FDA Approves New Treatment for a Type of Late-Stage Skin Cancer

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SILVER SPRING, Md., March 25, 2011 /PRNewswire-USNewswire/ --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.

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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,
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