Libtayo Improves Survival in People With Advanced Lung Cancer

Among patients with high tumor PD-L1 expression, Libtayo lowered mortality by 43%.

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When given as a first-line treatment, Libtayo (cemiplimab) significantly extended overall survival and progression-free survival compared with platinum chemotherapy in people with advanced non-small-cell lung cancer (NSLSC), especially those with a particular tumor biomarker. These findings were presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020.

Libtayo, from Regeneron and Sanofi, is the newest PD-1 checkpoint inhibitor, a type of immunotherapy. It is approved in the United States and Europe as a treatment for cutaneous squamous cell carcinoma, a type of skin cancer.

PD-1, a receptor on T cells that regulates immunity, can sometimes be commandeered by a tumor to turn off immune responses. Drugs that block PD-1 or its binding partner, known as PD-L1, can release the brakes and restore T-cell activity. Tumors with higher levels of PD-L1 tend to respond better to this type of treatment. Such immunotherapies have changed the landscape of treatment for people with advanced NSCLC.

The Phase III EMPOWER-Lung 1 trial enrolled people with locally advanced or metastatic NSCLC. The companies announced top-line interim results in April, reporting that Libtayo decreased mortality by 32% in people with tumors with high PD-L1 levels. Additional results were reported at ESMO 2020.

This Phase III trial included 710 participants with advanced NSCLC who did not qualify for surgical resection or chemoradiation or whose cancer had progressed despite chemoradiation. Some people with previously untreated metastatic NSCLC were included. More than 1 in 10 had cancer that had spread to the brain. Over 80% were men.

Through random selection, half the population received Libtayo by IV infusion every three weeks for up to 108 weeks, while the other half received platinum-based chemotherapy for four to six cycles. People whose cancer progressed were able to modify their treatment; those on chemotherapy were allowed to switch over to Libtayo (about three quarters did so), and those on Libtayo were allowed to add chemotherapy. The primary endpoints were overall survival and

progression-free survival (PFS); overall response rate, duration of response and quality of life were secondary endpoints.

Overall, the median length of treatment was 27 weeks for Libtayo and 18 weeks for chemotherapy.

After a median follow-up period of 13.1 months in the intent-to-treat group, which included all participants who were enrolled and initially randomized to either treatment group, the median overall survival time was 22.1 months and 14.3 months in the immunotherapy and chemotherapy arms, respectively. Libtayo lowered mortality risk by 32%. Further, the risk of disease progression was 41% lower, with a median PFS time of 6.2 months and 5.6 months in the Libtayo and chemotherapy groups, respectively. For this population, the overall response rate, meaning complete or partial reduction in tumor size, was 37% in the immunotherapy arm and 21% in the chemotherapy arm; 3% and 1%, respectively, had complete remission.

People with a tumor PD-L1 expression level of at least 50% had better outcomes. Among the 563 people in this category, the median follow-up time was 11 months. In this group, Libtayo lowered mortality by 43%. The median overall survival time was 14 months among those on chemotherapy, but this could not yet be determined for those assigned to Libtayo because most participants were still alive. Further, the risk of disease progression was 46% lower, with PFS times of 8.2 months and 5.7 months, respectively. In this group, the overall response rates were 39% in the Libtayo arm and 20% in the chemotherapy arm.

The team also reported that the overall response rate was associated with PD-L1 expression for Libtayo but not for chemotherapy. For tumors with 90% or greater tumor PD-L1 expression, the response rate was 46%. After around six months, tumors regressed by more than 40%.

“This is notable given that nearly three-quarters of patients crossed over from chemotherapy following disease progression, and 12% of patients had pretreated and stable brain metastases,” Ahmet Sezer, MD, of Başkent University in Adana, Turkey, said in a press release. “These results support Libtayo as a potential new option for anti–PD-1 monotherapy in first-line advanced non-small-cell lung cancer.”

Treatment was generally safe, but side effects were common in both groups. Some 37% of participants in the Libtayo arm and 49% in the chemotherapy arm experienced severe (Grade 3 or higher) adverse events. Anemia, fatigue, pneumonia, decreased appetite, constipation and nausea were the most common adverse events, and they occurred more frequently among those on chemotherapy than those on Libtayo.

Immune-mediated adverse events—such as pneumonitis, hepatitis, hyperthyroidism and hypothyroidism, arthritis and others—were experienced by 17% of those given Libtayo.

Although treatment related-adverse events were more common overall among those on chemotherapy, more people on Libtayo discontinued treatment for this reason.

Results from the EMPOWER-Lung 1 trial will be submitted for regulatory approval in the U.S. and Europe, according to Regeneron and Sanofi. Libtayo is also being studied in combination with chemotherapy in a pivotal trial of patients with advanced NSCLC irrespective of PD-L1 expression.

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