FDA Approves First Treatment for Advanced Form of the Second Most Common Skin Cancer

Libtayo targets the cellular pathway known as PD-1, which may help the body's immune system fight cancer.

September 28, 2018 By Food and Drug Administration (FDA)

The U.S. Food and Drug Administration today approved Libtayo (cemiplimab-rwlc) injection for intravenous use for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. This is the first FDA approval of a drug specifically for advanced CSCC.

Libtayo works by targeting the cellular pathway known as PD-1 (protein found on the body's immune cells and some cancer cells). By blocking this pathway, the drug may help the body's immune system fight the cancer cells.

"We're continuing to see a shift in oncology toward identifying and developing drugs aimed at a specific molecular target. With the Libtayo approval, the FDA has approved six immune checkpoint inhibitors targeting the the PD-1 / PD-L1 pathway for treating a variety of tumors, from bladder to head and neck cancer, and now advanced CSCC," said Richard Pazdur, MD, director of the FDA's Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "This type of cancer can be difficult to treat effectively when it is advanced and it is important that we continue to bring new treatment options to patients."

CSCC is the second most common human cancer in the United States with an estimated annual incidence of approximately 700,000 cases. The most common form of skin cancer is basal cell cancer. Squamous cells are thin, flat cells that look like fish scales and are found in the tissue that forms the surface of the skin. CSCC usually develops in skin areas that have been regularly exposed to the sun or other forms of ultraviolet radiation. While the majority of patients with CSCC are cured with surgical resection, a small percentage of patients will develop advanced disease that no longer responds to local treatments including surgery and radiation. Advanced CSCC may cause disfigurement at the site of the tumor and local complications such as bleeding or infection, or it may spread (metastasize) to local lymph nodes, distant tissues and organs and become life-threatening.

The safety and efficacy of Libtayo was studied in two open label clinical trials. A total of 108 patients (75 with metastatic disease and 33 with locally-advanced disease) were included in the efficacy evaluation. The study's primary endpoint was objective response rate, or the percentage of patients who experienced partial shrinkage or complete disappearance of their tumor(s) after treatment. Results showed that 47.2 percent of all patients treated with Libtayo had their tumors shrink or disappear. The majority of these patients had ongoing responses at the time of data analysis.

Common side effects of Libtayo include fatigue, rash and diarrhea. Libtayo must be dispensed with a patient Medication Guide that describes uses of the drug and its serious warnings. Libtayo can cause the immune system to attack normal organs and tissues in any area of the body and can affect the way they work. These reactions can sometimes become severe or life-threatening and can lead to death. These reactions include the risk of immune-mediated adverse reactions including lung problems (pneumonitis), intestinal problems (colitis), liver problems (hepatitis), hormone gland problems (endocrinopathies), skin (dermatologic) problems and kidney problems. Patients should also be monitored for infusion-related reactions.

Libtayo can cause harm to a developing fetus; women should be advised of the potential risk to the fetus and to use effective contraception.

The FDA granted this application Breakthrough Therapy and Priority Reviewdesignations.

The FDA granted the approval of Libtayo to Regeneron Pharmaceuticals, Inc.

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