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US revokes Roche's Avastin for breast cancer

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US health officials on Friday revoked the authorization of Roche's Avastin for breast cancer treatment, saying it concluded the drug had "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, the US Food and Drug Administration said in a statement.

"This was a difficult decision," FDA Commissioner Margaret Hamburg said.

"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."

The latest move followed the recommendation of an expert panel that said the drug, also known under the generic name bevacizumab, carries risks such as severe high blood pressure and hemorrhage and does not prolong overall survival in women suffering from breast cancer.

The FDA had accepted the expert report that Avastin was not an effective treatment for breast cancer but Roche decided to appeal.

Hamburg said studies indicate 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," she added.

Avastin, which is marketed in the United States by the firm Genentech for its Swiss parent Roche, was approved for metastatic breast cancer in February 2008 under the FDA's accelerated approval program.

The program provides early access to promising new drugs to treat serious or life-threatening conditions while clinical trials to confirm their efficacy are conducted.

In the case of Avastin, the accelerated approval was based on promising results from one study that suggested it could extend the lives of women with advanced breast cancer.

Genentech said in a statement it was "disappointed with the outcome."

"We remain committed to the many women with this incurable disease and will continue to provide help through our patient support programs to those who may be facing obstacles to receiving their treatment in the United States," said Hal Barron, chief medical officer of the group.

"Despite today's action, we will start a new Phase III study of Avastin in combination with paclitaxel in previously untreated metastatic breast cancer and will evaluate a potential biomarker that may help identify which people might derive a more substantial benefit from Avastin."

European medical experts have urged that the drug be restricted to use in combination with paclitaxel only instead of other forms of chemotherapy because benefits were uncertain.

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