are at higher risk of developing brain metastases than those with other types of NSCLC.[4] Once the disease returns it often spreads to other parts of the body, at which point it is usually considered incurable.[2,5] Comprehensive biomarker testing is essential to helping physicians secure a complete, personalised diagnosis and identify the right treatment for each patient.

Results from the primary analysis of the ALINA study showed median DFS was not yet reached for Alecensa compared with 41.3 months for chemotherapy (95% CI: 28.5, not evaluable [NE]) in patients with stage IB (tumour ≥4cm) to IIIA disease.[3] Grade 3 or 4 adverse events (AEs) occurred in 30% of people receiving Alecensa, compared with 31% of those receiving chemotherapy.[3] No Grade 5 events were observed in either treatment arm.[3] For those receiving Alecensa, 5.5% of patients discontinued treatment due to AEs versus 12.5% in the chemotherapy arm.[3]

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 completely resected stage IB (tumour ≥4cm) to IIIA (UICC/AJCC 7th edition) anaplastic lymphoma kinase (ALK)-positive NSCLC. The study includes 257 patients who were randomly assigned to either the investigational or control treatment arm. The primary endpoint is disease-free survival. Secondary outcome measures include overall survival and percentage of patients with adverse events.

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 lung cancer

Lung cancer is one of the leading causes of cancer death globally.[6] Each year 1.8 million people die as a result of the disease; this translates into more than 4,900 deaths worldwide every day.[6] Lung cancer can be broadly divided into two major types: non-small cell lung cancer (NSCLC) and small-cell lung cancer (SCLC). NSCLC is the most prevalent type, accounting for around 85% of all cases.[7] 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.[1] 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.[2]

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 thirteenth 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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