



FDA Renders Decision to Revoke Approval of Avastin to Treat Breast Cancer

November 18, 2011 — The FDA announced today that it is removing Avastin from the list of approved breast cancer therapies. While FORCE favored retaining FDA approval for Avastin’s use in the treatment of breast cancer, we respect the FDA’s decision.

FORCE represents the estimated 750,000 people living with a BRCA genetic mutation or hereditary cancer risk, many of whom have benefitted from Avastin. This decision only highlights the importance of further research to determine which patients benefit most from Avastin and an array of other cancer therapies.

Federal officials have indicated that Medicare will continue its coverage of Avastin’s use in breast cancer, though the government plans to “monitor the issue and evaluate coverage options.” FORCE is concerned, however, that this label change will harm those currently benefitting from the drug and restrict access for women newly diagnosed with metastatic breast and ovarian cancer—women who could benefit from the medication. Avastin will remain available for treatment of other cancers, including colon, lung, kidney and brain cancers. As such, doctors may be able to prescribe it “off-label” for breast cancer patients. This ruling does not impact approval of Avastin for metastatic breast cancer outside of the U.S.

FORCE applauds Genentech’s plan to continue research on Avastin including a Phase III study of Avastin in combination with paclitaxel in previously untreated metastatic breast cancer and further research to evaluate biomarkers that may help identify which people might derive a more substantial benefit from Avastin.

FORCE supports additional studies to determine which patients benefit most from this therapy. The need to move beyond a one-size-fits-all approach to cancer treatment is imperative.

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