Researchers to present progression-free survival results

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Results from the final analysis of progression-free survival, response rate, and safety for the randomized, phase III Breast Cancer Trials of Oral Everolimus-1 (BOLERO-1) are to be presented here at the 2014 San Antonio Breast Cancer Symposium, held Dec. 9–13.

"BOLERO-1 is a randomized, double-blind, phase III clinical trial evaluating whether the addition of everolimus, an mTOR inhibitor, to trastuzumab and paclitaxel improves progression-free survival for patients with HER2-positive, advanced breast cancer who have received no prior treatments for advanced disease," said Sara A. Hurvitz, MD, an associate clinical professor of medicine and director of the Breast Oncology Program in the University of California, Los Angeles, Division of Hematology/Oncology.

"In San Antonio, we will be presenting data on progression-free survival for the overall patient population and in the subpopulation of patients with hormone receptor-negative disease," continued Hurvitz. "We will also show our analysis of secondary endpoints of the study, including safety."

Last year, results from the BOLERO-3 study showed that the addition of everolimus to trastuzumab and chemotherapy (vinorelbine) significantly improved progression-free survival for patients with trastuzumab-resistant, HER2-positive metastatic breast cancer who had previously been treated with a taxane-based chemotherapy.

"We are interested in evaluating whether inhibiting the mTOR pathway early in metastatic disease will help delay the development of resistance to HER2-targeted therapy," said Hurvitz.

Hurvitz and colleagues enrolled in the BOLERO-1 study 719 women with advanced, HER2-positive breast cancer who had not received prior treatment with trastuzumab or chemotherapy after the advanced disease diagnosis. Among them, 480 patients were randomly assigned to everolimus in combination with weekly paclitaxel and trastuzumab, and 239 patients to placebo plus weekly paclitaxel and trastuzumab. The final analysis was performed after 425 patients in the full population were observed to have disease progression.

Provided by American Association for Cancer Research

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