U.S. Food and Drug Administration

FDA NEWS RELEASE

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FDA approves new treatment for a type of late-stage skin cancer
Melanoma patients lived longer with treatment

The U.S. Food and Drug Administration today approved Yervoy (ipilimumab) to treat patients with late-stage (metastatic) melanoma, the most dangerous type of skin cancer.

Melanoma is the leading cause of death from skin disease. An estimated 68,130 new cases of melanoma were diagnosed in the United States during 2010 and about 8,700 people died from the disease, according to the National Cancer Institute.

"Late-stage melanoma is devastating, with very few treatment options for patients, none of which previously prolonged a patient's life," said Richard Pazdur, M.D., director of the Office of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research. "Yervoy is the first therapy approved by the FDA to clearly demonstrate that patients with metastatic melanoma live longer by taking this treatment."

Yervoy is a monoclonal antibody that blocks a molecule known as cytotoxic T-lymphocyte antigen or CTLA-4. CTLA-4 may play a role in slowing down or turning off the body's immune system, affecting its ability to fight off cancerous cells. Yervoy may work by allowing the body's immune system to recognize, target, and attack cells in melanoma tumors. The drug is administered intravenously.

Yervoy's safety and effectiveness were established in a single international study of 676 patients with melanoma. All patients in the study had stopped responding to other FDA-approved or commonly used treatments for melanoma. In addition, participants had disease that had spread or that could not be surgically removed.

The study was designed to measure overall survival, the length of time from when this treatment started until a patient's death. The randomly assigned patients received Yervoy plus an experimental tumor vaccine called gp100, Yervoy alone, or the vaccine alone.

Those who received the combination of Yervoy plus the vaccine or Yervoy alone lived an average of about 10 months, while those who received only the experimental vaccine lived an average of 6.5 months.

Common side effects that can result from autoimmune reactions associated with Yervoy use include fatigue, diarrhea, skin rash, endocrine deficiencies (gland or hormone), and inflammation of the intestines (colitis). Severe to fatal autoimmune reactions were seen in 12.9 percent of patients treated with Yervoy. When severe side effects occurred, Yervoy was stopped and corticosteroid treatment was started. Not all patients responded to this treatment. Patients who did respond in some cases did not see any improvement for several weeks.

Due to the unusual and severe side effects associated with Yervoy, the therapy is being approved with a Risk Evaluation and Mitigation Strategy to inform health care professionals about these serious risks. A medication guide will also be provided to patients to inform them about the therapy's potential side effects.

Yervoy is marketed by New York City-based Bristol-Myers Squibb.

For more information:

FDA: Office of Oncology Drug Products[1]

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