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Chugai's Alecensa Reduces the Risk of Disease Recurrence or Death by 76% in People with ALK-Positive Early-Stage Non-Small Cell Lung Cancer

- These Phase III data are the first 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

TOKYO, October 20, 2023 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) today announced results from the primary analysis of the Phase III ALINA study of anti-cancer agent/ALK inhibitor Alecensa® (alectinib), demonstrating a statistically significant and clinically meaningful improvement in disease-free survival (DFS; primary endpoint).

The study results showed that Alecensa 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.[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 Japan, Europe, and the U.S.

"We are delighted that new data of Alecensa, a Chugai originated drug, was announced as the first ALK inhibitor to demonstrate a significant reduction in the risk of recurrence or death in early stage ALK-positive NSCLC in a Phase III study." said Dr. Osamu Okuda, Chugai's President and CEO. "There is a significant need for adjuvant therapy to potentially cure early-stage NSCLC, which recurs in about half of patients. We are committed to collaborate with Roche towards submitting this data, which demonstrated Alecensa's potential to become a new treatment option, to regulatory authorities around the world so that this drug can be delivered to patients as soon as possible."

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324 Japan
Media Relations Group TEL:+81-(0)3-3273-0881 E-mail:pr@chugai-pharm.co.jp
Investor Relations Group TEL:+81-(0)3-3273-0554 E-mail:ir@chugai-pharm.co.jp

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 plays an important role in identifying the right treatment for each patient based on their genetic mutation.

Results from the primary analysis of the ALINA study showed that 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

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. In Japan, Alecensa has also been approved for the treatment of recurrent or refractory *ALK* fusion gene-positive anaplastic large cell lymphoma.

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]

Sources

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