



Chugai Obtains Approval for Additional Indication of Alecensa for Recurrent or Refractory *ALK* Fusion Gene-Positive Anaplastic Large Cell Lymphoma

- Alecensa receives approval based on the results of a Japanese investigator initiated study in children and adults with the rare disease *ALK* fusion gene-positive anaplastic large-cell lymphoma (ALK-positive ALCL)
- Alecensa is now available as a new treatment option for recurrent or refractory ALK-positive ALCL

TOKYO, February 21, 2020 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced today that it has obtained approval for its anti-cancer agent/ALK inhibitor, Alecensa[®] capsule 150 mg (nonproprietary name: alectinib hydrochloride) from the Ministry of Health, Labour and Welfare for an additional indication of recurrent or refractory *ALK* fusion gene-positive anaplastic large-cell lymphoma.

“Chemotherapy is usually used for the treatment of ALCL. However, standard therapies have not been established in patients with post-chemotherapy recurrent ALCL, resulting in a growing demand for new pharmaceutical products,” said Dr. Osamu Okuda, Chugai’s Executive Vice President, Co-Head of Project & Lifecycle Management Unit. “The approval for the additional indication of Alecensa will offer a new treatment option to patients with these unmet medical needs. We will strive to make Alecensa as one of the standard therapies for ALK-positive non-small cell lung cancer, with the aim of making a significant contribution to the treatment of hematologic cancers.”

This approval is based on the results from the investigator initiated study (the ALC-ALCL study) started in May 2015. The study was conducted as a part of the “Research Project on Practical Application of Innovative Cancer Therapy” by Japan Agency for Medical Research and Development. In the ALC-ALCL study, the response rate (primary endpoint, assessed by the central review committee) and safety were evaluated in 10 patients with relapsed or refractory ALK-positive ALCL who are 6 years or older (6-70 years). The response rate which was the primary endpoint was 80.0% (two-sided 90% confidence interval: 56.15-95.91%). The incidence of adverse reactions was 100.0%. The most common adverse reactions were maculopapular rash (40.0 %, 4/10 cases), upper respiratory tract infection, bronchitis and increased blood alkaline phosphatase (30.0 %, 3/10 cases), respectively.

[Reference information]

Media release issued by Chugai on June 3, 2019

Title: Chugai Files for Additional Indication of ALK Inhibitor ALECENSA for Recurrent or Refractory *ALK* Fusion Gene-Positive Anaplastic Large Cell Lymphoma (ALCL)

https://www.chugai-pharm.co.jp/english/news/detail/20190603163000_622.html

About ALK-positive anaplastic large-cell lymphoma (ALCL)

ALCL is non-Hodgkin's lymphoma originated in T-cells in lymphocytes, which is one of four subtypes of peripheral T-cell lymphoma classified as malignant lymphoma. The malignancy is categorized as “intermediate-grade,” in which disease progression is observed on a monthly basis. In Japan, the percentage of ALCL in malignant lymphomas is from 1.5 to 2.0%^{1,2)}, about half of which have been reported as ALK-positive.^{3,4)} Considering that the 5-year survival rate with successful treatment has been reported to be 60% in patients with ALK-positive ALCL who received chemotherapy in another global study, the percentage of recurrent and refractory cases is estimated to be 40%.³⁾

Prescribing Information * The underlined parts were newly added.

Product name: Alecensa® capsule 150 mg

Nonproprietary name: alectinib hydrochloride

Indications: ○ *ALK* fusion gene positive unresectable, recurrent / advanced non-small cell lung cancer
○ Recurrent or refractory *ALK* fusion gene-positive anaplastic large cell lymphoma

Dosage and administration:

〈*ALK* fusion gene-positive unresectable, recurrent or advanced non-small cell lung cancer〉

The usual adult dosage is 300 mg alectinib administered orally twice daily.

〈Recurrent or refractory *ALK* positive anaplastic large-cell lymphoma〉

The usual dosage is 300 mg of alectinib administered orally twice daily. The usual dosage in adults and children weighing less than 35 kg is 150 mg of alectinib administered orally twice daily.

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Sources

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- 2 Aoki R, Karube K, Sugita Y, Nomura Y, Shimizu K, Kimura Y, et al. Distribution of malignant lymphoma in Japan: Analysis of 2260 cases. 2001-2006. *Pathol Int.* 2008 Mar; 58(3): 174-82
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