Phase III efficacy data on bevacizumab plus chemotherapy in early breast cancer to be presented

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Results of the GeparQuinto study, randomized Phase III efficacy data on the use of bevacizumab plus chemotherapy to treat women with early breast cancer will be presented at the 33rd Annual CTRC-AACR San Antonio Breast Cancer Symposium.

Gunter von Minckwitz, M.D., Ph.D., managing director of the German Breast Group, and colleagues are conducting final analyses on efficacy data from this study, which will detail the early treatment of more than 1,900 patients with HER2-negative breast cancer treated with chemotherapy with or without bevacizumab.

"So far, no efficacy data from Phase III trials have been reported for early breast cancer. This will be the first," said von Minckwitz. "If the pathological complete response rate is higher with bevacizmab than without bevacizumab, it will provide a new option to improve neoadjuvant treatment in HER2-negative breast cancer."

Bevacizumab is currently approved in the United States in combination with paclitaxel for the first-line treatment of metastatic breast cancer. In July 2010, the Food and Drug Administration's Oncologic Drugs Advisory Committee voted 12 to 1 to eliminate this indication from the treatment label of bevacizumab.

"A negative or positive result might have a significant effect on this

picture," said von Minckwitz. "However, pathological response as a surrogate for outcome is only confirmed for chemotherapy. Long-term follow up, as well as results from adjuvant studies have to be awaited."

The researchers investigated whether adding bevacizumab to treatment with four cycles of epirubicin/cyclophosphomide, followed by four cycles of docetaxel improved the rate of pathological complete response, which was defined as no invasive or non-invasive residual cancer in the breast or nodes.

Between May 2007 and June 2010, 944 patients were assigned chemotherapy treatment with epirubicin/cyclophosphamide followed by docetaxel; 945 patients were assigned this treatment plus bevacizumab.

After the first four cycles, the researchers performed an interim assessment; 24 percent of patients treated without bevacizumab and 17 percent of patients treated with bevacizumab showed no response and were discontinued from treatment.

Interim safety data from the trial, published earlier this year, indicated that treatment with bevacizumab was feasible. Patients assigned bevacizumab experienced more leukopenia, infections, mucositis and hypertension, but less edema. This safety profile is no different from that reported in first-line metastatic trials or Phase II adjuvant trials of bevacizumab, according to von Minckwitz.

Full results on the histological response and surgical outcome will be reported during the symposium.

"The results will provide an important signal as to whether bevacizumab will be effective as an adjuvant treatment," said von Minckwitz.