LIVING BEYOND BREAST CANCER
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Living Beyond Breast Cancer Statement on FDA's Decision to Remove Approval of Avastin for Metastatic Breast Cancer

December 17, 2010 – HAVERFORD, PA – The U.S. Food and Drug Administration (FDA) yesterday announced that it plans to begin the process necessary to withdraw approval of Avastin (bevacizumab) as a treatment for metastatic breast cancer. Roche/Genentech, the manufacturer of bevacizumab, plans to appeal FDA's decision. During the appeal process, bevacizumab remains available as a treatment for metastatic breast cancer.

Regardless of FDA's ultimate ruling, Living Beyond Breast Cancer (LBBC) encourages insurance carriers and the federal government to continue reimbursing payment for Avastin for women currently taking it who are responding to it. Additionally, we strongly encourage the manufacturer to continue its program to assist women in need who are taking Avastin and are responding.

LBBC feels very strongly that clinical trials of Avastin should continue in the metastatic setting because they could help identify the cancers most likely to respond. In addition, biomarkers and a tool should be developed to properly screen cancers for Avastin sensitivity.

"The FDA decision today with respect to Avastin in the treatment of metastatic breast cancer is disappointing," said Julie R. Gralow, MD, director of breast medical oncology at the University of Washington School of Medicine and Seattle Cancer Care Alliance and member of LBBC's Medical Advisory Board. "It is clear that some breast cancer patients derive substantial benefit from Avastin. We don't know how to select those tumors or patients yet. It is looking like patient factors, not tumor factors, might be the best way to select those who benefit. To withhold this drug from all patients because some don't benefit is incorrect. We have lots of cancer agents that are approved for all breast cancer patients that don't result in 100 percent response rates—we don't withhold in all because they only work in an as yet unidentified subset."

We understand this issue raises concerns for women with metastatic disease. If you are currently taking bevacizumab, we encourage you to speak with your healthcare team. Additionally, please submit your public comments to the FDA. You may send them to LBBC via e-mail at editor@lbbc.org or directly to FDA through agency Docket FDA-2010-N-0621.

LBBC will continue to serve as a trusted source for women, providers and others who want to learn about the issue and give feedback; we will post comments and submit them as they arrive.

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