Kisqali Improves Outcomes for Premenopausal Women With Advanced Breast Cancer

CDK4/6 inhibitor plus hormone therapy extends progression-free survival for younger women.

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Premenopausal and perimenopausal women with advanced or metastatic breast cancer who added Kisqali (ribociclib) to standard hormone therapy took about twice as long to experience disease progression as those treated with hormone blockers and a placebo, researchers reported last month at the San Antonio Breast Cancer Symposium (SABCS).

MONALEESA-7 is a Phase III clinical trial evaluating first-line Kisqali plus hormone therapy for pre- and perimenopausal women with HR-positive/HER2-negative advanced breast cancer. Around 30 to 40 percent of women with this type of breast cancer are pre- or perimenopausal, and the disease tends to be more aggressive in this younger age group, according to presenter Debu Tripathy, MD, of the University of Texas MD Anderson Cancer Center.

Breast cancer is classified according to the type of receptors it expresses. A majority of breast tumors carry hormone receptors for estrogen or progesterone (known as HR-positive). Estrogen and progesterone encourage the growth of HR-positive cancer, and treatment usually 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. Triple-negative breast cancer doesn't express any of these receptors.

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 blocking them can slow the growth of cancer cells. Kisqali plus hormone therapy was previously shown to be effective and is already approved by the Food and Drug Administration (FDA) for first-line treatment of postmenopausal women with advanced or metastatic breast cancer.

This international study included 672 women with a median age of 44. Just over half were white and nearly a third were Asian. More than half had breast cancer that had metastasized, or spread to internal organs, and a quarter had bone metastases. About 40 percent had previously used hormone blockers as adjuvant therapy to prevent the return of cancer after surgery, but they had not used hormone therapy or more than one type of chemotherapy for advanced disease. Another

40 percent had de novo metastatic breast cancer, meaning it was first diagnosed at an advanced stage.

The women were randomly assigned to receive Kisqali tablets (600 milligrams once daily) or a placebo, both in combination with hormone therapy using either tamoxifen or a nonsteroidal aromatase inhibitor plus Zoladex (goserelin), which suppresses ovarian function in premenopausal women. This is the only Phase III study that has evaluated a CDK4/6 inhibitor in combination with tamoxifen, according to Novartis.

The median progression-free survival—meaning patients were still alive with no worsening of disease—was 23.8 months in the Kisqali group compared with 13.0 months in the placebo group, Tripathy reported. Kisqali worked better than the placebo when paired with either tamoxifen (22.1 versus 11.0 months) or an aromatase inhibitor (27.5 versus 13.8 months).

The overall response rate among patients with measurable disease—meaning partial or complete tumor shrinkage—was 51 percent in the Kisqali group compared with 36 percent in the placebo group.

Overall survival could not be determined because most of the women were still alive; only three patients died in each group. Fifty-two percent of women in the Kisqali group and 36 percent in the placebo group were still on treatment and follow-up is ongoing.

Treatment was generally safe, but side effects were common. Just 4 percent of women in the Kisqali group and 3 percent in the placebo group stopped treatment permanently due to adverse events. However, a majority of patients taking Kisqali lowered their doses or interrupted treatment temporarily because of side effects.

The most frequent adverse event was neutropenia (low white blood cell count), reported by 76 percent of women in the Kisqali group and 8 percent in the placebo group. Loss of white blood cells increases the risk of infection, but only 2 percent of Kisqali recipients and 1 percent of placebo recipients reported neutropenia associated with fever and infections. Nausea was a bit more common in the Kisqali group (32 percent versus 20 percent). Other side effects occurred at similar rates in the two groups, including hot flashes (34 percent), joint pain (about 28 percent), fatigue (about 24 percent), headache (about 23 percent) and diarrhea (about 20 percent).

Despite having more side effects, women taking Kisqali had better overall health status scores, maintained their quality of life longer and reported more improvement in pain than those in the placebo group.

“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,” Tripathy said in a SABCS press release. “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.”

Based on these findings, Tripathy suggested that new biological agents such as CDK4/6 inhibitors plus hormone therapy could replace traditional chemotherapy for first-line treatment of advanced breast cancer.

On January 3, Novartis announced that based on the MONALEESA-7 results, Kisqali received an FDA breakthrough therapy designation for initial treatment of premenopausal women with HR-positive/HER2-negative advanced breast cancer. This designation is intended to speed up development of therapies that treat serious or life-threatening conditions and represent an improvement over available options.

Two other CDK4/6 inhibitors, Eli Lilly's Verzenio (abemaciclib) and Pfizer's Ibrance (palbociclib), are FDA-approved for use in combination with hormone therapy for women with HR-positive/HER2-negative advanced or metastatic breast cancer.

Click here to read the study abstract.

Click here to read the SABCS press release about the study.

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