Libtayo Immunotherapy Improves Cervical Cancer Survival

Study participants who received Libtayo had a 31% lower risk of death than those treated with chemotherapy.

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Libtayo (cemiplimab), the newest checkpoint inhibitor, led to an improvement in overall survival for women with advanced cervical cancer in a late-stage clinical trial, according to an announcement from Sanofi and Regeneron. Based on these findings, the study was stopped ahead of schedule, and the companies plan to apply for Food and Drug Administration (FDA) approval this year.

Cervical cancer is usually caused by human papillomavirus (HPV). Although HPV vaccines can prevent cervical, anal and oral cancer, and precancerous cervical cell changes can be detected early using Pap smears and HPV tests, invasive cervical cancer is difficult to treat once it reaches advanced stages, making it the fourth leading cause of cancer death among women worldwide.

Libtayo is a monoclonal antibody that helps the immune system fight cancer. It blocks PD-1, a checkpoint receptor on T cells that regulates immune function. Some tumors can hijack PD-1 to turn off immune responses. Medications that block the interaction between PD-1 and its binding partner on tumor cells, known as PD-L1, can restore T-cell activity. Tumors with a high PD-L1 level tend to respond better to this type of treatment. Libtayo was first approved in 2018 for the treatment of advanced cutaneous squamous cell carcinoma, a type of skin cancer. Earlier this year, it received additional FDA indications for basal cell carcinoma and non-small-cell lung cancer.

The Phase III trial (ClinicalTrials.gov NCT03257267) enrolled more than 600 women in 14 countries; the median age was 51. They had recurrent or metastatic squamous cell carcinoma or adenocarcinoma—the two main types of cervical cancer—that had progressed despite platinum-based chemotherapy. Patients were eligible regardless of the level of PD-L1 expression in their tumors.

The participants in this open-label study were randomly assigned to receive Libtayo, administered by IV infusion every three weeks, or standard chemotherapy using pemetrexed, vinorelbine, topotecan, irinotecan or gemcitabine.

In the full study population, the median overall survival time was 12.0 months in the Libtayo group

compared with 8.5 months in the chemotherapy arm, representing a 31% reduction in the risk of death. Among patients with squamous cell carcinoma (78% of the study population), overall survival times were 11.1 months for Libtayo recipients versus 8.8 months for chemotherapy recipients, a 27% improvement. Among those with adenocarcinoma (22% of the study population), survival times were 13.3 months and 7.0 months, respectively, a 44% improvement.

Sanofi and Regeneron did not release overall response rates or progression-free survival data, indicating that detailed results would be presented at an upcoming medical meeting (perhaps the American Society of Clinical Oncology annual meeting in June). But overall survival is the highest bar for cancer treatment trials, and a key metric for full FDA approval.

Treatment with Libtayo was generally safe, and no new safety concerns were reported, according to the companies. A similar proportion of people in the Libtayo and chemotherapy group experienced serious adverse events (30% and 27%). The most common adverse events were anemia, nausea, fatigue, vomiting and constipation; all but fatigue occurred more often in the chemotherapy group. Adverse events that occurred more often in the Libtayo group included fatigue, urinary tract infections, back pain and joint pain. However, just 8% of Libtayo recipients and 5% of chemotherapy recipients stopped treatment due to adverse events.

“Libtayo monotherapy is the first medicine to demonstrate an improvement in overall survival in women with recurrent or metastatic cervical cancer following progression on platinum-based chemotherapy in a Phase III trial,” study investigator Krishnansu Tewari, MD, of the University of California at Irvine, said in a press release. “This landmark clinical achievement will bring hope to women with advanced cervical cancer who are often younger than patients with other cancers.”

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