

Imfinzi Before and After Surgery Improved Outcomes for Patients With Non-Small-Cell Lung Cancer

People treated with a durvalumab-based regimen before and after surgery had a 32% lower risk of disease recurrence or progression.

April 19, 2023 By American Association for Cancer Research

Durvalumab-Based Treatment Before and After Surgery Improved Outcomes for Patients With Resectable Non-Small Cell Lung Cancer

Patients with treatment-naïve resectable non-small cell lung cancer (NSCLC) who received neoadjuvant durvalumab (Imfinzi) plus chemotherapy and adjuvant durvalumab monotherapy had improved event-free survival (EFS) and pathological complete response (pCR) compared with those who received neoadjuvant chemotherapy alone, according to results from the phase III placebo-controlled [AEGEAN](#) clinical trial, which were presented at the [AACR Annual Meeting 2023](#), held April 14-19.

“Non-small cell lung cancer remains the leading cause of cancer mortality, and historically, about half of patients who undergo resection experience recurrence,” said presenter John V. Heymach, MD, chair of Thoracic/Head and Neck Medical Oncology at The University of Texas MD Anderson Cancer Center. “Anything we can do to increase cure rates for these patients could potentially be a tremendous advance.”

Recent studies indicate the benefit from the use of an adjuvant immune checkpoint inhibitor in NSCLC, especially in patients with PD-1-positive tumors, but whether a more comprehensive approach could improve outcomes has yet to be established, Heymach explained.

In AEGEAN, a randomized, double-blind, placebo-controlled trial, 802 patients with treatment-naïve resectable NSCLC, irrespective of PD-L1 expression, were randomly assigned (1:1) to receive either neoadjuvant durvalumab plus platinum-based chemotherapy or neoadjuvant placebo plus platinum-based chemotherapy every three weeks for four cycles; following surgery, patients continued to receive either durvalumab or placebo every four weeks for up to 12 cycles.

After excluding patients whose tumors had EGFR/ALK alterations, 740 patients in the modified

intent-to-treat population were assessed in this planned interim analysis evaluating the primary endpoint of EFS, defined as the length of time from randomization to an event, such as disease progression precluding definitive surgery, disease recurrence, or death. Final analyses for the additional primary endpoint of pCR, defined as no viable tumor left in the surgical specimen (including lymph nodes) following neoadjuvant therapy, was also evaluated.

Following neoadjuvant treatment, pCR was 17.2% in the treatment arm, versus 4.3% in the placebo arm, a difference of 13.0%.

Overall, 77.6% of patients in the treatment arm and 76.7% of patients in the placebo arm underwent surgery following neoadjuvant therapy.

“Before the study started, there was a concern that giving neoadjuvant immunotherapy might make it harder for some patients to get to surgery. But in fact, we were happy to see that almost an identical number of patients were able to get surgery in both arms, suggesting that the inclusion of neoadjuvant immunotherapy does not reduce the number of patients who can go on to complete surgery,” Heymach said.

After a median follow-up time of 11.7 months, median EFS was not reached in the durvalumab-based regimen arm, versus 25.9 months in the chemotherapy alone arm. Patients in the durvalumab-based regimen arm showed a 32% reduction in the risk of disease progression precluding definitive surgery, disease recurrence, or death compared with those in the chemotherapy alone arm.

Grade 3-4 any cause adverse events occurred in 42.3% and 43.4% of patients in the durvalumab-based regimen arm and the chemotherapy alone arm, respectively. Heymach noted that the data on adverse events were consistent with earlier studies, and no unexpected adverse events related to the treatment were observed.

“We are excited to see that the trial has achieved both its primary endpoints of improving pCR and significantly reducing the likelihood of disease progression, recurrence, or death,” Heymach said. “The good news for patients with NSCLC is there are now multiple different regimens that have shown improvements in outcomes. This study has laid the foundation that we can build on by designing new combination regimens on top of this effective backbone.”

He added, “This is a new treatment paradigm for this patient population, but one that requires investment from multidisciplinary teams—a greater integration of medical oncology, molecular pathology, and surgical oncology teams all working together to improve clinical outcomes.”

Data on secondary endpoints, including overall survival, will be needed in the future to understand the full impact of this treatment approach for patients with treatment-naïve resectable non-small cell lung cancer, Heymach noted.

The study was conducted by AstraZeneca.

This [news release](#) was published by the American Association for Cancer Research on April 16, 2023.

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