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SARAH CANNON RESEARCH INSTITUTE

July 29, 2010

Commissioner Margaret Hamburg, MD
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Hamburg:

As Chief Medical Officer of Sarah Cannon Research Institute and a practicing medical oncologist, I would like to express our collective concerns about the recent Oncology Drug Advisory Committee (ODAC) hearing regarding the use of bevacizumab (Avastin) in metastatic breast cancer.

The FDA ODAC recommendation to withdraw approval for bevacizumab in metastatic breast cancer was disappointing. While withdrawing an indication may be justifiable in certain situations, we respectively submit that this decision does not appear to be supported by the data.

The independently reviewed ECOG E2100 trial combining bevacizumab with paclitaxel yielded both the longest progression free survival (PFS) (11.3 months) and absolute difference (5.5 months) seen to date in randomized trials in this setting. These findings were further supported by a statistically significant and clinically relevant prolongation of PFS observed in two large and well-conducted studies, AVADO and RIBBON 1. There were no increases in treatment-related mortality and no new safety signals were observed.

While the median benefit and hazard ratios of these studies were less impressive than observed in E2100, both AVADO and RIBBON 1 confirmed a treatment effect attributable to bevacizumab. Taken together, these three studies demonstrated a 31% to 52% decrease in the risk of the cancer worsening for women who added bevacizumab to their chemotherapy (HR=0.48-0.69). Tumors shrank or disappeared in an additional 11.8% to 27.6% of woman above and beyond the chemotherapy alone.

Additional work remains to be done to determine which patients may benefit most from this and other new therapies, but eliminating breast cancer as an indication completely could create significant barriers to access, limit treatment choices and would not be an appropriate course of action.

Successfully demonstrating benefit through well-conducted clinical trials has been the hallmark of oncology drug development in this country and has translated, through clinical practice, into meaningful gains against breast cancer.

While the ODAC expressed concerns about the risks of bevacizumab, as physicians treating patients with metastatic breast cancer, we know the biggest risk these women face is the daily suffering from the complications of their disease. We should trust oncologists to interpret study results and to treat their patients appropriately.

Best Regards,

Howard A. Burris, III, MD
Chief Medical Officer
Director, Drug Development
Sarah Cannon Research Institute

Cc: Dr. Janet Woodcock, Dr. Richard Pazdur, Senator Robert Corker, Senator Lamar Alexander, Congressman Jim Cooper

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