FDA Approves Kisqali for Premenopausal Women With Advanced Breast Cancer

First approval using a new FDA process to speed up cancer drug reviews.

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The Food and Drug Administration (FDA) last week approved Kisqali (ribociclib) in combination with an aromatase inhibitor for first-line treatment of premenopausal and perimenopausal women with HR-positive/HER2-negative advanced breast cancer. It was also approved with Faslodex (fulvestrant) for postmenopausal women, either as initial treatment or after disease progression on hormone therapy.

This was the first drug to be approved using the FDA's new Real-Time Oncology Review pilot program and Assessment Aid, with approval granted less than one month after submission of a supplemental New Drug Application.

Breast cancer is classified by the type of receptors it expresses. A majority of breast tumors carry hormone receptors for estrogen or progesterone (known as HR-positive). These hormones encourage the growth of HR-positive cancer, and treatment usually includes hormone-blocking medications. Tumors may also express HER2 (human epidermal growth factor receptor 2), making them susceptible to HER2-blocking drugs such as Herceptin (trastuzumab). Triple-negative breast cancer doesn't express any of these receptors and is harder to treat.

Kisqali, from Novartis, is a cyclindependent 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.

Kisquali was already approved with aromatase inhibitors (drugs that block an enzyme that converts other hormones into estrogen) for initial treatment of postmenopausal women with HR-positive/HER2-negative advanced or metastatic breast cancer, as are two other CDK4/6 inhibitors, Eli Lilly's Verzenio (abemaciclib) and Pfizer's Ibrance (palbociclib). Kisqali is the first one to be approved for pre- and perimenopausal women.

As reported at the 2017 San Antonio Breast Cancer Symposium, Debu Tripathy, MD, of the University of Texas MD Anderson Cancer Center, and colleagues evaluated the safety and efficacy

of Kisqali in younger women. Around 30 to 40 percent of women with HR-positive/HER2-negative advanced breast cancer are pre- or perimenopausal, and the disease tends to be more aggressive in this age group, Tripathy said.

The Phase III MONALEESA-7 study included 672 women with a median age of 44. 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 breast cancer that was first diagnosed at an advanced stage.

The women were randomly assigned to receive once-daily Kisqali tablets or a placebo in combination with hormone therapy using either an aromatase inhibitor or tamoxifen plus Zoladex (goserelin), a drug that suppresses ovarian function in premenopausal women.

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 an aromatase inhibitor (27.5 versus 13.8 months) or tamoxifen (22.1 versus 11.0 months). Overall survival could not be determined because most participants were still alive. The overall response rate among, meaning complete or partial tumor shrinkage, was 51 percent in the Kisqali group compared with 36 percent in the placebo group.

Treatment was generally safe, but side effects were common. While just 4 percent of women in the Kisqali group permanently stopped treatment due to adverse events, a majority lowered their doses or interrupted treatment temporarily. The most common Kisqali side effect was neutropenia (low white blood cell count). Despite having more side effects, women taking Kisqali reported better overall health, maintained their quality of life longer and had more improvement in pain.

Another Phase III study, MONALEESA-3, evaluated Kisqali in combination with Faslodex as first- or second-line hormone therapy in 726 postmenopausal women with HR-positive/HER2-negative advanced breast cancer. Here too, adding Kisqali significantly improved progression free survival compared with a placebo (20.5 months versus 12.8 months, respectively).

The FDA's Real-Time Oncology Review is intended to make the development and review of cancer drugs more efficient, while improving the agency's rigorous standard for evaluating efficacy and safety, according to an FDA news release. The program enables the FDA to start reviewing clinical trial data sooner, before it is formally submitted, allowing the agency to provide feedback to the drug company about how best to analyze the results. The Assessment Aid is a new structured format to streamline drug approval submissions.

"With this approval, we've demonstrated some of the benefits of the new programs that we're piloting for our review of cancer drugs, to improve regulatory efficiency while enhancing the process for evaluating the data submitted to us," said FDA Commissioner Scott Gottlieb, MD. "These new processes are good for patients, good for health care providers, good for product

developers, and good for the FDA by allowing our staff to have more time to engage with product developers and focus on the key aspects of drug reviews."

Click here for full prescribing information for Kisqali.

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