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Chugai's Alecensa Approved in Taiwan as an Adjuvant Treatment for Early Stage ALK-Positive Non-Small Cell Lung Cancer (NSCLC)

TOKYO, August 2, 2024 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519, hereafter, Chugai) announced that Chugai Pharma Taiwan Ltd. (hereafter, CPT), a wholly-owned subsidiary of Chugai, obtained an import drug license from the Taiwan Food and Drug Administration (TFDA) for Chugai's Alecensa® (alectinib) as an adjuvant treatment following tumor resection (tumors ≥ 4 cm or node positive) for patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), on August 1, 2024. CPT is responsible for the development, regulatory submission, import, and sales of Chugai-originated products in Taiwan.

"We are very pleased that Alecensa has been approved in Taiwan as adjuvant therapy for early-stage ALK-positive NSCLC. The results of the ALINA study, which demonstrated a 76% reduction in the risk of recurrence or death, have generated significant anticipation in clinical settings. We believe this approval will have a positive impact on lung cancer treatment in Taiwan. We remain committed to delivering this medication to patients awaiting treatment as swiftly as possible," said Takashi Okamoto, President of CPT.

The approval is based on results from the ALINA study, a global Phase 3 study of Alecensa as an adjuvant therapy in people with completely resected IB (tumor ≥ 4 cm) to IIIA (UICC/AJCC 7th edition) ALK-positive NSCLC.

[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,

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metastatic NSCLC, including in the United States, Europe, Japan, China, and Taiwan. 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]).

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