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Alecensa Approved by FDA as the First Adjuvant Treatment for People with ALK-Positive Early-Stage Non-Small Cell Lung Cancer

- Approval based on Phase III ALINA study showing Alecensa reduced the risk of disease recurrence or death by 76% in people with ALK-positive early-stage resected non-small cell lung cancer (NSCLC)
- This approval helps address the unmet medical need, with about half of people living with early-stage NSCLC experiencing disease recurrence following surgery, despite adjuvant chemotherapy

TOKYO, April 19, 2024 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that the U.S. Food and Drug Administration (FDA) has approved anaplastic lymphoma kinase (ALK) inhibitor Alecensa® (generic name : alectinib) for adjuvant treatment following tumor resection for patients with-ALK positive non-small cell lung cancer (NSCLC) (tumors ≥ 4 cm or node positive) as detected by an FDA-approved test. Alecensa is now the only ALK inhibitor approved for people with ALK-positive early-stage NSCLC who have undergone surgery to remove their tumor. Outside the U.S., the medicine is currently under review for the indication by health authorities including in Europe, Japan, and Taiwan.

“We are very pleased that Alecensa, a Chugai originated medicine, is now approved by the FDA as the first adjuvant therapy for ALK-positive early-stage NSCLC. Alecensa has shown in a clinical trial to reduce the risk of death or recurrence by 76%. Bringing patients a new treatment option with the possibility of cure, may become a turning point in the treatment of ALK-positive early-stage NSCLC. We will work closely with Roche to deliver this treatment to patients awaiting all over the world, as soon as possible,” said Chugai’s President and CEO, Dr. Osamu Okuda.

The approval 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<0.001) compared with platinum-based chemotherapy in people with completely resected IB (tumor ≥ 4 cm) to IIIA (UICC/AJCC 7th edition) ALK-positive NSCLC.[1] An exploratory analysis also showed improvement of central nervous system (CNS)-disease-free survival, reducing the risk of disease recurrence or death by 78% (HR=0.22; 95% CI: 0.08-0.58) compared with platinum-based chemotherapy.[1] The safety and tolerability of Alecensa in this trial were generally 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 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.

Alecensa is a kinase inhibitor currently approved as first- and second -line treatment for ALK-positive metastatic NSCLC. It has demonstrated efficacy in patients, including those with CNS metastases, and now with this approval, these benefits could extend to people with early-stage NSCLC. Routine testing of resected

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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®), to support clinicians' decision-making. Approximately5% of people with NSCLC are ALK-positive, equating to approximately 90,000 people worldwide diagnosed each year.[2,3,4]

About the ALINA study

The ALINA study [NCT03456076] is a Phase III, randomized, active-controlled, multicenter, open-label study evaluating the efficacy and safety of adjuvant Alecensa (alectinib) compared with platinum-based chemotherapy in people with completely resected stage IB (tumor ≥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, central nervous system-DFS 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 tumors 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.[5] Each year 1.8 million people die as a result of the disease; this translates into more than 4,900 deaths worldwide every day.[5] In Japan, 127 thousand people are affected by this disease (2019).[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.[8] 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.[9]

Source:

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