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Comments by Robert Erwin on behalf of the Marti Nelson Cancer Foundation

July 20, 2010 ODAC Meeting – Open Public Hearing

Today you are reviewing a substantial body of data, the totality of which is disappointing because the use of bevacizumab, in combination with various chemotherapeutic agents, to treat patients with first-line HER2-negative metastatic breast cancer, failed to yield a statistically significant increase in overall survival. However, dramatic clinical progress against cancer is unfortunately rare, and those of us who have worked in the cancer field long enough have come to value incremental advances.

New combinations of therapy introduced over the past twenty years have led to a steady increase in median survival of people with metastatic breast cancer. While we would prefer to see much more rapid progress in extending survival, the good news is that treatment innovations of the past are providing benefit to patients today. But, past successes are also making it increasingly difficult to assess the contributions that new agents are making to what is undoubtedly a continuing trend toward improved survival. While everyone hopes for a breakthrough of sufficient magnitude to be easily seen, it is essential that we not let hope or impatience interfere with incremental clinical progress.

Is bevacizumab an important incremental advance in the treatment of metastatic breast cancer?

Today, you will hear conflicting arguments as you consider the votes you will cast. We ask you to consider the following points prior to your recommendations to the FDA.

1. An improvement in progression-free survival of sufficient magnitude is clinically important for metastatic breast cancer patients. We believe the enhanced PFS demonstrated as a result of adding bevacizumab to chemotherapy in the clinical trials currently under review represents a meaningful clinical benefit for many people.

2. There were no safety surprises in the data from these clinical trials, and there is no reason, on the basis of safety alone, to conclude that bevacizumab should be withheld from patients with metastatic breast cancer. Although the addition of bevacizumab to chemotherapy increases reported adverse events over chemotherapy alone, many of the reported events, such as increased hypertension, are not subjectively experienced by most patients, nor perceived as lowering their quality of life.

3. Although many patients treated with bevacizumab derive no benefit from the treatment, others experience substantial benefit, including in a minority of cases, prolonged survival. We do not believe in denying a minority of patients a realistic opportunity for benefit solely because the majority will not benefit. The data supporting the existence of a clinical benefit are based on large numbers and good statistics. This is not one of those unfortunate cases that occasionally comes before the FDA where inadequate data has been dredged retrospectively in support of invalid conclusions.

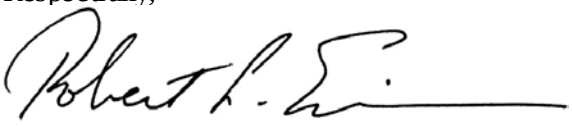
4. Bevacizumab has shown greater efficacy in the treatment of other types of cancer than it has against breast cancer. It is clearly an active agent with a role in controlling the progression of certain tumors, including certain breast tumors. A substantially increased effort must be made to develop a reliable clinical laboratory test to predict which patients will benefit and which will not.

We are in favor of bevacizumab remaining on the market for use in combination with chemotherapy as an option for the first-line treatment of metastatic HER2-negative breast cancer. Make no mistake—we are not advocating a new standard of care, but simply the continuation of an important treatment option for this lethal disease.

We recommend that the FDA allow people with metastatic breast cancer, in consultation with informed physicians, to have bevacizumab as one of their first-line therapeutic options. Over time, either improved knowledge of the complex biology involved in the success and failure of bevacizumab in the treatment of breast cancer will guide its use, resulting in significantly improved outcomes, or something better will replace it.

About Us and Disclosures: The Marti Nelson Cancer Foundation, established in 1994, is an independent, not-for-profit, all-volunteer advocacy organization committed to helping cancer patients access the best clinically-validated treatments and technologies. We work collaboratively with government, researchers, companies, advocacy groups and individual patients. Our funding has historically come from individuals, foundations and corporations. In the past, we have received unrestricted funding from Genentech and other biotech and pharmaceutical companies. Our public statements and the recommendations we make to patients are not influenced by the sources of our funding.

Respectfully,



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