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Media Contact:
Jeremy Moore
(215) 446-7109
Jeremy.Moore@aacr.org
In San Antonio:
(210) 582-7021

Exemestane Plus Everolimus Increased Progression-Free Survival for Women With Metastatic Breast Cancer

- Everolimus in combination with exemestane was well tolerated.
- BOLERO-2 results establish “a new standard of care” in advanced breast cancer.

SAN ANTONIO — Everolimus in combination with exemestane has shown promise for the treatment of breast cancer.

“For postmenopausal patients with hormone receptor (HR)-positive metastatic breast cancer, the addition of everolimus to exemestane markedly improves the duration of disease control,” said Gabriel N. Hortobagyi, M.D., FACP, professor of medicine, chair of the department of breast medical oncology and director of the Multidisciplinary Breast Cancer Research Program at the University of Texas MD Anderson Cancer Center in Houston.

Hortobagyi presented findings from Breast Cancer Trials of Oral Everolimus (BOLERO-2), a phase 3 clinical trial, at the 2011 CTRC-AACR San Antonio Breast Cancer Symposium, held Dec. 6-10, 2011.

BOLERO-2 researchers enrolled 724 postmenopausal patients with HR-positive metastatic breast cancer and evidence of progressive disease while receiving anastrozole or letrozole. They randomly assigned patients to treatment with exemestane plus everolimus or with exemestane plus placebo.

Results revealed a median progression-free interval of **3.2 months** for 239 patients treated with exemestane plus placebo. Among the 485 patients treated with exemestane plus everolimus, researchers found a median progression-free interval of **7.4 months**, “a highly significant difference,” Hortobagyi said.

Clinical benefit rates, which include complete response, partial response, or stable disease exceeding six months, were **25.5 percent** among patients treated with exemestane and placebo and **50.5 percent** among those treated with exemestane and everolimus.

“The original hypothesis predicted this increased benefit from the combination, based on compelling preclinical experiments and preliminary results from earlier, smaller clinical trials. These results establish a new standard of care for this group of patients,” Hortobagyi said.

He continued, “These results highlight the progress being made in understanding the evolving mechanisms of resistance to standard therapies.”

Researchers were not yet able to measure survival analysis in BOLERO-2. However, treatment was well tolerated, with oral mucositis, fatigue, pneumonitis and hyperglycemia being the most common side effects.

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The mission of the CTRC-AACR San Antonio Breast Cancer Symposium is to produce a unique and comprehensive scientific meeting that encompasses the full spectrum of breast cancer research, facilitating the rapid translation of new knowledge into better care for patients with breast cancer. The Cancer Therapy & Research Center (CTRC) at The University of Texas Health Science Center at San Antonio, the American Association for Cancer Research (AACR) and Baylor College of Medicine are joint sponsors of the San Antonio Breast Cancer Symposium. This collaboration utilizes the clinical strengths of the CTRC and Baylor and the AACR’s scientific prestige in basic, translational and clinical cancer research to expedite the delivery of the latest scientific advances to the clinic. The 34th annual symposium is expected to draw nearly 8,000 participants from more than 90 countries.