February 14, 2011

Margaret A. Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Room 2217
Silver Spring, MD 20993

Re: Docket No. [FDA-2010-N-0621]

Dear Dr. Hamburg:

Thank you for the opportunity to provide comments on the proposal to withdraw marketing approval for Avastin for metastatic breast cancer. We are writing today to encourage a public hearing to discuss the manufacturer's appeal in this matter. The Avastin question brings into sharp focus the many issues around research advances and the process of getting safe and effective treatments to patients as quickly as possible, particularly for serious and difficult to treat diseases such as metastatic cancer.

We acknowledge the FDA's thorough investigation into this drug and FDA's concerns about the side effects of this treatment. We understand the FDA was faced with a difficult decision, and its recommendation against Avastin for breast cancer treatment was based on a broad public health view. We appreciate the focus of the recent Oncologic Drug Advisory Committee (ODAC) meeting on reviewing the accelerated approval process, which allows cancer patients to gain access to new therapies more quickly. With this process, however, comes the obligation to confirm the meaningful clinical benefit.

The FDA cited studies that indicate Avastin did not affect overall survival of metastatic breast cancer patients and had significant side effects for many. However, we know that for some number of women, Avastin works and works well. We have heard from women who are gaining not just months, but years, with a high quality of life, from this treatment.

We are concerned about the potential impact on women who are benefiting from Avastin if the FDA ultimately removes its approval for the drug for metastatic breast cancer treatment. We want to be sure that women who are using Avastin, and for whom it is working, can continue to have access to it, that their insurers will continue to pay for it and that the drug's manufacturer, Genentech/Roche, continues making the drug available to women through its patient support programs and considers an expanded access program. We also urge Genentech/Roche to continue research on a biomarker for Avastin to determine which women will benefit from the drug.

We are supportive of the drug development process and hope that manufacturers will continue to develop medications for the treatment of metastatic breast cancer. We will only succeed in finding new treatments for cancer by bringing new drugs to the clinic. In an era of personalized medicine, we must be able to identify patients who will respond to a treatment in order to demonstrate a clinically meaningful benefit.

As a patient advocate organization, we call on all stakeholders — government, private industry, academia and the nonprofit community — to invest in the development of biomarkers and new drugs and to get the new technology and treatments to patients' bedsides as safely and as quickly as possible. To that end, we encourage FDA to develop or clarify regulatory policies that will encourage and streamline the development testing and approval of such biomarker-therapeutic combinations.

Today, the issue is Avastin. In coming years, there will be other treatments that may be controversial, but will help some number of women and men with breast cancer live longer, high-quality lives, and perhaps to "beat" breast cancer altogether. We must encourage and nurture that research for those who face the most difficult and aggressive forms of this disease. And we must make it possible for these treatments to be available to all who will benefit from them. The decision on Avastin is precedent-setting and deserves to be considered in a public setting.

Respectfully submitted,

Elizabeth Thompson
President
Susan G. Komen for the Cure

cc: Dockets Management Branch
Food and Drug Administration