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High-risk, HR+, HER2-, early-stage BC patients continue to benefit from abemaciclib

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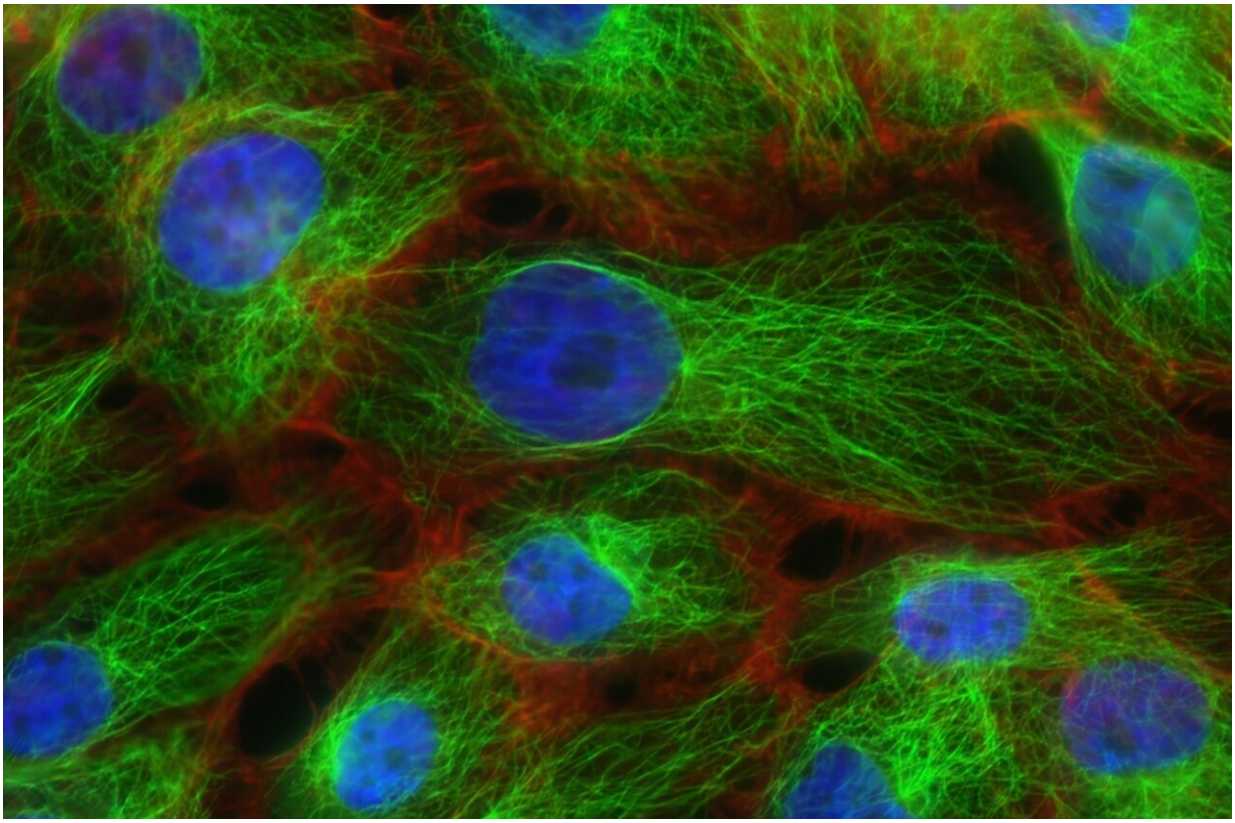

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Extended follow-up data from the phase III monarchE trial showed that adding the cyclin-dependent kinase (CDK) inhibitor abemaciclib (Verzenio) to standard adjuvant endocrine therapy continued to improve

invasive disease-free survival (IDFS) among patients with high-risk, node-positive, early-stage, HR-positive, HER2-negative breast cancer, according to data presented at the 2020 San Antonio Breast Cancer Symposium, held Dec. 8-11.

"While many patients with HR-positive early breast cancer will not experience recurrence on endocrine therapy alone, approximately 20 percent may experience disease recurrence in the first 10 years, often in the form of incurable metastatic breast cancer," said Priya Rastogi, MD, associate professor at the University of Pittsburgh Department of Medicine and medical director of the National Surgical Adjuvant Breast and Bowel Project (NSABP) Foundation.

"The risk of recurrence is higher among patients whose cancer has certain clinical and/or pathological risk factors such as a high number of positive lymph nodes, large tumor size, or a high cellular proliferation as measured by tumor grade or biomarkers," Rastogi continued. "There is a significant unmet need for this patient population, and research must be done to find new treatment options to help prevent early breast cancer from returning for these patients."

Earlier results from an interim analysis of the monarchE trial, which is comparing abemaciclib plus adjuvant endocrine therapy with endocrine therapy alone in 5,637 patients with high-risk, node-positive, early-stage, HR-positive, HER2-negative breast cancer, have been previously reported. After a median follow-up of 15.5 months and 323 invasive disease-free events, it was found that the addition of abemaciclib to endocrine therapy reduced the risk of invasive disease by 25 percent. The two-year IDFS rates in the combination arm and the endocrine therapy alone arm were 92.2 percent and 88.7 percent, respectively.

The current study describes an extended follow-up of this trial, capturing results from 395 invasive disease-free events with a median follow-up

time of 19 months.

Following surgery, and radiotherapy and/or chemotherapy as indicated, patients were randomly assigned to receive standard of care adjuvant endocrine therapy with or without abemaciclib (150 mg twice per day for two years). Eligibility criteria included having at least four positive nodes, or having one to three positive nodes in combination with either grade 3 disease, a tumor of at least 5 cm, or centrally assessed high Ki-67 status (where 'high' is defined as at least 20 percent positivity in tumor cells). Higher levels of Ki-67 protein are indicative of a fast-growing, aggressive tumor with increased probability of recurrence.

At the time of this analysis, 1,437 patients (25.5 percent) had completed the two-year treatment period and 3,281 patients (58.2 percent) were in the two-year treatment period. Compared with patients who received endocrine therapy alone, those who also received abemaciclib had a 28.7 percent reduced risk of invasive disease. The two-year IDFS rate in the combination arm and the endocrine therapy alone arm was 92.3 percent and 89.3 percent, respectively. Further, the researchers observed an improvement in the two-year distant relapse-free survival (DRFS) rate among patients who received the combinatorial treatment compared with those who received endocrine therapy alone (93.8 percent versus 90.8 percent, respectively).

The researchers also evaluated outcomes among 2,498 patients with centrally assessed high Ki-67 status. Among patients in this cohort, those who received the combination treatment had a 30.9 percent decreased risk of invasive disease compared with those who received endocrine therapy alone. The two-year IDFS rates in the combination arm and the endocrine therapy alone arm were 91.6 percent and 87.1 percent, respectively.

"Across the spectrum of data for abemaciclib, we have observed a

consistent benefit, in all subgroups," said Rastogi. Safety data from this trial were consistent with the known safety profile of abemaciclib and no new safety signals were observed.

"These results may mark a notable treatment advance in the last two decades for people living with high-risk, node-positive, HR-positive, HER2-negative early breast cancer," Rastogi continued. "These clinically meaningful results have the potential to change how high-risk, HR-positive, HER2-negative early breast cancer is treated."

Rastogi noted that overall survival data are immature at this time, and additional follow-up is warranted.

Provided by American Association for Cancer Research

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