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Ribociclib Improved Progression-free Survival for Pre- and Perimenopausal Women With Hormone Receptor–positive Advanced Breast Cancer

SAN ANTONIO — Adding the CDK4/6 inhibitor ribociclib (Kisqali) to standard endocrine therapy with temporary ovarian suppression significantly improved progression-free survival for pre- and perimenopausal women with advanced hormone receptor–positive (HR-positive), HER2-negative breast cancer, according to data from the MONALEESA-7 phase III clinical trial presented at the 2017 San Antonio Breast Cancer Symposium, held Dec. 5–9.

"Three anticancer therapeutics that target cell-cycle mediators CDK4 and CDK6, so-called CDK4/6 inhibitors, have been approved by the U.S. Food and Drug Administration for use in combination with hormonal drugs, either aromatase inhibitors or fulvestrant, for treating postmenopausal women with HR-positive, HER2-negative advanced breast cancer," said Debu Tripathy, MD, professor of medicine and chair of the Department of Breast Medical Oncology at The University of Texas MD Anderson Cancer Center in Houston. "These new therapeutics have not yet been evaluated in a dedicated large, randomized trial as a potential treatment for the 30 to 40 percent of women with HR-positive, HER2-negative advanced breast cancer who are pre- or perimenopausal.

"MONALEESA-7 is the first clinical trial to have the statistical power to show that ribociclib has clinical benefit specifically for pre- and perimenopausal women with HR-positive, HER2-negative advanced breast cancer," continued Tripathy. "It is also the first trial to show that ribociclib can be safely and effectively combined with either tamoxifen or a nonsteroidal aromatase inhibitor together with ovarian suppression using goserelin."

Among the 672 patients enrolled in the clinical trial by Tripathy and colleagues, 335 were randomized to ribociclib in combination with either tamoxifen or a nonsteroidal aromatase inhibitor (letrozole or anastrozole) and goserelin, and 337 were randomized to placebo in combination with the same oral hormonal therapy options and goserelin. The primary endpoint of the trial was progression-free survival.

The study met its primary endpoint: Progression-free survival was significantly improved in the ribociclib arm compared with the placebo arm. Median progression-free survival was 23.8 months in the ribociclib arm compared with 13.0 months in the placebo arm.

Data are available for some of the secondary endpoints. For example, the overall response rate, which is the percentage of patients who had a partial or a complete response, was significantly higher among patients with measurable disease at baseline in the ribociclib arm compared with the placebo arm (51 percent versus 36 percent).

As expected, the most frequent adverse event was neutropenia, which was reported in 76 percent of patients in the ribociclib arm compared with 8 percent in the placebo arm. Grade 3/4 neutropenia was reported in 61 percent of patients in the ribociclib arm compared with 4 percent in the placebo arm, but it was asymptomatic in most patients; neutropenia associated with fever and infection was reported in 2 percent of patients in the ribociclib arm and 1 percent in the placebo arm. Other adverse events included hot flashes, nausea, leukopenia, and joint pain/stiffness. Adverse events leading to permanent discontinuation of treatment occurred in 4 percent of patients in the ribociclib arm compared with 3 percent in the placebo arm.

"Longer follow-up is needed to determine whether the trial will meet its secondary endpoint of overall survival," said Tripathy. "However, these initial results are very exciting because the World Health Organization reports that breast cancer is the leading cause of cancer-related death among women aged 20–59 years worldwide."

This study was supported by funds from Novartis. Tripathy serves as a paid consultant for Novartis. The University of Texas MD Anderson Cancer Center received funds from Novartis to conduct this study.

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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, 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 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.