Innovation all for the patients

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

- Alecensa reduced the risk of disease recurrence or death by 76% in people with ALK-positive resected non-small cell lung cancer (NSCLC), as demonstrated in the Phase III ALINA study
- Alecensa's approval helps address a significant unmet need where about half of people living with early-stage NSCLC experience disease recurrence following surgery, despite adjuvant chemotherapy

TOKYO, June 10, 2024 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that the European Commission has approved a Chugai originated anaplastic lymphoma kinase (ALK) inhibitor Alecensa® (generic name : alectinib) monotherapy, as adjuvant treatment following tumour resection for adult patients with ALK-positive non-small cell lung cancer (NSCLC) at high risk of recurrence (Stage IB [tumors ≥ 4 cm]–IIIA NSCLC [7th edition UICC/AJCC]). Data from the Phase III ALINA trial, where Alecensa demonstrated a 76% reduction in the risk of disease recurrence or death in people with resected ALK-positive NSCLC, supported the marketing authorisation application.[1]

"We are very pleased that Alecensa, a Chugai originated medicine, received approval in Europe following the U.S. approval for adjuvant treatment of ALK-positive early-stage NSCLC. We believe that this approval will have a significant impact, providing a new treatment opportunity for patients who have dealt with the risk of recurrence even after undergoing tumor resection. We remain committed to working with Roche to bring the benefits of this drug to patients around the world." said Chugai's President and CEO, Dr. Osamu Okuda.

In the ALINA study, Alecensa reduced 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 IB (tumors ≥ 4 cm) to IIIA (UICC/AJCC 7th edition) ALK-positive NSCLC.[1] In an exploratory analysis, an improvement of central nervous system disease-free survival was observed (HR=0.22; 95% CI: 0.08-0.58) compared with platinum-based chemotherapy.[1] This is of particular importance for people with ALK-positive NSCLC, who are at greater risk of developing brain metastases than those with other types of NSCLC.[2] The safety and tolerability of Alecensa in the ALINA trial were generally consistent with previous trials in the metastatic setting and no unexpected safety findings were observed.[1] These data were published in the New England Journal of Medicine in April 2024.

Alecensa is the preferred treatment option for patients with advanced ALK-positive NSCLC. Approved in more than 100 countries as a first- and second-line treatment, more than 94,000 patients with advanced disease have been treated with Alecensa in clinical practice. Following its approval in the adjuvant

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treatment setting, Alecensa could play a pivotal role in ALK-positive resectable disease, where there is a significant unmet medical need. Today's approval in Europe follows the April 2024 U.S. Food and Drug Administration (FDA) approval of Alecensa as adjuvant treatment following tumor resection for patients with ALK-positive NSCLC (tumors ≥ 4 cm or node positive), as detected by an FDA-approved test. Submissions to additional health authorities worldwide are ongoing to bring this new treatment option to as many patients as possible.

To support clinicians' decision-making, testing of resected surgical tissue or biopsy for ALK, EGFR and PD-L1 biomarkers in patients with stage IB to IIIA and selected IIIB (UICC/AJCC 8th edition) NSCLC, in addition to in the advanced setting, is recommended by international guidelines, including the National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology (NCCN Guidelines®).

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 resected Stage IB (tumors ≥ 4 cm) to IIIA (UICC/AJCC 7th edition) anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC). The study included 257 patients who were randomly assigned to either the Alecensa or chemotherapy 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, for people with NSCLC whose tumors are identified as 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. Alecensa was approved by the U.S. Food and Drug Administration (FDA) in April 2024 as adjuvant treatment following tumor resection for patients with ALK-positive NSCLC (tumors ≥ 4 cm or node positive), as detected by an FDA-approved test, and in June 2024 by the European Commission, as a monotherapy for adjuvant treatment following tumor resection for adult patients with ALK-positive NSCLC at high risk of recurrence (Stage IB [tumors ≥ 4 cm]–IIIA NSCLC [7th edition UICC/AJCC]). 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.[3] Each year 1.8 million people die as a result of the disease; this translates into more than 4,900 deaths worldwide every day.[3] In Japan, 127 thousand people are affected by this disease (2019).[4] Lung cancer can be broadly divided into two major types: non-small cell lung cancer (NSCLC) and small-cell lung cancer. NSCLC is the most prevalent type, accounting for around 85% of all cases.[5] 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.[6] 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.[7]

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Source:

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