FDA Approves Tevimbra Immunotherapy for Esophageal Cancer

New PD-1 checkpoint inhibitor reduced the risk of death by 30% compared with chemotherapy.

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On March 14, the Food and Drug Administration (FDA) approved Tevimbra (tislelizumab), a new immune checkpoint inhibitor for the treatment of advanced or metastatic esophageal cancer after prior chemotherapy. Esophageal cancer is often diagnosed late, and the five-year expected survival rate is round 6% for people with metastatic disease.

Tevimbra, developed by BeiGene, is a type of immunotherapy that helps the immune system fight cancer. It is a monoclonal antibody that blocks PD-1, a checkpoint receptor on T cells that regulates immune function. 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, known as PD-L1, release the brakes and restore T-cell activity.

The FDA approval is supported by data from the Phase III RATIONALE 302 trial (NCT03430843), an international study that evaluated Tevimbra as a second-line treatment for people with inoperable locally advanced or metastatic esophageal squamous cell carcinoma (ESCC). More than 500 participants were randomly assigned to receive Tevimbra or the investigator's choice of chemotherapy after prior systemic therapy that did not include another PD-1 or PD-L1 checkpoint inhibitor.

The study showed that Tevimbra conferred "a statistically significant and clinically meaningful survival benefit," according to a BeiGene news release. The median overall survival time was 8.6 months in the Tevimbra group compared with 6.3 months in the chemotherapy group. The 12-month overall survival rates were 37% and 24%, respectively. The overall response rate, indicating tumor regression, was twice as high for Tevimbra recipients (20% versus 10%).

"Patients diagnosed with advanced or metastasized ESCC, the most common histologic subtype of esophageal cancer, often progress following initial therapy and are in need of new options," Syma Iqbal, MD, of the University of Southern California Norris Comprehensive Cancer Center, said in the news release. "The RATIONALE 302 trial showed that patients with previously treated ESCC who received Tevimbra saw a clinically meaningful survival benefit, highlighting its potential as an important treatment option for these patients."

Treatment with Tevimbra is generally safe, though side effects are common. The most frequent adverse reactions include fatigue, musculoskeletal pain, weight loss, cough, decreased white blood cell counts, anemia and various laboratory abnormalities such as elevated liver enzymes. One concern with checkpoint inhibitors is that unleashing T cells against cancer can also cause the immune system to attack organs and tissues. The Tevimbra product label includes a warning about immune-mediated adverse reactions.

Tevimbra was first approved in China in December 2019 for the treatment of Hodgkin lymphoma. Its first FDA approval was delayed for more than a year because preapproval inspections in China could not be done during the early years of the COVID-19 pandemic. The new treatment is expected to be available in the second half of 2024. The FDA is also considering Tevimbra as a first-line treatment for advanced esophageal cancer, as well as for advanced stomach cancer or gastroesophageal junction carcinoma. Those decisions are expected later this year.

Click here for full prescribing information for Tevimbra.
