Medical Xpress

Experts veto Avastin as a breast cancer treatment

July 20 2010, By MATTHEW PERRONE , AP BUSINESS WRITER

(AP) -- A panel of cancer experts said Tuesday that the government should remove its endorsement of Roche's drug Avastin for breast cancer, after follow-up studies failed to show benefits for patients.

A Food and Drug Administration panel of experts voted 12-1 in favor of removing the drug's approval for use against breast cancer alongside chemotherapy.

The FDA is not required to follow the advice of its panel, though it often does.

The negative vote is the first major setback for a blockbuster cancer drug that has racked up approvals for a half dozen forms of the disease. Avastin is also approved for colon, lung, kidney and brain cancer. The panel's ruling only pertains to Avastin's use in breast cancer.

Roche scientists argued Tuesday that patients taking Avastin experienced improved quality of life as tumor growth and other symptoms are delayed - but panelists were not convinced.

"The study shows there's very little benefit to patients - with significant toxicity risks and no clear survival benefit," said Natalie Compagni Portis, the panel's patient representative.

A spokeswoman for Roche's Genentech unit said the company will continue discussions with the agency.

"Avastin should be an option for patients with this incurable disease," said Charlotte Arnold, in a statement.

Even if the FDA withdraws the drug's approval for breast cancer, doctors will still have the option to prescribe the drug "off-label." However, medical societies and hospitals tend to follow FDA guidance, influencing prescribing patterns for thousands of U.S. physicians.

The FDA in 2008 approved Avastin for breast cancer patients based on a trial showing it extended the amount of time until the disease worsened by more than five months. The decision was considered controversial by some cancer doctors because the drug had not been shown to extend patients' lives.

As a condition of approval, Roche was required to conduct follow-up studies to demonstrate the benefits of adding Avastin to conventional chemotherapy.

But two follow-up studies recently submitted by the Swiss drugmaker did not show the same degree of delay in cancer progression as earlier studies. Additionally, patients taking Avastin did not show a significant improvement in lifespan, the gold standard of cancer treatment effectiveness.

Panelists said they worried the drug could do more harm than good because of serious side effects, including high blood pressure, fatigue and abnormal levels of white blood cells.

"I think the burden of proof is that a drug is helpful, not that it doesn't make patients worse," said panel chair Dr. Wyndham Wilson of the National Cancer Institute. "We have definitive evidence that Avastin causes harmful side effects and we've now seen a number of well-done studies that show no advantage to lifespan."

Breast cancer is the second most-common cause of cancer death among U.S. women, according to the Centers for Disease Control. Last year more than 40,000 deaths in the U.S. were attributed to the disease.

Roche is headquartered in Basel, Switzerland. Last year the company acquired South San Francisco-based Genentech, which makes Avastin and a several other leading cancer therapies.

Avastin was the first drug approved to fight cancer by stopping nutrients from reaching tumors. Such "targeted therapies" were thought to hold promise for eliminating chemotherapy, but the two approaches are now used in combination.

The drug is a synthetic protein grown from hamster ovary cells.

Since 1992, the FDA has granted accelerated approval to drugs based on so-called surrogate endpoints, or initial measures that suggest the drug will make real improvements in patient health. For cancer drugs, delayed tumor growth is considered a predictor of increased survival.

Drugmakers favor the program because it helps them get products to market sooner.

But the program has not escaped criticism from government watchdogs.

Last fall the Government Accountability Office issued a report saying the FDA should do more to track whether drugs approved based on preliminary results actually have lived up to their promise.

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