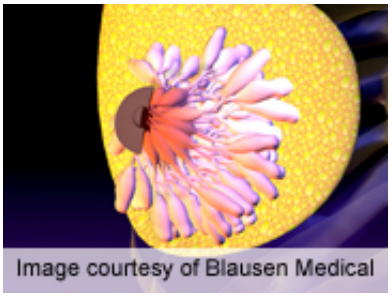
SABCS: PD 0332991 + letrozole studied in ER+ breast cancer

December 5 2012



For women with estrogen receptor-positive/human epidermal growth factor receptor 2-negative breast cancer, the investigational agent PD 0332991 plus letrozole improves progression-free survival versus letrozole alone; and fulvestrant 500 mg correlates with improved survival versus the 250-mg dose, according to two studies presented at the annual San Antonio Breast Cancer Symposium, held from Dec. 4 to 8.

(HealthDay)—For women with estrogen receptor (ER)-positive/human epidermal growth factor receptor 2 (HER2)-negative breast cancer, the investigational agent PD 0332991 plus letrozole improves progression-free survival versus letrozole alone; and fulvestrant 500 mg correlates with improved survival versus the 250-mg dose, according to two studies presented at the annual San Antonio Breast Cancer Symposium, held from Dec. 4 to 8.

Richard S. Finn, M.D., from the University of California Los Angeles, and colleagues compared PD 0332991 plus letrozole versus letrozole

alone for the first-line treatment of ER-positive/HER2-negative breast cancers in a two-part phase II study (66 women, Part 1; 99 women with certain genomic alterations, Part 2). The researchers identified significantly improved median progression-free survival in the combination arm of the Part 1 group (hazard ratio [HR], 0.35). This significant improvement in median progression-free survival with the combination treatment continued to be observed in the 99 patients making up the Part 2 group (HR, 0.32).

In a second study, Angelo Di Leo, M.D., Ph.D., from the Hospital of Prato in Italy, and colleagues compared fulvestrant 500 mg (362 women) with 250 mg (374 women) in postmenopausal women with advanced ER-positive breast cancer that had recurred or progressed with prior endocrine therapy. In the follow-up analysis of this phase III trial, the researchers found that median overall survival was significantly improved for fulvestrant 500 mg versus fulvestrant 250 mg (26.4 versus 22.3 months; HR, 0.81; P = 0.016). No clinically important differences were seen in the serious adverse event profiles between the treatment groups.

"For those postmenopausal women with recurrent or progressing ER-positive locally advanced or metastatic breast cancer for whom fulvestrant is the appropriate treatment choice, the standard of care is a 250-mg dose," Di Leo said in a statement. "Our results indicate that this should be modified to a 500-mg dose."

Several authors from the Finn study are employees of Pfizer, which is developing PD 0332991. One author from the Di Leo study disclosed financial ties to AstraZeneca, the manufacturer of fulvestrant.

More information: Press Release - Finn
Press Release - Di Leo
More Information