Alectinib Approved for (ALK) Positive Metastatic Non-Small Cell Lung Cancer

FDA grants regular approval to Alecensa for anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer.

November 6, 2017 By Food and Drug Administration (FDA)

On November 6, 2017, the Food and Drug Administration granted regular approval to alectinib (ALECENSA, Hoffmann-La Roche, Inc./Genentech, Inc.) for treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC), as detected by an FDA-approved test.

In December 2015, alectinib received accelerated approval for treatment of patients with ALK-positive metastatic NSCLC whose disease progressed on or who were intolerant of crizotinib based on an independent review committee (IRC)-assessed overall response rate (ORR) of 38% and 44% among 87 and 138 patients, respectively, in two single arm trials.

This current approval is based on data from ALEX (NCT02075840), a randomized, multi-center, open-label, active-controlled trial conducted in 303 patients with ALK-positive NSCLC who had not received prior systemic therapy for metastatic disease. All patients were required to have evidence of ALK-rearrangement identified by the VENTANA ALK (D5F3) CDx Assay performed through central laboratory testing. Patients were randomized 1:1 to receive alectinib 600 mg orally twice daily (n=152) or crizotinib 250 mg orally twice daily (n=151).

ALEX demonstrated an improvement in progression-free survival (PFS) as assessed by blinded IRC (BIRC), with a hazard ratio (HR) of 0.53 (95% CI: 0.38, 0.73; $p<0.0001$). The estimated median PFS for patients randomized to alectinib was 25.7 months (95% CI: 19.9, not estimable [NE]) compared with 10.4 months (95% CI: 7.7, 14.6) for those randomized to crizotinib. The time to cause-specific central nervous system (CNS) progression as assessed by IRC was also significantly improved; there was a lower incidence of progression in the CNS as first site of disease progression, alone or concurrent with systemic progression, in the alectinib arm (12%) compared to the crizotinib arm (45%). Confirmed ORR was 79% (95% CI: 72, 85) and 72% (95% CI: 64, 79) in the alectinib and crizotinib arms, respectively. Among the 120 responders in the alectinib arm and the 109 responders in the crizotinib arm, the proportion of patients with response duration of ≥12 months was 64% and 36%, respectively.

CNS involvement was assessed in all patients. Among the 43 patients with measurable CNS lesions

on baseline brain scans, the CNS ORR, assessed by BIRC neuro-radiologist, was 81% (95% CI: 58, 95) in the alectinib arm and 50% (95% CI: 28, 72) in the crizotinib arm. Among patients with measurable CNS lesions and a CNS response, the proportion of patients with a CNS response duration of ≥12 months was 59% in the alectinib arm and 36% in the crizotinib arm.

The most common adverse reactions (occurring in ≥20% of patients taking alectinib in ALEX) were fatigue, constipation, edema, myalgia, and anemia. Serious adverse reactions occurred in 28% of patients treated with alectinib. Adverse reactions leading to alectinib discontinuation occurred in 11%. Adverse reactions that led to alectinib discontinuation in 1% or more of patients were renal impairment, hyperbilirubinemia, increased alanine aminotransferase, and increased aspartate aminotransferase. Dose interruption due to adverse reactions occurred in 19% of alectinib-treated patients, while dose reductions were required in 16%.

The recommended dose of alectinib is 600 mg orally twice daily with food.

Full prescribing information is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208434s003lbl.pdf.

FDA granted breakthrough therapy designation to alectinib for this indication in September 2016. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics, available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System by completing a form online at http://www.fda.gov/medwatch/report.htm, by faxing (1-800-FDA-0178) or mailing the postage-paid address form provided online, or by telephone (1-800-FDA-1088).

Follow the Oncology Center of Excellence on Twitter @FDAOncology.

Check out recent approvals at the OCE's new podcast, Drug Information Soundcast in Clinical Oncology (D.I.S.C.O.), available at www.fda.gov/DISCO.

This announcement was original published on the FDA website.

© 2026 Smart + Strong All Rights Reserved.