Tagrisso After Lung Cancer Surgery Cuts Risk of Death by Half

The oral targeted therapy led to a 51% improvement in survival for patients with EGFR-mutated non-small-cell lung cancer.

June 5, 2023 By Liz Highleyman

Lung cancer patients with specific tumor mutations who took Tagrisso (osimertinib) after surgery saw a significant improvement in survival over five years, according to study results presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, underway this week in Chicago. The findings underscore the importance of genomic testing to determine whether patients are eligible for targeted therapy.

In the Phase III ADAURA trial, the five-year risk of death for people with epidermal growth factor receptor (EGFR) tumor mutations who received adjuvant (post-surgery) treatment with Tagrisso was 51% lower than that of patients who received a placebo. This is the first late-phase international study to see a significant improvement in both disease-free-survival and overall survival in this patient population.

“Overall survival has historically been considered the gold standard efficacy endpoint for randomized adjuvant clinical trials,” lead study author Roy Herbst, MD, PhD, of Yale Cancer Center, said in an ASCO news release. “Together with the practice-changing disease-free survival data from our primary analysis, the overall survival benefit instills confidence that adjuvant osimertinib is the standard of care for patients with resected EGFR-mutated Stage IB to IIIA non-small-cell lung cancer. This further reinforces the need to identify these patients with available biomarkers at the time of diagnosis and before treatment begins.”

The ADAURA trial (NCT02511106) enrolled 682 participants in 26 countries with Stage IB, Stage II or Stage IIIA non-small-cell lung cancer (NSCLC), meaning the cancer may have spread to nearby lymph nodes or surrounding structures but is not yet metastatic. About two thirds were women, 64% were Asian and the average age was about 63 years. Many had never smoked. They underwent surgery to completely remove their tumors, which were found to have EFGR mutations suggesting that the cancer would respond to Tagrisso. About 60% had used chemotherapy after surgery.

AstraZeneca’s Tagrisso, first approved in 2015, is a tyrosine kinase inhibitor that interferes with EGFR proteins that play a role in cell proliferation. Certain EGFR mutations (exon 19 deletions or

exon 21 L858R mutations) can promote lung tumor growth and metastasis. Around 10% to 20% of lung cancer in the United States and Europe and up to 40% in Asia has EGFR mutations, which tend to be more common among nonsmokers. Unlike some other EGFR inhibitors, Tagrisso gets into the brain, potentially helping prevent metastasis.

The study participants were randomly assigned to take a Tagrisso or placebo pill once daily until they experienced disease recurrence, completed the three-year trial regimen or developed unacceptable side effects.

Herbst and colleagues previously reported that Tagrisso dramatically improved disease-free survival, meaning patients were still alive without cancer recurrence. Based on those findings, the Food and Drug Administration approved Tagrisso in 2020 for post-surgery treatment of lung cancer with exon 19 deletions or exon 21 L858R mutations. Now, the researchers have reported final overall survival results at the ASCO meeting and in The New England Journal of Medicine.

> A mutation in the EGFR gene is found in ~25% of lung cancers. Reported @NEJM and @ASCO today: a pill directed at this mutation cut deaths by 50% through 5 years in a randomized trial following surgical resectionhttps://t.co/XqjSilWTfd pic.twitter.com/JxtCaFGrMP
>
> — Eric Topol (@EricTopol) June 4, 2023

In the overall study population, the five-year overall survival rate was 88% in the Tagrisso group versus 78% in the placebo group. Among those with Stage II to IIIA NSCLC, the overall survival rates were 85% and 73%, respectively. The median overall survival time could not be determined because a majority of patients were still alive. The results did not differ for those who had and had not received chemotherapy.

Adjuvant Tagrisso “demonstrated an unprecedented, highly statistically significant and clinically meaningful overall survival benefit” after complete tumor resection, with or without adjuvant chemotherapy, the study authors concluded.

Treatment was generally safe, although side effects were common. The most frequently reported

adverse effects of Tagrisso include low white blood cell and platelet counts, diarrhea, anemia, rash, muscle and joint pain, nail problems, dry skin, mouth sores, fatigue and cough. In this study, 13% of Tagrisso recipients and 3% of placebo recipients stopped treatment due to adverse events. There was one new serious event since the earlier analysis, a case of COVID-19 pneumonia.

Improvement in earlier metrics like progression-free survival or disease-free survival do not always lead to improved overall survival with longer follow-up, so the latest data are reassuring. But the optimal duration of Tagrisso treatment remains unknown. The ADAURA study tested a three-year regimen, but shorter therapy might be sufficient, which would mean cost savings and less time with side effects. What's more, participants in this trial who experienced disease recurrence in the placebo group were not given Tagrisso, and some experts think starting Tagrisso when relapse occurs could be more cost-effective with fewer side effects.

"We have been using one-size-fits-all adjuvant chemotherapy for every patient with lung cancer despite a decade of advances in targeted treatments for select groups of patients that result in dramatically better outcomes," ASCO expert Nathan Pennell, MD, PhD, of the Cleveland Clinic Taussig Cancer Institute, said in the ASCO news release. "In a first for the lung cancer field, adjuvant osimertinib unequivocally improves survival in people with resected EGFR-mutated non-small-cell lung cancer. This should be the new standard of care for these patients."

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