Libtayo Immunotherapy OK'd for More Lung Cancer Patients

The checkpoint inhibitor is now approved for people with advanced non-small-cell lung cancer regardless of PD-L1 biomarker levels.

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On November 8, the Food and Drug Administration (FDA) extended its approval of the checkpoint inhibitor Libtayo (cemiplimab) to include a broader group of people with locally advanced or metastatic non-small cell lung cancer (NSCLC). The new indication covers NSCLC patients who do not have mutations that would make them eligible for targeted therapies, regardless of tumor PD-L1 expression.

Libtayo, from Regeneron, is a monoclonal antibody that blocks PD-1, a checkpoint receptor on T cells that regulates immune function. It was first approved in 2018 as a treatment for advanced cutaneous squamous cell carcinoma, a type of skin cancer.

Some tumors can hijack PD-1 to turn off immune responses against them. Medications that block the interaction between PD-1 and its binding partner on cancer cells, known as PD-L1, release the brakes and restore T-cell activity. Tumors with a high PD-L1 level tend to respond better to this type of treatment, but some people with lower PD-L1 expression also respond well.

Libtayo was previously approved in February 2021 as a single agent for first-line treatment of locally advanced or metastatic NSCLC in people with high PD-L1 expression. The new indication covers patients whose tumors lack EGFR, ALK or ROS1 mutations (which can be targeted with other drugs) regardless of PD-L1 levels. For the new indication, Libtayo is used in combination with platinum-based chemotherapy—the same as indication as the widely used checkpoint inhibitor Keytruda (pembrolizumab).

The expanded approval was based on results from a randomized clinical trial (NCT03409614) that enrolled 466 NSCLC patients who had not received prior systemic treatment. They had either metastatic NSCLC or locally advanced cancer that could not be surgically removed or treated with radiation and chemotherapy. Patients could enroll regardless of PD-L1 level, unlike an earlier trial that limited enrollment to those with at least 50% PD-L1 expression.

The participants were randomly assigned to receive either Libtayo or a placebo plus platinum-based chemotherapy via IV infusion every three weeks for four cycles, followed by Libtayo or the

placebo and maintenance chemotherapy.

People who received the Libtayo combination saw a “statistically significant and clinically meaningful” improvement in overall survival compared with the placebo plus chemotherapy, according to the FDA. The median overall survival times were 21.9 months versus 13.0 months, respectively, reflecting a 29% reduction in the risk of death. The overall response rate (tumor shrinkage) was 43% with Libtayo versus 23% in the placebo group.

Treatment with Libtayo is generally safe, but side effects are common. The most common adverse reactions to Libtayo used alone are musculoskeletal pain, fatigue, rash and diarrhea. Using it with chemotherapy can lead to additional side effects such as hair loss, nausea and peripheral neuropathy. Immune-related adverse are also a concern with checkpoint inhibitors. While restoring immune responses against cancer, these drugs can also cause the immune system to attack healthy tissue, resulting in excessive inflammation of organs throughout the body.

“The approval is based on a Phase III trial designed to closely resemble a patient population with varied disease presentations that physicians manage in everyday clinical practice,” David Gandara, MD, of the University of California Davis Comprehensive Cancer Center, said in a Regeneron press release. “Clearly, this is an advance which is clinically meaningful for our patients with advanced stage non-small cell lung cancer.”

Click here for full prescribing information for Libtayo.

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