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[Home](#) > FDA committee votes no for breast cancer drug

Generic Name:

Bevacizumab

Trade Name:

Avastin

Company:

Genentech

Notes:

In late June, [FDA's Oncologic Drugs Advisory Committee](#) voted unanimously that FDA withdraw its approval of bevacizumab for use in metastatic breast cancer. Bevacizumab is currently approved for use in combination with paclitaxel chemotherapy for previously untreated HER2-negative metastatic breast cancer. A review of data from 5 randomized clinical trials with more than 3,500 patients showed that none of these trials demonstrated a significant improvement in overall survival or quality of life. In addition, none of these subsequent studies confirmed the magnitude of benefit seen in the original trial (E2100 trial), which provided the evidence for accelerated approval of bevacizumab for metastatic breast cancer in 2008.

Given the risks of bevacizumab, such as intestinal perforation and hemorrhage, the committee concluded that bevacizumab has not been shown to present a clinical benefit that justifies the risks associated with use of the product for this indication and that it should not remain approved while Genentech designs and conducts additional studies to verify the drug's benefit. The FDA Commissioner will make a final decision on whether bevacizumab should remain approved for metastatic breast cancer.

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