FDA Approves Alecensa as Adjuvant Therapy for ALK-Positive Lung Cancer

Alectinib after surgery delayed disease progression for patients with ALK-positive non-small-cell lung cancer.

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By Sharon Reynolds

Some people with non-small-cell lung cancer (NSCLC) that can be removed surgically should be treated afterward with the targeted therapy alectinib (Alecensa), results from a large clinical trial suggest.

Participants in the ALINA trial had tumors with changes in the ALK gene, often called ALK-positive lung cancer. Those treated with alectinib after surgery lived longer without their cancer coming back than those treated with chemotherapy after surgery, the current standard treatment.

In the trial, about 94% of people treated with alectinib after surgery (adjuvant therapy) were alive two years later without their cancer returning compared with about 64% of people treated with adjuvant chemotherapy, according to results published April 10 in the New England Journal of Medicine.

In addition, cancer spread to the brain in far fewer people treated with alectinib than those who received chemotherapy.

On April 18, based on the ALINA trial results, the Food and Drug Administration (FDA) approved alectinib as adjuvant therapy for people with ALK-positive NSCLC.

Although participants were treated with alectinib for a much longer time than those treated with chemotherapy, there were only slightly more serious side effects in the alectinib group.

Trial participants are still being followed to see if those treated with alectinib live longer overall than those treated with chemotherapy. At the time the results were published, only 2 of 130 people treated with alectinib and 5 of 127 who received chemotherapy had died.

Although those differences are modest, the far fewer recurrences seen with alectinib to date in the ALINA trial are cause for optimism, said Benjamin Solomon, MBBS, PhD, of the Peter MacCallum Cancer Centre in Melbourne, Australia, who helped lead the study.

“I am very cautious about using the word cure. But if [lung] cancer comes back, you can’t be cured,” Dr. Solomon said. “The first step towards [cure] is to delay or prevent recurrences. And preventing cancer from coming back is really meaningful for patients.”

Preventing lung cancer recurrence and spread

People with ALK-positive NSCLC tend to be younger and to have never smoked compared with people diagnosed with ALK-negative NSCLC. Overall, only about 4% to 5% of non-small-cell lung cancers are ALK-positive.

“But lung cancer is the most common cancer worldwide, and it causes the most cancer-related deaths,” said Dr. Solomon. “So even small subgroups of lung cancer represent a significant number of people.”

Alectinib targets cancer cells that have specific changes, called rearrangements, in the ALK gene. The drug has been shown to increase how long people with ALK-positive metastatic NSCLC live and has become a mainstay for treatment of people with this form of lung cancer. The treatment also reduces the risk of the cancer spreading to the brain, a common occurrence in people with lung cancer.

“Brain metastases can have such a big impact on a patient. You’re not able to drive. You may have an impaired ability to work or look after your family,” Dr. Solomon said. “So preventing cancer from coming back in the brain is also super important.”

Given the beneficial effects of alectinib in people with more advanced forms of ALK-positive NSCLC, the ALINA trial was launched to see if it could lead to similar improvements in people with earlier-stage disease.

With alectinib, less chance of cancer spreading to the brain

All participants in ALINA—funded by F. Hoffmann-La Roche/Genentech, the drug’s manufacturer—had ALK-positive lung tumors that could be removed surgically and had not yet spread anywhere else in the body.

Of the 257 people who joined the trial, 130 were randomly assigned to receive alectinib—which is taken as a pill—twice a day, every day, for up to 2 years. The other 127 participants received one of several standard chemotherapy regimens, which are given intravenously in four 3-week cycles.

After following the study participants for a median of just over 2 years, there were a total of 65 disease recurrences or deaths overall: 15 in the alectinib group and 50 in the chemotherapy group.

Among a subgroup of 231 people with more advanced tumors that could still be removed

surgically, almost 94% of the alectinib group were alive without evidence of disease recurrence, compared with 63% of people who got chemotherapy.

For the cancers that did recur during the study, the most common site of metastasis was the brain.

But only 4 people in the alectinib group experienced brain metastases during the trial, compared with 14 in the chemotherapy group.

The most common side effects from alectinib were constipation and changes in blood biomarkers that are an early sign of kidney damage. People in the chemotherapy group were most likely to experience nausea and decreased appetite. About 5% of people in the alectinib group and 12% of people in the chemotherapy group stopped treatment early because of side effects.

A growing need for genetic information about lung tumors

Many questions remain about how best to give alectinib after surgery, including the optimal length of treatment, said Dr. Solomon. “We don’t know if [taking the drug for longer] will result in [fewer cancer recurrences],” he explained.

He singled out people whose cancer, based on several different factors, is at particularly high risk of coming back as a group for whom longer treatment should be further studied. Studies combining chemotherapy or other drugs with alectinib after surgery will also be important for those at higher risk of recurrence, explained Dr. Solomon.

Liquid biopsy tests that can analyze blood for indications that a patient is at high risk of their cancer coming back may one day identify people who need more intensive adjuvant therapy, he added.

Before receiving alectinib—either after surgery or for cancer that has metastasized—people with lung cancer must have the ALK status of their tumors confirmed by an FDA-approved test.

The number of drugs that target specific genetic changes in lung cancer highlights the importance of ensuring that oncologists test tumors in all of their patients, including those with earlier stage disease, explained Chen Zhao, MD, of NCI’s Center for Cancer Research, who was not involved in the study.

While such testing is now standard for people with metastatic lung cancer, Dr. Zhao said, it’s not necessarily done automatically for people with tumors that can be removed surgically, he said.

With so many clinical trials testing targeted therapies as adjuvant treatments, genetic tumor testing can also help patients find clinical trials of approved and experimental targeted therapies and immunotherapies, Dr. Zhao added.

“So patients with lung tumors that can be removed with surgery may need to advocate for

themselves to get tested," he said.

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