

FDA panel backs Glaxo drug for rare sarcoma cancer

March 20 2012, By MATTHEW PERRONE , AP Health Writer

(AP) -- A panel of cancer experts overwhelmingly backed the approval of a GlaxoSmithKline drug for a rare type of tumor, noting there are few other treatment options for patients.

The [Food and Drug Administration](#) panel voted 11-2 that the benefits of the pill Votrient outweigh its side effects, even when considering that it did not significantly prolong life for patients with soft tissue sarcomas. The vote is not binding, but the agency usually follows its recommendations.

Glaxo's studies of Votrient showed the drug halted growth off the deadly tumors for three months on average. However, patients didn't ultimately live significantly longer than those taking [chemotherapy drugs](#). Chemotherapy has been the standard treatment for sarcomas for decades.

Most patients taking Votrient lived about 12.6 months after beginning treatment with the drug. That was only two months more than patients taking chemotherapy, and the FDA said the difference was not statistically significant.

Despite the lack of [survival benefit](#) overall, doctors noted that a small group of patients lived four months or longer than the chemotherapy group.

"I feel the effect is marginal but there does appear to be a group of

patients who have benefited from this for longer periods of time," said panel chair Dr. Wyndham Wilson of the [National Cancer Institute](#).

Soft tissue sarcomas are a rare class of tumors that form in the fat, muscles and joints, often around the limbs and chest. An estimated 11,000 people in the U.S. were diagnosed in 2011 and 3,900 died from the disease, according to the National Cancer Institute.

Many [cancer drugs](#) approved by the FDA do not actually extend survival, but instead slow the growth of tumors or their spread to other parts of the body. In recent years, cancer experts have debated the significance of such results, particularly given the potentially dangerous side effects.

Side effects with Glaxo's pill included [liver toxicity](#), [high blood pressure](#) and [heart problems](#). But most panelists said chemotherapy can cause similar problems and there is a serious need for new drugs to treat sarcoma.

"There are no drugs approved by the FDA specifically for this indication and that's what drove my decision to vote yes," said Dr. Mikkael Sekeres of the Cleveland Clinic.

Soft tissue sarcoma is often curable if detected early. The patients studied by Glaxo had cancer that had spread to other parts of the body, despite chemotherapy. After that occurs life expectancy ranges between a year and a year and a half.

Shares of London-based GlaxoSmithKline PLC rose 9 cents to \$45.58 in midday trading.

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