Innovation all for the patients

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Alecensa Approved in Japan for the Additional Indication of Adjuvant Treatment for People with ALK-Positive Early-Stage Non-Small Cell Lung Cancer

- Approval based on the results of the first global Phase III clinical study in people with early-stage ALK-positive resected non-small cell lung cancer (NSCLC) demonstrating efficacy, ALINA study, which demonstrated reduction of the risk of disease recurrence or death by 76%
- 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, August 28, 2024 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that the Ministry of Health, Labour and Welfare (MHLW) has approved today the additional indication of Alecensa® (generic name: alectinib), a Chugai originated antineoplastic agent/ALK inhibitor, for "adjuvant therapy for *ALK* fusion gene-positive non-small cell lung cancer." The application for regulatory approval for Alecensa was filed in December 2023, followed by an orphan drug designation subject to priority review, in the same month.

"We are very pleased that Alecensa, a Chugai originated medicine, received approval in Japan following the U.S. and Europe for the additional indication of adjuvant therapy for ALK-positive NSCLC. In early-stage NSCLC, approximately half of patients who received tumor resection surgery may experience recurrence. With this additional indication, we are confident in not only reducing the risk of post-operative recurrence but also being able to expect complete cure and long-term survival in patients with ALK-positive NSCLC in Japan. We believe this greatly improves the quality of life for patients and their families. We will continue working to promptly provide proper use information," said Chugai's President and CEO, Dr. Osamu Okuda.

The approval is based on results from the ALINA study, a global Phase 3 study conducted in patients with completely resected ALK-positive early NSCLC stage IB (tumors ≥ 4 cm) to IIIA (UICC/AJCC 7th edition). In the 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 to IIIA ALK-positive NSCLC.[1] 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]

Chugai Pharmaceutical, a leading oncology company, is committed to promoting the proper use of Alecensa so that it can contribute to the treatment of ALK-positive early non-small cell lung cancer as a new treatment option in the adjuvant setting.

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Electronic Package Insert Information ※Underlined parts were changed and added

Brand Name : ALECENSA® Capsules 150 mg

Generic Name : alectinib capsules

Indications : Adjuvant therapy for *ALK* fusion gene-positive non-small cell lung cancer

Dosage and administration :

<Adjuvant therapy for *ALK* fusion gene-positive non-small cell lung cancer >

The usual adult dosage is 600 mg of alectinib administered orally twice daily after a meal. The treatment period should be up to 24 months, and the dose may be reduced according to the patient's condition.

[Reference Information]

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 (Press release on October 20, 2023)

https://www.chugai-pharm.co.jp/english/news/detail/20231020170000_1017.html

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, China and Taiwan. ALK-positive lung cancer is said to account for approximately 3-5% of non-small cell lung cancers[2]. In Japan, Alecensa has also been approved for the treatment of recurrent or refractory *ALK* fusion gene-positive anaplastic large cell lymphoma.

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 addition, it has been approved in Japan as an adjuvant therapy following complete tumor resection for ALK-positive NSCLC.

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].

Source:

1. Solomon B, et al. ALINA: efficacy and safety of adjuvant alectinib versus chemotherapy in patients with early-stage ALK+ non-small cell lung cancer (NSCLC). Presentation at: European Society for Medical oncology Congress; 2023 October 20-24. Late-breaking abstract #LBA2.
2. Biomarker Committee of the Japan Lung Cancer Society. Guidance for ALK Gene Testing in Lung Cancer Patients Version 4.0 (Japanese only)
3. Thandra KC, et al. Epidemiology of lung cancer. Contemp Oncol. 2021;21(1):45-52.
4. Cancer Statistics, Cancer Information Service, National Cancer Center, Japan (National Cancer Registry) [Internet; cited 2024 August] Available from: https://ganjoho.jp/reg_stat/statistics/stat/cancer/12_lung.html (Japanese Only)
5. American Cancer Society: What Is Lung Cancer? [Internet; cited 2024 August] Available from: https://www.cancer.org/cancer/types/lung-cancer/about/what-is.html.
6. Pignon JP, et al. Lung adjuvant cisplatin evaluation: a pooled analysis by the LACE collaborative group. J Clin Oncol. 2008;20;26(21):3552-9.
7. Hendricks LE, et al. Oncogene-addicted metastatic non-small-cell lung cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. Ann Oncol. 2023;34(4):339-357.

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