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Chugai's Alecensa Delivers Positive 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

TOKYO, September 1, 2023 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that the Phase III ALINA study evaluating its anti-cancer agent/ALK inhibitor 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 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 Japan, Europe, and the U.S..

"We are excited to see that Alecensa, widely used as a first-line treatment for ALK-positive advanced NSCLC, has demonstrated a reduction in the risk of disease recurrence or death in patients with early-stage NSCLC" said Dr. Osamu Okuda, Chugai's President and CEO. "There are currently no ALK inhibitors approved in the adjuvant setting for NSCLC, despite the importance of preventing disease recurrence in order to bring a greater number of patients with early-stage NSCLC the potential for cure. We will closely collaborate with Roche towards submitting this data to regulatory authorities in Japan and other countries so that this drug can be used as soon as possible for patients who need it."

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

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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

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.

Sources

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