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Older Women with HR-positive Breast Cancer May Receive Similar Benefit from CDK 4/6 Inhibitors as Younger Women

SAN ANTONIO — Older women with hormone receptor (HR)-positive, HER2-negative metastatic breast cancer who were treated with cyclin-dependent kinase inhibitors 4 and 6 (CDK4/6) achieved progression-free survival at a rate similar to that of younger women, according to data presented at the 2017 [San Antonio Breast Cancer Symposium](#), held Dec. 5–9.

In the past two years, the U.S. Food and Drug Administration (FDA) has approved three CDK4/6 inhibitors: palbociclib (Ibrance), ribociclib (Kisqali), and abemaciclib (Verzenio). The drugs work by blocking the function of proteins CDK4 and CDK6, both of which drive cell multiplication, fueling tumor growth. [Previous research](#) has shown that for patients with HR-positive metastatic breast cancer, combining a CDK4/6 inhibitor with endocrine therapy improves progression-free survival (PFS) compared to endocrine therapy alone.

“As we approve new drugs to treat cancer, it is important to try to improve our understanding of the efficacy and safety of these drugs in our older patients,” said the study’s lead author, Harpreet Singh, MD, scientific liaison for Cancer in Older Adults and a medical officer in the Office of Hematology and Oncology Products, Center for Drug Evaluation and Research at the FDA. “Older patients traditionally have been underrepresented in oncology clinical trials, so pooling outcomes of older patients across clinical trials in the same drug class allows us to gain insight into how these patients may benefit.”

In this study, Singh and colleagues pooled and analyzed data from prospective, randomized studies of three different CDK4/6 inhibitors in combination with an aromatase inhibitor for the initial treatment of postmenopausal patients with HR-positive metastatic breast cancer. Using Kaplan-Meier estimates and a Cox-proportional hazard model, they explored the effect of age on progression-free survival.

Of 1,334 total patients, 42 percent were 65 or older, and 24 percent were 70 or older. For patients 70 or older who were treated with a CDK4/6 inhibitor in combination with an aromatase inhibitor, the estimated PFS was not reached, compared with an estimated PFS of 18 months for those treated only with an aromatase inhibitor.

For patients under 70 treated with a CDK4/6 inhibitor, the estimated PFS was 23.5 months, compared with an estimated 13.8 months for those treated only with an aromatase inhibitor.

The researchers also evaluated safety in the patients who had taken at least one dose of CDK4/6 inhibitor. The study showed that the older patients were more likely than the younger patients to discontinue treatment due to side effects: 20 percent of the patients 70 or older discontinued treatment, compared with 17 percent of the patients 65 or older and 8 percent of the patients

under age 65. Singh said the most common events that led to discontinuation of treatment across all age groups were infection, fatigue, blood count abnormalities (neutropenia), liver enzyme abnormalities, and diarrhea.

“Our findings suggest that there is no treatment difference across age subgroups in terms of efficacy of CDK4/6 inhibitors,” Singh said. “This is an important piece of information as health care providers and patients weigh their treatment options as new therapies are approved.”

Coauthor Lynn Howie, MD, a medical officer in the same division of the FDA, added that the potential benefit for older breast cancer patients should be weighed against risk of toxicity. In addition to the higher rates of discontinuation of treatment, older patients often required more modification of dosages to help them manage side effects.

“Health care providers should counsel each patient individually on the potential benefit of these therapies as well as the potential risks, taking into account the patient’s disease characteristics, performance status, comorbidities, social support, and treatment preferences,” Howie said.

The authors added that as the population ages, the FDA and other stakeholders are exploring ways to increase the representation of older patients in clinical trials to gain more information on how to treat older adults with cancer.

The study’s primary limitation is the relatively small numbers of older patients enrolled in the clinical trials, particularly those over 75. Singh noted that many older adults who enroll in clinical trials are healthier than their peers, with fewer comorbidities and less frailty, so their results may not be representative of the broader population.

The study was run by the FDA, and the authors have no conflicts of interest.

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The mission of the 2017 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 [UT Health San Antonio Cancer Center](http://www.utmsd.edu/UTHealthCancerCenter/), the [American Association for Cancer Research](http://www.aacr.org/) (AACR), and [Baylor College of Medicine](http://www.baylor.edu/) are joint sponsors of the San Antonio Breast Cancer Symposium. This collaboration utilizes the clinical strengths of the UT Health San Antonio Cancer Center 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.