



BREASTCANCER.ORG

June 30, 2010

U.S. Food and Drug Administration
Oncologic Drugs Advisory Committee
10903 New Hampshire Avenue
WO51-6100
Silver Spring, Maryland 20993-0002

Dear ODAC Committee Members:

As you consider label changes for Avastin, Breastcancer.org asks you to consider the treatment needs, expectations, and preferences of women diagnosed with metastatic breast cancer. In contrast to most women with early-stage breast cancer, most women with metastatic disease need continuous treatment in order to live. Despite the desperation many people with metastatic disease experience, they often have a remarkable ability to measure the pros and cons of each treatment decision with purpose, clarity, and precision. No two women or their cancers nor their treatment histories are the same. Aggregate clinical trial results include individuals with greater than expected benefit as well as those with a disappointing response. We doctors are limited in our ability to figure out who will and who won't get the important benefit of any particular treatment whether in the first-line setting or beyond. But we must have treatment options to turn to for our patients who need and desire them. Women with metastatic disease are prepared to make treatment decisions with greater risk since prior forms of treatments have already failed them. They deserve that choice.

As a non-profit organization dedicated to providing the most reliable, complete, and up-to-date information about breast health and breast cancer, Breastcancer.org is committed to help everyone affected by breast cancer -- including family members and caregivers -- make sense of complex medical information so they can make the best decisions for their unique situations. Hundreds of thousands of women diagnosed with metastatic breast cancer have turned to

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Breastcancer.org to better understand their available treatment options, as well as the results of studies that may influence their future treatment choices.

Through 10 years of dialogue with women diagnosed with metastatic breast cancer, Breastcancer.org has learned a great deal from these women about their feelings, perspectives, needs, and experiences with the disease and treatments:

- Current treatments for metastatic breast cancer offer modest benefits and a cure remains frustratingly unobtainable.
- What makes sense, treatment-wise, for any specific woman should be determined by:
 - the characteristics of the disease
 - science-based evidence about a particular treatment
 - the woman's expectations and treatment preferences, as well as her assessment of the treatment's risks and benefits
- A woman's individual experience with a treatment may be different (and more important to her) than the aggregate results from a clinical trial.
- Women want and need access to the widest array of beneficial, safe treatment options.
- Longer progression-free survival is a meaningful benefit for many women.

The U.S. Food and Drug Administration's approval process determines which treatments are available to treat metastatic breast cancer and influences whether insurance companies will cover the treatment.

As a voice for women diagnosed with metastatic breast cancer, Breastcancer.org asks you to consider the importance of a woman's access to treatment options. We also ask you to consider the importance of an individual woman's preferences and her perception of treatment benefits.

Thank you.

Marisa Weiss, M.D. on behalf of Breastcancer.org
President and Founder
Breastcancer.org



