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US panel rejects Avastin for breast cancer use

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An expert panel urged the US Food and Drug Administration on Wednesday to strip the Roche-made drug Avastin of its label for use against breast cancer because it is neither safe nor effective.

After a rare two-day appeal hearing by Genentech, a US unit of the Swiss pharmaceutical giant, the panel voted 6-0 to uphold its earlier recommendation in December to stop the use of Avastin for breast cancer.

The drug, also known as bevacizumab, carries risks such as severe high blood pressure and hemorrhage and does not prolong overall survival in women suffering from breast cancer, the panel said.

A final decision by the FDA commissioner must be issued, but will not likely come before the end of July. The FDA does not have to follow the recommendations of the expert panel but it usually does.

The docket will remain open until July 28 for public comment, and a final decision will follow, though an exact date has not been announced.

"The commissioner's decision related to breast cancer will not affect Avastin's approved indications for use in colon, lung, kidney, and brain cancers," the FDA said.

"That is, regardless of the final decision on metastatic breast cancer approval, Avastin will remain on the market."

Some members of the public, including women dressed in pink who carried signs that read: "I am more than a statistic" had clustered outside the FDA building where the hearing took place, according to media reports.

Breast cancer patients who were taking Avastin were allowed to talk about their experiences.

Afterward, Terry Kalley, founder of Freedom of Access to Medicines (FAMEDS), said he was disappointed, but not surprised, with the decision.

"This panel that has passed judgment on a life or death matter with breast cancer should have been made up of breast cancer specialists and oncologists, but it had zero breast cancer specialists or oncologists on it," Kalley said in a press release Wednesday after the decision.

"We had breast cancer oncologists testifying on our behalf yesterday to keep patient access to Avastin."

Kalley's wife has late stage breast cancer and has been "immensely helped by Avastin," according to the statement.

However, the FDA panel decided that arguments in favor of the drug were not enough to sway the panel from its earlier decision.

Initial trial results that showed patients had an extra five months of "progression-free survival" could not be replicated, and some deaths were associated with the drug, the FDA said.

"The hearing has also provided an opportunity for the public to observe and participate in the type of difficult decision-making process that the FDA engages in each day as it considers the approval or the withdrawal

of approval, of drug products," said Karen Midthun, director of the Center for Biologics Evaluation and Research who presided over the hearing.

"As illustrated by the public presentations at the beginning of the hearing, FDA's focus is always on the effect that our decisions will have on patients who will use those products, including those patients who may be benefited by them, and those who may also be harmed by them."

Genentech said the drug would remain approved for use in combination with the chemotherapy drug paclitaxel for first-line treatment of metastatic HER2-negative breast cancer until the FDA makes a final decision.

"We are very disappointed by the committee's recommendation and hope the commissioner does not decide to remove this important medicine for women with an incurable disease who already have too few treatment options," said Hal Barron, Genentech's chief medical officer and head of global product development.

Avastin is designed to prevent new blood vessels from reaching tumors and providing them with the nutrients they feed on to grow. During the first clinical trial, when combined with Taxotere, the drug had stifled cancer progression and increased patient survival.

"We remain ready to collaborate with the FDA to find a solution that is in the best interest of patients who need Avastin," Barron added.

Roche could lose $1 billion in annual revenue if Avastin is taken off the market for breast cancer treatment, according to figures cited in the media.

European medical experts have called for the drug to be restricted to use

in combination with paclitaxel only instead of other forms of chemotherapy because benefits were uncertain.

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