Media & Investor Release

Roche's Alecensa delivers unprecedented Phase III results for people with ALK-positive early-stage lung cancer

- **ALINA data demonstrate Alecensa reduces disease recurrence in the early setting for people with ALK-positive non-small cell lung cancer (NSCLC), building on its long-established benefit in the advanced setting**
- **About half of people with NSCLC experience disease recurrence following surgery, despite adjuvant chemotherapy, therefore new treatments are urgently needed to provide the best chance for cure**
- **These data will be submitted to health authorities globally and presented at an upcoming medical meeting**

Basel, 01 September 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the Phase III ALINA study evaluating Alecensa® (alectinib), compared with platinum-based chemotherapy, met its primary endpoint of disease-free survival (DFS) at a prespecified interim analysis. Alecensa demonstrated a statistically significant and clinically meaningful improvement in DFS as adjuvant therapy 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). Alecensa is the first and only ALK inhibitor to demonstrate a reduction in the risk of disease recurrence or death for people with early-stage ALK-positive NSCLC in a Phase III trial.

Overall survival (OS) data were immature at the time of this analysis. No unexpected safety findings were observed. Results from the ALINA study will be presented at an upcoming medical meeting and submitted to health authorities globally, including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

"Alecensa has transformed outcomes for people with advanced ALK-positive NSCLC, and now these strong results provide evidence for the first time that this medicine could also play a pivotal role in early-stage disease where there is significant unmet need," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "If approved, Alecensa has the potential to treat cancer before it has spread in a setting where treatment can increase the chances of cure, which is our ultimate goal at Roche. We look forward to sharing these data with regulatory authorities in hopes of bringing this to patients as quickly as possible."

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] Recent treatment innovations, including immunotherapies, have improved the outlook for some patients with early-stage NSCLC; however, there are no approved ALK inhibitors for

early-stage ALK-positive disease.[2] Approximately five percent of people with NSCLC are ALK-positive.[3] ALK-positive NSCLC is often found in younger people – usually 55 and under – who have a light or non-smoking history.[4,5] National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend biomarker testing of resected surgical tissue or biopsy for ALK rearrangements in patients with stage IB to IIIA and IIIB NSCLC, in addition to in the advanced setting.

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 non-small cell lung cancer (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 (DFS). Secondary outcome measures include overall survival (OS) 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 now approved in over 100 countries as an initial (first-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.

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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