

Drug boosts survival in major skin cancer study

June 5 2010, By MARILYNN MARCHIONE, AP Medical Writer

(AP) -- Researchers have scored the first big win against melanoma, the deadliest form of skin cancer. An experimental drug significantly improved survival in a major study of people with very advanced disease.

The results, reported Saturday at a cancer conference, left doctors elated.

"We have not had any therapy that has prolonged survival" until now, said Dr. Lynn Schuchter of the Abramson Cancer Center at the University of Pennsylvania, a <u>skin cancer</u> specialist with no role in the new study or ties to the drug's maker.

The drug, ipilimumab, (ip-ee-LIM-uh-mab), works by helping the immune system fight tumors. The federal <u>Food and Drug Administration</u> has pledged a quick review, and doctors think the drug could be available by the end of this year.

"People are going to have a lot of hope and want this drug, and it's not on their doctors' shelves," although some may be able to get it through special programs directly from its maker, Bristol-Myers Squibb Co., Schuchter said.

The study involved 676 people around the world with advanced, inoperable melanoma who had already tried other treatments - a very grim situation. They were given one of three treatments: ipilimumab by itself, with another immune-stimulating treatment, or the immune-



stimulating treatment alone.

After two years, 24 percent of those given the drug alone or in combination were alive, versus 14 percent of those given just the immune-stimulating treatment.

Average survival was 10 months with ipilimumab versus just over 6 months for the others, which worked out to a 67 percent improvement in survival for those on the drug, said one of the study's leaders, Dr. Steven O'Day of the Angeles Clinic and Research Institute in Los Angeles.

Doctors hope the drug can provide more benefit if given earlier in the course of the disease and to less sick patients.

Ten percent to 15 percent of patients on ipilimumab had serious side effects related to the drug's actions on the <u>immune system</u>. Most were treatable with high doses of steroids, but 14 deaths were thought to be related to the treatment. That's still far fewer than deaths due to the cancer.

The study was funded by Bristol-Myers and Medarex Inc., a company that co-developed the drug and was bought by Bristol-Myers last year. A spokeswoman said Bristol-Myers has not yet set a price for the drug, but similar treatments for other cancers cost several thousand dollars a month or more.

Results were reported at the American Society of Clinical Oncology's annual conference in Chicago and published online by the New England Journal of Medicine.

Melanoma is the most serious form of skin cancer. Last year in the United States, there were about 68,720 new cases and 8,650 deaths from the disease. Worldwide, more than 50,000 people die of melanoma each



year.

More information: Cancer meeting: http://www.asco.org

National Cancer Institute: http://www.cancer.gov

New England Journal of Medicine: http://www.nejm.org

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Citation: Drug boosts survival in major skin cancer study (2010, June 5) retrieved 26 April 2024 from https://medicalxpress.com/news/2010-06-drug-boosts-survival-major-skin.html

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