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To interview Sara A. Hurvitz, contact Julia Gunther at julia.gunther@aacr.org or 267-250-5441. For a photo of Hurvitz, click [here](#).

Phase II Trial of Presurgery Abemaciclib Treatment for Early-stage HR-positive, HER2-negative Breast Cancer Met Primary Endpoint

SAN ANTONIO — Presurgery treatment with the investigational therapeutic abemaciclib, either alone or in combination with the aromatase inhibitor anastrozole, reduced levels of Ki67, a marker of cell proliferation, in hormone receptor (HR)-positive, HER2-negative breast cancer cells, compared with anastrozole alone, according to data from the [neoMONARCH](#) phase II clinical trial presented at the 2016 [San Antonio Breast Cancer Symposium](#), held Dec. 6–10.

“Anticancer therapeutics that target CDK4 and CDK6 have largely been studied as treatments for advanced HR-positive, HER2-negative breast cancer, with one such drug, palbociclib (Ibrance), [approved](#) for use in this setting,” said [Sara A. Hurvitz, MD](#), associate professor of medicine at the University of California, Los Angeles (UCLA), and medical director of UCLA’s Jonsson Comprehensive Cancer Center Clinical Research Unit. “We set out to investigate whether the CDK4 and CDK6 inhibitor abemaciclib would have measurable biological effects on early-stage HR-positive, HER2-negative breast cancer.

“We found that abemaciclib reduced levels of Ki67 in HR-positive, HER2-negative breast cancer cells,” continued Hurvitz. “Reduced Ki67 levels, which indicate reduced cell proliferation, have been shown in other studies to correlate with improved outcomes. Therefore, our data suggest that CDK4/6 inhibitors may benefit patients with early-stage disease. More definitive clinical evaluation of these therapeutics in the early-stage setting should be a priority.”

Hurvitz explained that treatment before surgery, which is called neoadjuvant therapy, aims to reduce the size of the tumor and eradicate any cells that may have spread beyond the breast. For patients with early-stage HR-positive, HER2-negative breast cancer, neoadjuvant therapy usually consists of chemotherapy or endocrine therapy, she said.

The researchers randomly assigned 223 postmenopausal women with early-stage HR-positive, HER2-negative breast cancer to neoadjuvant therapy with anastrozole, abemaciclib, or anastrozole plus abemaciclib for two weeks. All patients then received anastrozole plus abemaciclib for 14 weeks, at which point they had surgery. To assess the primary outcome

measure of change in Ki67 levels from baseline to two weeks, core biopsies taken before and after the first two weeks of treatment were analyzed for Ki67.

The study met its primary endpoint by showing that Ki67 levels were significantly reduced in breast cancer cells from the 107 patients who received abemaciclib, either alone or in combination with anastrozole, compared with the 54 patients who received anastrozole only.

Treatment with abemaciclib plus anastrozole led to a reduction in tumor size in most patients, as assessed by clinical and radiological evaluation.

“Even though the results of this study were positive and promising, they will not change the standard of care because this was a proof of concept study,” said Hurvitz. “The duration of therapy was relatively short and did not allow us to robustly assess pathologic responses, nor were we able to follow patients to evaluate long-term outcome. Nonetheless, the data generated are important and support continued evaluation of this drug in early-stage breast cancer.”

This study was funded by Eli Lilly and Company. Hurvitz has received remuneration for research funding and/or travel from Amgen, Bayer, Biomarin, Boehringer Ingelheim, Dignitana, Eli Lilly and Company, Genentech, GSK, Medivation, Merrimack, Novartis, OBI Pharma, Pfizer, Puma Biotechnology, and Roche.

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The mission of the 2016 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 CTCRC 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. For more information about the symposium, please visit www.sabcs.org.