FDA NEWS RELEASE
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FDA Commissioner announces Avastin decision

Drug not shown to be safe and effective in breast cancer patients

FDA Commissioner Margaret A. Hamburg, M.D., said today she is revoking the agency's approval of the breast cancer indication for Avastin (bevacizumab) after concluding that the drug has not been shown to be safe and effective for that use.

Avastin will still remain on the market as an approved treatment for certain types of colon, lung, kidney and brain cancer (glioblastoma multiforme).

"This was a difficult decision. FDA recognizes how hard it is for patients and their families to cope with metastatic breast cancer and how great a need there is for more effective treatments. But patients must have confidence that the drugs they take are both safe and effective for their intended use," Dr. Hamburg said. "After reviewing the available studies it is clear that women who take Avastin for metastatic breast cancer risk potentially life-threatening side effects without proof that the use of Avastin will provide a benefit, in terms of delay in tumor growth, that would justify those risks. Nor is there evidence that use of Avastin will either help them live longer or improve their quality of life."

Avastin's risks include severe high blood pressure; bleeding and hemorrhaging; heart attack or heart failure; and the development of perforations in different parts of the body such as the nose, stomach, and intestines.

Today's decision, outlined in Dr Hamburg's 69-page opinion, involves Avastin used in combination with the cancer drug paclitaxel for those patients who have not been treated with chemotherapy for their form of metastatic breast cancer known as HER2 negative. This indication must now be removed from Avastin's product labeling.

Dr. Hamburg's decision is based on an extensive record, which includes thousands of pages submitted to a public docket, data from several clinical trials and the record from a two-day hearing held in June, 2011.

Avastin was approved for metastatic breast cancer in February 2008 under the FDA's accelerated approval program, which allows a drug to be approved based on data that are not sufficiently complete to permit full approval. The accelerated approval program provides earlier patient access to promising new drugs to treat serious or life-threatening conditions while confirmatory clinical trials are conducted. If the clinical trials do not justify the continued approval of the drug or a specific drug indication, the agency may revoke its approval. In this case, the accelerated approval was based on

promising results from one study that suggested that the drug could provide a meaningful increase in the amount of time from when treatment is started until the tumor grows or the death of the patient.

After the accelerated approval of Avastin for breast cancer, the drug's sponsor, Genentech, completed two additional clinical trials and submitted the data from those studies to the FDA. These data showed only a small effect on tumor growth without evidence that patients lived any longer or had a better quality of life compared to taking standard chemotherapy alone – not enough to outweigh the risk of taking the drug.

FDA's Center for Drug Evaluation and Research, which is responsible for the approval of this drug, ultimately concluded that the results of these additional studies did not justify continued approval and notified Genentech it was proposing to withdraw approval of the indication.

Genentech did not agree with the Center's evaluation of the data and, following the procedures set out in FDA regulations, requested a hearing on the Center's withdrawal proposal, with a decision to be made by the Commissioner. That two-day hearing, which took place June 28-29, 2011, included recommendations from the FDA's Oncologic Drugs Advisory Committee (ODAC), voting 6-0 in favor of withdrawing approval of Avastin's breast cancer indication. After the hearing, the public docket remained open until Aug. 4, 2011. (In an earlier meeting of the ODAC, that committee had voted 12-1 in favor of the removal of the breast cancer indication from the Avastin label).

"FDA is committed to working with sponsors to bring promising cancer drugs to market as quickly as possible using tools like accelerated approval," Dr. Hamburg said. "I encourage Genentech to consider additional studies to identify if there are select subgroups of women suffering from breast cancer who might benefit from this drug."

For more information:

Avastin Decision

http://www.fda.gov/NewsEvents/Newsroom/UCM279485

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