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To interview Mothaffar F. Rimawi, contact Julia Gunther at <u>julia.gunther@aacr.org</u> or 267-250-5441. For a photo of Rimawi, click here.

Adding an Aromatase Inhibitor to Presurgery Treatment for HR-positive, HER2-positive Breast Cancer Provided No Additional Benefit

SAN ANTONIO — Adding an aromatase inhibitor to presurgery treatment with docetaxel, carboplatin, trastuzumab (Herceptin), and pertuzumab (Perjeta) did not significantly increase or decrease the percentage of patients with hormone receptor (HR)-positive, HER2-positive breast cancer who had a pathologic complete response (pCR), according to data from a <u>phase III</u> <u>clinical trial</u> presented at the 2016 <u>San Antonio Breast Cancer Symposium</u>, held Dec. 6–10.

"Many patients with HR-positive, HER2-positive breast cancer who have large, operable breast tumors or evidence that the cancer has spread to underarm lymph nodes receive docetaxel, carboplatin, trastuzumab, and pertuzumab before surgery, a treatment approach called neoadjuvant chemotherapy," said Mothaffar F. Rimawi, MD, associate professor and medical director at the Lester and Sue Smith Breast Center, part of the Dan L Duncan Comprehensive Cancer Center at Baylor College of Medicine in Houston. "However, many of them don't respond optimally, especially if their tumors are also HR-positive. Preclinical and clinical data led us to test whether adding an aromatase inhibitor to this neoadjuvant treatment regimen in this patient group would increase the percentage of patients who have a pCR, meaning that they have no residual invasive cancer detectable in breast tissue and lymph nodes removed during surgery."

Among 308 patients who were randomly assigned docetaxel, carboplatin, trastuzumab, pertuzumab, and an aromatase inhibitor, 71 had a pCR (46.1 percent). Sixty three of the 154 patients who were randomly assigned docetaxel, carboplatin, trastuzumab, pertuzumab, and no aromatase inhibitor had a pCR (40.9 percent).

"We saw a modest numerical increase in the number of patients who had a pCR in the aromatase inhibitor arm of the study, but the increase was not statistically significant. There had been concern that chemotherapy and endocrine therapy may have opposing (antagonistic) effects. We did not see that," said Rimawi. "At this point, we cannot recommend a change to the standard-of-care neoadjuvant treatment regimen for patients with HR-positive, HER2-positive breast cancer but, the combination was safe and well tolerated. We are further analyzing tissue samples from

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the patients to investigate whether there are subgroups of patients who might benefit from the inclusion of an aromatase inhibitor in the neoadjuvant setting.

"Ultimately, we would like to de-escalate treatment for as many patients as it is safely possible to do so," continued Rimawi. "Discovering which patients need more therapy and which patients need less is crucial. Correlative studies from this and our other research efforts will provide critical information to move in that direction."

<u>About 10 percent</u> of breast cancer cases diagnosed in the United States are HR-positive, HER2-positive.

Rimawi and colleagues randomly assigned 315 patients with operable, locally advanced HR-positive, HER2-positive breast cancer 1:1 to neoadjuvant docetaxel, carboplatin, trastuzumab, and pertuzumab treatment with or without an aromatase inhibitor. Premenopausal women randomly assigned aromatase inhibitor therapy also received ovarian function suppression with goserelin or an equivalent agent.

The proportion of patients who had grade 3 or grade 4 adverse events was similar among those whose neoadjuvant treatment included an aromatase inhibitor.

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