Clinical trial shows benefit to adding avastin to neoadjuvant chemotherapy in breast cancer patients

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Amid the controversy surrounding the Food and Drug Administration's ruling that Avastin should no longer be used to treat metastatic breast cancer, a new multinational Phase III clinical trial shows that Avastin significantly increased tumor response rates in breast cancer patients when given before surgery.

At the annual meeting for the American Society of Clinical Oncology, the nation's premier association of clinical oncologists, Harry D. Bear, M.D., Ph.D., Chair, Division of Surgical Oncology at Virginia Commonwealth University Massey Cancer Center, presented the Avastin findings from the National Surgical Adjuvant Breast and Bowel Project (NSABP) Protocol B-40 clinical trial. Bear, who served as the trial's protocol chair, explained that Avastin, when added to preoperative chemotherapy regimens, increased toxicity but also increased pathologic complete response rates by more than 6 percent (34.5 percent versus 28.4 percent) and clinical complete response rates by approximately 8 percent (64.3 percent versus 55.8 percent). Pathologic complete response was defined in the study as no remaining invasive cancer left in the breast, and clinical complete response was defined as a complete disappearance of cancer with no evidence of disease progression. Patients with hormone receptor positive breast cancers appeared to benefit most from the treatment.

"While encouraging, the results of this study will probably not affect

standard neoadjuvant or adjuvant chemotherapy practices in the near term," says Bear. "There are many different types of breast cancer, and we need more definitive biological predictors of response in order to more accurately identify the patients who will benefit most from Avastin."

Though hormone receptor positive patients benefited most from the addition of Avastin in the NSABP Protocol B-40 trial, a second study presented during the same session at the ASCO meeting seemed to contradict the findings. The second study, known as GeparQuinto, was conducted in Germany and found that Avastin benefitted patients with triple negative cancers, but not patients with hormone receptor positive cancers.

"The more we understand tumor biology, the more personalized cancer care becomes. By identifying the factors that made Avastin beneficial, we can hopefully test future breast cancer patients to determine whether or not it should be included in their treatment," says Bear.

The NSABP Protocol B-40 trial included 1,206 patients with operable HER2-negative breast cancer and tested different preoperative, or "neoadjuvant," chemotherapy regimens. The trial had two objectives. The first was to determine whether adding the chemotherapy agents capecitabine or gemcitabine to the standard neoadjuvant chemotherapy regimen of docetaxel followed by a combination of doxorubicin and cyclophosphamide increased the pathologic complete response rate. The second objective was to test whether adding Avastin to chemotherapy before surgery increased the pathologic complete response rate. While the addition of Avastin did improve the pathologic complete response rate, the addition of the chemotherapy agents capecitabine and gemcitabine did not.

"We need more research focusing on patient biology and tumor

differences to understand why Avastin works for some but not others. We hope to gain insight by analyzing tumor biopsies and blood samples from patients in the B-40 trial and other recent Avastin studies," says Bear. "In addition, since the patients who received Avastin preoperatively also received it after surgery, it is possible the drug may improve long-term outcomes. We will follow these patients for many years to come to determine whether Avastin increased cure rates."

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