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Kisqali After Surgery Reduces Breast Cancer Recurrence

The targeted therapy delayed disease progression in patients with the most common type of early-stage breast cancer.

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Adding the CDK4/6 inhibitor Kisqali (ribociclib) to hormone therapy after surgery reduced the risk of recurrence by 25% for women with Stage II or III hormone receptor-positive/HER2-negative breast cancer, researchers reported at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting.

“While early, these results are very promising and suggest that there will be a role for adjuvant ribociclib for Stage II and higher hormone receptor-positive, HER2-negative breast cancer,” ASCO expert Rita Nanda, MD, of the University of Chicago, said in news release.

Breast cancer is classified according to it receptors. A majority of breast tumors carry hormone receptors for estrogen or progesterone (HR-positive), making them susceptible to hormone therapy. Tumors that express a receptor called HER2 can be treated with HER2-blocking drugs like Herceptin (trastuzumab). HR-positive/HER2-negative breast cancer is the most common type, accounting for more than two thirds of all breast cancer cases in the United States.

Kisqali, from Novartis, is an oral cyclindependent 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.

Kisqali is currently approved for the treatment of HR-positive/HER2-negative advanced or metastatic breast cancer, either in combination with an aromatase inhibitor as first-line therapy, or in combination with fulvestrant as initial or second-line treatment for postmenopausal women or men. The MONALEESA-2 trial previously showed that adding Kisqali to hormone therapy prolongs survival for postmenopausal women, while MONALEESA-7 showed that Kisqali improved overall survival for premenopausal or perimenopausal women with advanced or metastatic cancer.

Based on the new findings, Novartis intends to ask the Food and Drug Administration to expand the approval of Kisqali to include earlier breast cancer. Pfizer’s CDK4/6 inhibitor Ibrance (Palbociclib) has an indication similar to Kisqali’s current indication. Lilly’s Verzenio (abemaciclib) is already approved for adjuvant treatment of people with HR-positive/HER2-negative early breast

cancer that has spread to lymph nodes.

The international Phase III NATALEE trial (NCT03701334) included 5,101 premenopausal or postmenopausal women, as well as a small number of men, with HR-positive/HER2-negative breast cancer that was considered at risk for recurrence after surgery. They had Stage IIA, IIB, or III disease, meaning the cancer was either contained within the breast or had spread to nearby lymph nodes and surrounding tissue but had not spread to distant organs (Stage IV, or metastatic breast cancer). Around a third of people with Stage II breast cancer and more than half of those with Stage III cancer are expected to experience recurrence.

"Currently approved targeted treatments can only be used in a small population of patients diagnosed with HR-positive, HER2-negative early breast cancer, leaving many without an effective treatment option for reducing risk of the cancer returning," lead investigator Dennis Slamon, MD, PhD, of the UCLA Jonsson Comprehensive Cancer Center, said in the ASCO news release. "Thus, there is a significant unmet need for both reducing the risk of recurrence and providing a tolerable treatment option that keeps patients cancer-free without disrupting their daily life."

After surgery to remove as much of the cancer as possible, the study participants were randomly assigned to receive either adjuvant Kisqali for three years plus hormone therapy (daily letrozole or anastrozole, with goserelin in some cases) for at least five years or else hormone therapy alone. Those in the former group took Kisqali at a dose of 400 milligrams by mouth once daily for three weeks followed by a week off. (A higher dose, with more side effects, is used to treat metastatic breast cancer.)

People who added Kisqali saw significant improvement in invasive disease-free survival, meaning their cancer did not relapse and spread, Slamon reported. In an interim analysis after a median follow-up period of 34 months, 189 people (7.4%) in the Kisqali group developed invasive cancer or died, compared with 237 people (9.2%) who received hormone therapy alone. Three-year invasive disease-free survival rates were 90.4% and 87.1%, respectively. The subgroup of patients with early Stage II cancer that had not yet spread to lymph nodes appeared to benefit, but that finding did not reach statistical significance. The researchers saw a trend toward improved overall survival, but further follow-up is needed for this endpoint.

Treatment was safe and generally well tolerated, though side effects were common. The most common adverse effects in the Kisqali group were neutropenia (white blood cell deficiency that can increase the risk of infections) and joint pain. Gastrointestinal side effects, including diarrhea, were uncommon. The most common effects in the group that received only hormone therapy were joint pain and hot flashes. The most frequently reported severe (Grade 3 or higher) adverse events were neutropenia (44%) and elevated liver enzymes (8%).

Kisquali added to standard-of-care hormone therapy "demonstrated a statistically significant, clinically meaningful improvement in invasive disease-free survival with a well-tolerated safety profile," the researchers concluded.

"These landmark results will fundamentally change how we treat patients with Stage II and III HR-

positive/HER2-negtaive early breast cancer who are in need of new, well-tolerated options that prevent their cancer from coming back," Slamon said in a Novartis press release.

However, the drawback to expanding the use of Kisqali for people with earlier-stage breast cancer is that many patients who would not have experienced recurrence could be given extra treatment unnecessarily, adding to cost and side effects.

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