FDA panel backs Schering-Plough cancer drug

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(AP) -- Federal health advisers voted 6-4 on Monday that the potential benefits of a Schering-Plough drug outweigh its toxic risks as a treatment for late-stage skin cancer.

The Food and Drug Administration often follows the panel's advice, though it is not required to.

Schering-Plough has asked the FDA to approve its drug PegIntron for patients whose skin cancer has spread to their lymph nodes, requiring surgery. The drug is already approved as a treatment for hepatitis C.

Company studies of the drug showed it lengthened the period of time before cancer recurred by about nine months, though patients ultimately didn't live longer than those who did not receive the drug.

PegIntron was associated with high levels of toxicity, and 44 percent of patients dropped out of the study due to toxic side effects, which included fatigue, nausea and skin reactions.

Still, a majority of panelists said the drug's ability to slow the disease outweighed its negative side effects.

"I'm leaning in the direction that this may be helpful given that there are very few options for these patients," said panel chair Dr. Gary Lyman, of Duke University Medical Center.

The four panelists who voted against the drug said they could not endorse a product that did not appear to extend patients' lives.

"I voted no because I think survival has to be the primary endpoint here," said Dr. William Kelly, of Yale University.

Sales of Pegintron totaled $914 million in 2008. Kenilworth, N.J.-based Schering-Plough also markets Intron A, the only other FDA-approved drug for treatment of recurring skin cancer after surgery.

The panel vote was "an encouraging development toward the future treatment of melanoma," the company said in a statement.