News Release

Alecensa Extends Median Overall Survival to Over 80 Months in ALK-Positive Metastatic Non-Small Cell Lung Cancer

- Final results from the global Phase III ALEX study demonstrate that first-line treatment with Alecensa achieved a clinically meaningful median overall survival of 81.1 months and median duration of response of 42.3 months in patients with previously untreated, advanced ALK-positive non-small cell lung cancer (NSCLC), continuing to show long-term survival benefit[1]
- Latest results from the global Phase III ALINA study reaffirm the importance of Alecensa's role as standard therapy for patients with completely resected ALK-positive NSCLC[2]

TOKYO, October 21, 2025 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that the final data from the global Phase III ALEX study (NCT02075840) and the latest results from the global Phase III ALINA study (NCT03456076) of its anti-cancer agent/ALK inhibitor Alecensa (generic name: alectinib) for anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) were presented at the European Society for Medical Oncology (ESMO) 2025 Annual Congress.[1, 2]

In the final analysis of overall survival (OS), a secondary endpoint of the ALEX study, the median survival time for Alecensa was 81.1 months compared to 54.2 months for crizotinib (hazard ratio[HR]=0.78, 95% CI: 0.56-1.08).[1]
This survival advantage was consistent across all subgroups, including those with central nervous system metastases. The median duration of response was approximately four times longer with Alecensa compared to crizotinib (42.3 months vs 11.1 months, HR=0.41, 95% CI: 0.30-0.56), and the safety profile was consistent with the known profile of Alecensa. The main adverse event (≥30%) was constipation (40.1%), and despite a longer median treatment duration with Alecensa compared to crizotinib (28.1 months vs. 10.8 months), no new or unexpected safety signals were observed.[1]

Updated results from the ALINA study (NCT03456076) were also presented at ESMO 2025. ALINA is the Phase III trial of an ALK inhibitor with demonstrated efficacy in resectable stage IB-IIIA (UICC/AJCC 7th edition) ALK-positive NSCLC. In the primary analysis, Alecensa showed a significant disease-free survival (DFS) benefit compared to chemotherapy (HR=0.24, 95% CI: 0.13-0.43, p<0.001).[2]

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1 Nihonbashi-Muromachi 2-chome, Chuo-ku, Tokyo 103-8324 Japan
Media Relations Group TEL: +81-(0)3-3273-0881 E-mail: pr@chugai-pharm.co.jp
Investor Relations Group TEL: +81-(0)3-3273-0554 E-mail: ir@chugai-pharm.co.jp

After a median follow-up of four years, Alecensa continued to show improved DFS compared to chemotherapy in stage II-IIIA and stage IB-IIIA (ITT: intent-to-treat) patient populations. Alecensa reduced the risk of recurrence or death by 64% compared to platinum-based chemotherapy in completely resected stage II-IIIA ALK-positive NSCLC (HR=0.36, 95% CI: 0.23-0.56) and by 65% in the ITT population with completely resected stage IB-IIIA ALK-positive NSCLC (HR=0.35, 95% CI: 0.23-0.54). This DFS improvement was consistently demonstrated across subgroups, and a clinically meaningful improvement in CNS DFS was also maintained. Regarding safety, results were consistent with the primary analysis, with no new safety concerns or unexpected issues identified.[2]

About ALEX study[3]

The ALEX study (NCT02075840/B028984) is a randomized, multicenter, open-label Phase III study evaluating the efficacy and safety of Alecensa (alectinib) versus crizotinib in treatment-naïve ALK-positive NSCLC. Patients were randomly assigned in a 1:1 ratio to receive either Alecensa or crizotinib. Crossover between treatment groups before disease progression was not permitted. In the ALEX study, alectinib was administered orally at 600 mg twice daily, which differs from the approved dosage and administration in Japan. The primary endpoint of the ALEX study is progression-free survival (PFS) as assessed by the investigator. Secondary endpoints include PFS as assessed by an Independent Review Committee, time to central nervous system progression, objective response rate (as defined by RECIST criteria), duration of response, overall survival, health-related quality of life, and safety. This multicenter study was conducted in 303 patients across 161 sites in 31 countries.

About ALINA study[4]

The ALINA study (NCT03456076) is a randomized, active-controlled, multicenter, open-label Phase III study evaluating the efficacy and safety of adjuvant Alecensa compared with platinum-based chemotherapy in resected Stage IB (tumor ≥4 cm) to IIIA (UICC/AJCC 7th edition) ALK-positive NSCLC. The study enrolled 257 patients who were randomly assigned to either the Alecensa or chemotherapy treatment arm. The primary endpoint is disease-free survival. Secondary endpoints include overall survival and the percentage of patients experiencing adverse events.

About Alecensa

Alecensa is a highly selective, central nervous system-active, oral medicine created at Chugai Pharmaceutical Co., Ltd. for people with non-small cell lung cancer (NSCLC) whose tumors are identified as anaplastic lymphoma kinase (ALK) positive. *ALK* fusion /

rearrangement gene-positive lung cancer is found in approximately 3-5% of NSCLC cases.[5] Alecensa is already approved in over 100 countries as an initial (first-line) and second-line treatment for *ALK* fusion / rearrangement gene-positive metastatic NSCLC, including in the United States, Europe, Japan, China, and Taiwan. For adjuvant therapy of *ALK* fusion / rearrangement gene-positive NSCLC, Alecensa received approval in the United States in April 2024, followed by Europe in June 2024, and Japan in August 2024. In Japan, Alecensa has been approved for "*ALK* fusion gene-positive unresectable, advanced or recurrent non-small cell lung cancer," "adjuvant therapy of *ALK* fusion-positive non-small cell lung cancer," and "recurrent or refractory ALK fusion gene-positive anaplastic large cell lymphoma."

Sources

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3. ClinicalTrials.gov. A study comparing alectinib with crizotinib in treatment-naive anaplastic lymphoma kinase-positive advanced non-small cell lung cancer participants (ALEX) [Internet; cited 2025 October]. Available from: https://clinicaltrials.gov/ct2/show/NCT02075840.
4. ClinicalTrials.gov. A Study Comparing Adjuvant Alectinib Versus Adjuvant Platinum Based Chemotherapy in Patients With ALK Positive Non-Small Cell Lung Cancer. [Internet; cited 2025 October]. Available from: https://www.clinicaltrials.gov/study/NCT03456076
5. Biomarker Committee of the Japan Lung Cancer Society. Guidance for ALK Gene Testing in Lung Cancer Patients Version 4.0 (Japanese only)

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