ALECENSA® alectinib 150 mg capsules

Roche

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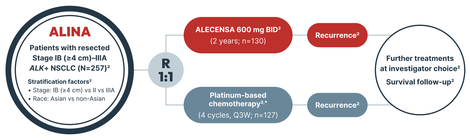
ADJUVANT ALECENSA: THE FIRST AND ONLY TARGETED TREATMENT FOR *ALK*+ RESECTED NSCLC[1]

ALINA (NCT03456076) is a global, Phase III, open-label, randomised clinical trial assessing the efficacy and safety of adjuvant ALECENSA compared with platinum-based chemotherapy[2]



KEY INCLUSION CRITERIA[2]

- ECOG PS 0–1
- Eligible to receive platinum-based chemotherapy
- Adequate end-organ function
- No prior systemic cancer therapy

ENDPOINTS[2]

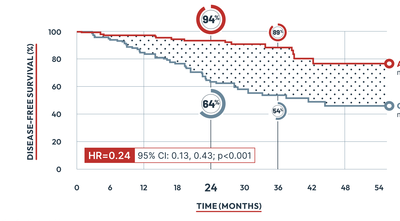
- **Primary:** DFS per investigator,[1] tested hierarchically (Stage II–IIIA → ITT [Stage IB–IIIA])
- Secondary: OS, safety
- Exploratory: CNS disease-free survival[1]

Baseline characteristics were overall well balanced between the ALECENSA and chemotherapy treatment arms, except for sex (female: 58% vs 47%, respectively) and smoking history (never smoked: 65% vs 55%, respectively)[2]

ADJUVANT ALECENSA SIGNIFICANTLY **REDUCED THE RISK OF DISEASE RECURRENCE OR DEATH BY 76%** COMPARED WITH PLATINUM-BASED CHEMOTHERAPY[2]

76% REDUCTION IN THE RISK OF RELAPSE WITH ALECENSA vs chemotherapy

ALINA disease-free survival: ITT (Stage IB–IIIA)[2,5]



No. of patients at risk

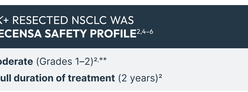
ALECENSA	130	123	123	118	74	55	39	22	10	3
Chemotherapy	127	112	98	89	55	41	27	18	11	2

- At the time of the primary DFS analysis, in the ITT population,[1] **median DFS was not reached** (95% CI: NE, NE) **for ALECENSA** and was **41.3 months** (95% CI: 28.5, NE) **for chemotherapy** (HR=0.24 [95% CI: 0.13, 0.43], p<0.001)[2]
- Median survival follow-up was **27.8 months for ALECENSA** and **28.4 months for chemotherapy**[2]

ALECENSA PROVIDED **CONSISTENT DFS BENEFIT ACROSS STAGE IB THROUGH TO STAGE IIIA**[2,4]

ALINA: subgroup analyses of DFS ITT (Stage IB–IIIA)[2,5]

Subgroup	No. of Events/ No. of Patients	Hazard ratio for disease recurrence or death (95% CI)
All patients	65/257	0.24 (0.14–0.43)
Age		
<65 yr	43/196	0.26 (0.13–0.52)
≥65 yr	22/61	0.24 (0.08–0.71)
Sex		
Male	35/123	0.26 (0.11–0.60)
Female	30/134	0.22 (0.10–0.50)
Race		
Asian	31/143	0.36 (0.17–0.79)
Non-Asian	34/114	0.16 (0.06–0.38)
ECOG performance-status score at baseline		
0	32/137	0.20 (0.09–0.46)
1	33/120	0.31 (0.14–0.69)
Smoking status		
Never smoked	37/154	0.27 (0.13–0.55)
Previous smoker	28/95	0.22 (0.08–0.57)
Current smoker	0/8	NE
Disease stage		
IB	6/26	0.21 (0.02–1.84)
II	22/92	0.24 (0.09–0.65)
IIIA	37/139	0.25 (0.12–0.53)
Regional lymph-node stage		
N0	11/39	0.19 (0.04–0.88)
N1	20/88	0.34 (0.13–0.89)
N2	34/130	0.21 (0.09–0.47)



ALECENSA PROVIDED A **78% REDUCTION IN RISK OF CNS RECURRENCE OR DEATH** COMPARED WITH PLATINUM-BASED CHEMOTHERAPY[2]

ALINA: CNS-DFS ITT (Stage IB–IIIA)[2,3,1,5]

No. of patients at risk

ALECENSA	130	124	124	118	74	55	39	22	10	3
Chemotherapy	127	113	98	90	57	43	27	18	11	2

THE SAFETY PROFILE OF ALECENSA IN *ALK*+ RESECTED NSCLC WAS **CONSISTENT WITH THE ESTABLISHED ALECENSA SAFETY PROFILE**[2,4–6]

- Most adverse events in ALINA were **mild-to-moderate** (Grades 1–2)[2,**]
- **94%** of patients on ALECENSA **completed the full duration of treatment** (2 years)[2]

NCCN GUIDELINES®

Alectinib (ALECENSA) has been recommended by NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) as a **NCCN Category 1 treatment option** for people with **completely resected Stage II-IIIA or stage IIIB** (T3, N2) who test positive for ***ALK* rearrangements**[7]

Staging classified as per the 8th edition of the UICC/AJCC

Testing early for PD-L1 expression, ***EGFR* mutations** and ***ALK* rearrangements in resected NSCLC** can help **identify appropriate treatment regimens** and should be **performed before initiating systemic therapy**[7,8]

IMPROVE OUTCOMES FOR YOUR PATIENTS WITH ALECENSA IN BOTH *ALK*+ RESECTED AND ADVANCED NSCLC

LEARN MORE

Please see the full EU Summary of Product Characteristics here.

This document is based on the EU SmPC for ALECENSA. Regulatory approval and reimbursement status or indication statements may differ in your country. You are advised to consult the product label applicable in your location or to get in touch with the appropriate national health authority for up-to-date product information and prescribing guidance.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via their national reporting system or via medinfo.roche.com.

*Cisplatin + pemetrexed, cisplatin + vinorelbine or cisplatin + gemcitabine; cisplatin could be switched to carboplatin in case of intolerability. †DFS defined as the time from randomisation to the first documented recurrence of disease or new primary NSCLC as determined by the investigator, or death of any cause.‡ ‖Defined as the time from randomisation to the first documented recurrence of disease in the CNS, or death by any cause; this endpoint was exploratory.¶ §Stage IB (tumours ≥4 cm), II or IIA NSCLC classified according to the 7th edition of the UICC/AJCC.# **These subgroup analyses are exploratory.†† ‡‡The safety-evaluable population included patients who underwent randomisation and received any amount of ALECENSA or platinum-based chemotherapy. Multiple occurrences of the same adverse event in an individual patient are counted only once.

AJCC: American Joint Committee on Cancer; ALK: anaplastic lymphoma kinase; BID: twice a day; CI: confidence interval; CNS: central nervous system; DFS: disease-free survival; ECOG PS: Eastern Cooperative Oncology Group performance status; EU: European Union; HR: hazard ratio; ITT: intention-to-treat; NCCN: The National Comprehensive Cancer Network; NE: not estimable; NSCLC: non-small cell lung cancer; OS: overall survival; PD-L1: programmed-death ligand 1; Q3W: every 3 weeks; R: randomised; SmPC: Summary of Product Characteristics; T: tumour; UICC: Union for International Cancer Control; yr: year.

1. Roche. ALECENSA (alectinib) Summary of Product Characteristics. 2024. Available here (accessed July 2024). 2. Wu Y-L, et al. *N Engl J Med* 2024;390(14):1265-1276. 3. Solomon BJ et al. Oral presentation at: European Society for Medical Oncology Congress; October, 2023; Madrid, Spain. 4. Hida T, et al. *Lancet* 2017;390(10089):29-39. 5. Peters S, et al. *N Engl J Med* 2017;377(9):829-838. 6. Zhou C, et al. *Lancet Respir Med* 2019;7(5):437-446.