FDA Begins Process to Remove Indication for Avastin for Metastatic Breast Cancer

Response from Dr. Len Lichtenfeld

The Food and Drug Administration (FDA) has begun the process to remove an indication for the use of bevacizumab (Avastin®) in metastatic breast cancer. The drug had received accelerated approval for that indication in February 2008 based on preliminary studies that found the drug increased progression-free survival –the time that patients went without symptoms getting worse. Subsequent studies found no differences in overall survival; that progression-free survival improved by less than three months; and that there was a high rate of side effects, including high blood pressure and internal bleeding. As a result of those studies, an advisory panel in July recommended by a vote of 12 to 1 that the FDA withdraw approval.

Below are comments from **Len Lichtenfeld, M.D.**, American Cancer Society deputy chief medical officer.

> “The Food and Drug Administration’s recommendation to remove approval of bevacizumab (Avastin®) as a treatment for advanced breast cancer will come as a disappointment to many breast cancer patients who may have benefitted from the drug. But it is important to understand the decision was based on the advice of an independent panel of experts who noted that larger studies showed some women lives were actually shortened on the drug and that toxicities associated with the drug were significant. Meanwhile, the net benefit for women taking the drug was quite modest.
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> “Clearly some women with metastatic breast cancer have benefitted from Avastin, but others not only have not benefitted, they’ve been harmed. What we clearly need is a way for doctors to more accurately predict which women will have a better chance of benefitting from this important targeted therapy. Until that tool is developed, giving all women with metastatic breast cancer Avastin may harm more women than it helps.
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> “It should be noted that this recommendation does not have any impact on the use of bevacizumab in the treatment of other forms of cancer where the FDA has given approval, such as colorectal and lung cancer. This review applies only to the specific recommendation regarding the use of bevacizumab in the treatment of metastatic breast cancer. Women currently on bevacizumab for the treatment of breast cancer should have a detailed discussion with their oncologists as to what course of action they should take.”

For more, see: "FDA Recommends Removing Breast Cancer Indication for Avastin."