Alecensa Delays Recurrence of Early-Stage Lung Cancer

People who received the targeted therapy after surgery were less likely to experience recurrence or brain metastasis.

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Alecensa (alectinib) taken after surgery reduced the risk of disease recurrence or death by 76% compared with chemotherapy for people with early-stage ALK-positive non-small-cell lung cancer (NSCLC), according to late-breaking study results presented at the European Society for Medical Oncology (ESMO) Congress.

“These potentially practice-changing data reinforce the potential of Alecensa as a new standard of care in the ALK-positive early lung cancer setting where treatment options are currently extremely limited,” lead investigator Benjamin Solomon, MD, PhD, of Peter MacCallum Cancer Centre in Melbourne, said in a Genentech press release. “The magnitude of disease-free survival observed in this study could represent a paradigm shift in the way we manage early-stage ALK-positive lung cancer.”

The Phase III ALINA trial (NCT03456076) enrolled 257 previously untreated people with Stage IB to Stage IIIA ALK-positive NSCLC that had been surgically removed. More than half were women, and most had never smoked. Around 30% to 40% of NSCLC patients have operable cancer at the time of diagnosis. But about half of people with lung cancer at these stages experience recurrence after surgery despite the use of adjuvant (post-surgery) chemotherapy, the current standard of care.

The participants in this open-label study were randomly assigned to receive adjuvant Alecensa, taken as twice-daily pills, or platinum-based chemotherapy, administered via IV infusion every three weeks. The median duration of treatment was two years in the Alecensa group but only two months in the chemotherapy group.

Alecensa is an oral kinase inhibitor that targets alterations in the anaplastic lymphoma kinase (ALK) gene that drive cancer growth. About 5% of NSCLC is ALK positive, making it susceptible to this type of treatment. Patients with ALK-positive lung cancer tend to be younger (half are diagnosed under age 50), many are nonsmokers and they often experience metastasis to the brain. Alecensa is approved for people with metastatic ALK-positive NSCLC but not yet for earlier stages.

The primary study endpoint was disease-free survival (DFS), meaning patients were still alive without cancer recurrence. After a median follow-up period of about two years, Alecensa led to a “statistically significant and clinically meaningful improvement” in disease-free survival, with a 76% reduction in the risk of recurrence or death, Solomon reported. People who received Alecensa were also 78% less likely to experience brain metastasis.

Two-year DFS rates were 94% in the Alecensa group and 64% in the chemotherapy group, falling to 89% and 54%, respectively, at three years. The median disease-free survival time was 41.3 months in the chemotherapy group but was not reached in the Alecensa group because a majority of patients had not yet experienced recurrence. Overall survival data are still immature, and follow-up is ongoing.

Treatment was generally safe, and side effects were consistent with those seen in previous studies of Alecensa and chemotherapy. The most common adverse events in the Alecensa group were constipation and laboratory abnormalities, including elevated liver enzymes and bilirubin. Severe side effects may include liver toxicity, muscle damage and anemia, according to the drug’s prescribing information. About 30% of ALINA participants in both treatment groups experienced severe adverse events, but people taking Alecensa were about half as likely as chemotherapy recipients to stop treatment for this reason (6% versus 13%).

This is the first and only study to show a significant improvement in disease-free survival for people with early ALK-positive NSCLC after surgery, according to Genentech. The company indicated that it would submit these results to the Food and Drug Administration, the European Medicines Agency and other health authorities to support expanding Alecensa’s approval to earlier stages of lung cancer.

Discussing the study findings, Marina Garassino, MD, of the University of Chicago, said she is not yet ready to give up on chemotherapy for this population—which has been shown to extend survival—until longer-term data are available.

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