Kisqali Improves Survival in Premenopausal Women With Advanced Breast Cancer

Recently approved CDK4/6 inhibitor plus hormone therapy extends overall survival by about a third.

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Younger women with advanced or metastatic breast cancer who added Kisqali (ribociclib) to hormone therapy increased their progression-free survival by about 11 months and their overall survival by 29%, according to study results to be presented at the American Society of Clinical Oncology (ASCO) annual meeting this week in Chicago and published in The New England Journal of Medicine.

“This is the first study to show improved survival for any targeted therapy when used with endocrine therapy as a first-line treatment for advanced breast cancer,” said lead researcher Sara Hurvitz, MD, of UCLA Jonsson Comprehensive Cancer Center in Los Angeles.

Last July, the Food and Drug Administration granted accelerated approval of Kisqali plus an aromatase inhibitor as first-line treatment for premenopausal and perimenopausal women with advanced breast cancer. Kisqali is also indicated for use in combination with Faslodex (fulvestrant) as first-line or second-line treatment for postmenopausal women.

The approval for younger women was based on results from the MONALEESA-7 trial, which showed an improvement in progression-free survival, meaning patients were still alive without worsening of disease. At the ASCO meeting, researchers presented updated findings showing that Kisqali extends overall survival as well—considered the gold standard of clinical benefit.

The Phase III MONALEESA-7 study evaluated first-line treatment with Kisqali plus hormone therapy for premenopausal women with hormone receptor-positive/HER2-negative advanced breast cancer.

A majority of breast tumors carry hormone receptors for estrogen and progesterone, which encourage cancer growth (HR-positive); standard treatment includes hormone-blocking medications. Tumors may also express a receptor called HER2 (human epidermal growth factor receptor 2), making them susceptible to HER2-blocking drugs like Herceptin (trastuzumab). Triple-

negative breast cancer doesn't express any of these receptors and is harder to treat. Around a third of women with HR-positive/HER2-negative breast cancer are premenopausal or perimenopausal, and the disease tends to be more aggressive in younger women.

MONALEESA-7 included 672 women under age 59 (median 44). More than half had breast cancer that had spread to internal organs and a quarter had bone metastases. They were being treated for advanced breast cancer for the first time, although about 40% had previously used hormone blockers as adjuvant therapy after surgery. Another 40% had de novo metastatic breast cancer, or cancer that was first diagnosed at an advanced stage.

Participants were randomly assigned to receive once-daily Kisqali tablets or a placebo, both in combination with Zoladex (goserelin), which suppresses ovarian function in premenopausal women, and either tamoxifen (which blocks the effects of estrogen in the breast) or a nonsteroidal aromatase inhibitor (a drug that interferes with an enzyme that converts other hormones into estrogen).

Kisqali, from Novartis, is a cyclin-dependent kinase inhibitor that blocks both CDK4 and CDK6. These proteins play a role in regulating cell division, and interfering with them can slow the growth of cancer cells.

At the 2017 San Antonio Breast Cancer Symposium, researchers reported that the median progression-free survival was 23.8 months in the Kisqali group and 13.0 months in the placebo group.

After 42 months of follow-up, the median overall survival was 40.9 months in the placebo group but was not reached in the Kisqali group because most participants were still alive, Hurvitz reported. The overall survival rate was 70.2% in the Kisqali group compared with 46.0% in the placebo group—a 29% relative reduction in the risk of death. Progression-free survival rates were 54.6% and 37.8%, respectively.

Overall survival rates were similar for women who used tamoxifen or an aromatase inhibitor. However, the FDA has not approved the combination of Kisqali and tamoxifen.

"The data from MONALEESA-7 provide clear evidence that ribociclib offers a significant survival advantage compared to hormone therapy alone in premenopausal patients," senior investigator Debu Tripathy, MD, of MD Anderson Cancer Center in Houston said in a university press release. "Breast cancer in younger women is known to be more aggressive and have distinct genetic changes compared to postmenopausal patients, so this provides a much-needed therapeutic option for these patients."

Treatment was generally safe, but adverse events were common. The most common side effect was neutropenia, or white blood cell deficiency, which increases the risk of infections. Although few women in the Kisqali group stopped treatment permanently because of adverse events, a majority did reduce their doses or interrupt treatment temporarily to manage side effects. No new or unexpected side effects were seen with longer follow-up. Despite having more side effects,

women taking Kisqali reported better overall health and quality of life.

The improved survival in the Kisqali group met the preset criteria for stopping the trial. The researchers are currently looking at patient-reported outcomes as well as biomarkers and circulating tumor DNA in an effort to predict which women are likely to benefit from Kisqali. Investigators are now studying Kisqali for people with early-stage HR-positive/HER2-negative breast cancer.

“Overall survival benefit is considered the ’gold standard’ in cancer trials but is challenging to achieve in HR+/HER2- metastatic breast cancer. MONALEESA-7 reached this important endpoint earlier than anticipated,” Hurvitz said in a Novartis press release. “Impactful results like these ribociclib findings are what we wish for in every clinical trial, and to achieve overall survival improvement in an incurable disease, like metastatic breast cancer, is truly an outstanding advancement for patients.”

Click here to read the study abstract.

Click here to read an ASCO press release about the study.

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