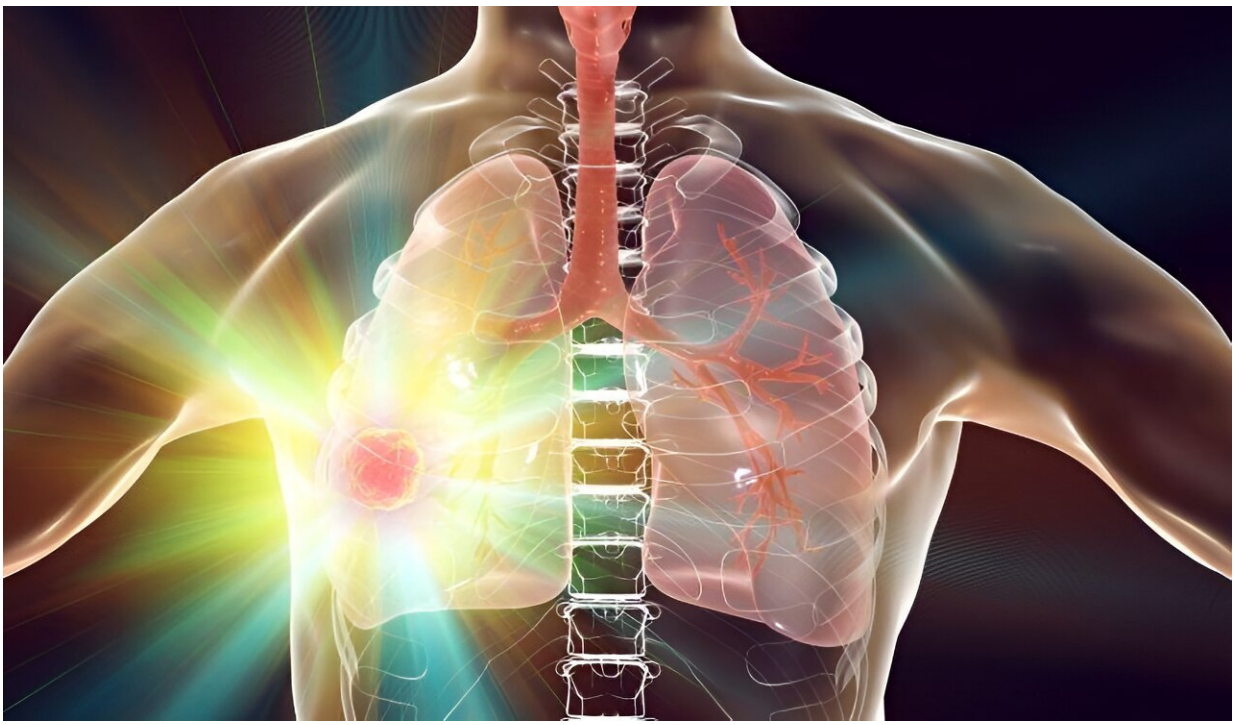
Alecensa approved as first and only anaplastic lymphoma kinase inhibitor for non-small cell lung cancer

April 23 2024, by Lori Solomon



The U.S. Food and Drug Administration has approved Genentech's Alecensa (alectinib) as adjuvant treatment following tumor resection in patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC).

The approval was based on positive results from the Phase III ALINA study that showed Alecensa reduced the risk for disease recurrence or death (hazard ratio, 0.24) versus platinum-based chemotherapy in patients with completely resected IB (tumor ≥4 cm) to IIIA ALK-positive NSCLC. An exploratory analysis showed an improvement of central nervous system disease-free survival (hazard ratio, 0.22). No unexpected safety findings emerged.

"The approval of Alecensa marks a pivotal moment for people newly diagnosed with early-stage ALK-positive lung cancer, who until now, were not able to receive ALK-specific therapy," Ken Culver, from ALK Positive Inc., said in a statement.

"Now, with this significant advance, it is more important than ever that all people diagnosed with early-stage lung cancer undergo testing for ALK and other recommended biomarkers to receive the treatment most appropriate for them."

More information: More Information

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