

Alecensa® (alectinib) - Expanded indication, new warning

- On November 6, 2017, <u>Genentech announced</u> the FDA approval of <u>Alecensa (alectinib)</u> for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.
 - Previously, Alecensa was only approved for this indication in patients who had progressed on or were intolerant to <u>Xalkori[®] (crizotinib</u>).
 - The FDA also converted Alecensa's initial accelerated approval to a full approval.
- The expanded indication for Alecensa was based on an open-label, active-controlled study (ALEX) of 303 patients with ALK-positive NSCLC who had not received prior systemic therapy for metastatic disease. Patients were treated with Alecensa or Xalkori. The major efficacy outcome was progression free survival (PFS).
 - Patients treated with Alecensa demonstrated a significant improvement in PFS vs. the Xalkori group (hazard ratio = 0.53 [95% CI 0.38, 0.73]; p < 0.0001).
 - The median PFS was 25.7 months (95% CI: 19.9, not estimable) vs. 10.4 months (95% CI: 7.7, 14.6) for patients treated with Alecensa vs. Xalkori.
 - The ORR was 79% (95% CI: 72, 85) with Alecensa vs. 72% (95% CI: 64, 79) with Xalkori. In addition, 13% vs. 6% of patients achieved a complete response with Alecensa vs. Xalkori, and 66% of patients in both groups achieved a partial response.
- The Warnings and Precautions section of the Alecensa drug label was also updated with information regarding renal impairment. Renal impairment occurred in 8% of patients in studies NP28761, NP28673, and ALEX.
 - The incidence of grade \geq 3 renal impairment was 1.7%, of which 0.5% were fatal events.
 - Dose modifications for renal impairment were required in 3.2% of patients. Median time to grade ≥ 3 renal impairment was 3.7 months (range 0.5 to 14.7 months).
 - Alecensa should be permanently discontinued for grade 4 renal toxicity. Alecensa should be withheld for grade 3 renal toxicity until recovery to ≤ 1.5 times the upper limit of normal, then resumed at a reduced dose.
- The recommended dosage of Alecensa is 600 mg orally twice daily with food until disease progression or unacceptable toxicity.
 - Patients should be selected for the treatment of metastatic NSCLC with Alecensa based on the presence of ALK positivity in tumor specimens.



optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.