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FDA approves new drug for advanced melanoma

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The U.S. Food and Drug Administration today approved the use of ipilimumab for the treatment of previously treated metastatic melanoma. It is the first drug approved for metastatic, or advanced, melanoma is more than a decade.

"Ipilimumab is the first in a new class of drugs that has been shown to offer a survival benefit for metastatic melanoma, which is often a fatal disease, and hopefully, this will lead to the development of related treatments for other cancers," said F. Stephen Hodi, MD, director of the melanoma treatment center at Dana-Farber Cancer Institute and a lead investigator of the national clinical study of ipilimumab.

The number of cases of metastatic melanoma, considered to be one the most serious form of skin cancer, has increased during the past 30 years, and its death rate is rising faster than most other cancers. The American Cancer Society estimated that the disease was diagnosed in more than 68,000 Americans and be responsible for 8,700 deaths in this country in 2010.

Ipilimumab, developed by Bristol-Myers Squibb and Medarex, is a monoclonal antibody that consists of millions of copies of a human antibody that binds to CTLA-4 protein molecule on T cells — white blood cells that patrol the body for signs of illness. CTLA-4 serves as a control switch for the immune system's response to disease. With no antibody attached, CTLA-4 suppresses the immune response. Ipilimumab reverses that condition, unleashing the immune attack on

abnormal cells, including cancer cells.

Last year, Hodi reported at the annual meeting of the American Society of Clinical Oncology and in the New England Journal of Medicine findings from a phase III trial involving 676 patients with advanced (stage III or IV), inoperable melanoma that had worsened during prior therapy for metastatic disease.

Patients were randomly assigned to receive one of three treatment regimens: ipilimumab and the gp100 vaccine (which seeks to spark an immune response by presenting the immune system with a protein fragment associated with cancer); ipilimumab alone; or gp 100 alone.

The median survival period for patients receiving ipilimumab plus gp100 was 10 months, compared with 6.4 months for those receiving gp100 alone. The median survival for participants receiving ipilimumab alone was 10.1 months.

In the ipilimumab-alone group, nine of 15 patients continued to benefit from the therapy for at least two years, as did four of 23 patients in the combination therapy group.

About 60 percent of the patients treated with ipilimumab experienced adverse side effects to the therapy, as did 32 percent of the patients treated with gp100. The complications were generally immune system-related and most often affected the skin and gastrointestinal tract. The most common included diarrhea, nausea, constipation, fatigue, decreased appetite, and rash. While the adverse effects could be severe and long-lasting, most of them were reversible with appropriate treatment.

"While ipilimumab, on average, extended the lives of patients by four months, there is also a group of patients who experienced a greater benefit and lived many months while being treated with this drug," said

Hodi. "This is a big step in the right direction because it demonstrates that this class of drugs can benefit cancer patients."

Provided by Dana-Farber Cancer Institute