FDA Approves Verzenio for Initial Treatment of Advanced Breast Cancer

Indication extended to include first-line treatment of HR-positive/HER2-negative advanced or metastatic disease.

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On February 26, the Food and Drug Administration (FDA) approved Verzenio (abemaciclib) as a first-line option with endocrine therapy for postmenopausal women with certain types of advanced or metastatic (spread elsewhere in the body) breast cancer.

The approval was based on data from the MONARCH 3 trial, which showed that Verzenio in combination with an aromatase inhibitor doubled progression-free survival, meaning that patients were still alive with no worsening of disease.

Breast cancer is classified by the kind 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 breast cancer, and treatment usually includes hormone-blocking drugs. Other tumors express the HER2 (human epidermal growth factor receptor 2) receptor and can be treated with HER2 inhibitors. Triple-negative breast cancer doesn't express any of these receptors and is hardest to treat.

The FDA has now approved Verzenio for postmenopausal women with HR-positive/HER2-negative advanced or metastatic breast cancer that is being treated for the first time. More than 70 percent of all breast cancers are HR-positive and HER2-negative, according to the American Cancer Society.

Verzenio was approved in September 2017 for use in combination with the estrogen blocker Falsodex (fulvestrant) for the treatment of women with HR-positive/HER2-negative advanced or metastatic breast cancer whose disease progresses after hormone therapy. It was also approved as monotherapy for adults—including men—who experience progression after hormone therapy and chemotherapy for metastatic breast cancer.

Verzenio, made by Eli Lilly and Company, is a cyclindependent kinase inhibitor that blocks both CDK4 and CDK6. These proteins play a role in regulating cell division, and blocking their action can slow the growth of cancer cells. Two other drugs in this class, Pfizer's Ibrance (palbociclib) and Novartis's Kisqali (ribociclib) are also approved for women with HR-positive/HER2-negative breast

cancer.

The Phase III MONARCH 3 trial included 493 postmenopausal women with HR-positive/HER2-negative locally advanced or metastatic breast cancer; the median age was 63. Most had cancer spread to their internal organs or bones. They were randomly assigned to receive either Verzenio or a placebo, taken by mouth twice daily, plus their physician's choice of Femara (letrozole) or Arimidex (anastrozole), two aromatase inhibitors that interfere with estrogen production after menopause.

The study showed that progression-free survival was 28.2 months in the Verzenio group compared with 14.8 months in the placebo group. The difference was significant, meaning that it probably was not attributable to chance. Overall response rates among those with measurable disease, meaning complete or partial tumor shrinkage, were 55.4 percent with Verzenio and 40.0 percent with the placebo. The median duration of response was 27.4 months versus 17.5 months, respectively.

The most frequent side effects of Verzenio were diarrhea, which was reported by about 80 percent of study participants and was usually mild to moderate, and neutropenia (low white blood cell count), which occurred in about 40 percent of patients. Diarrhea can be managed with antidiarrheal medications or Verzenio dose reduction. Other common side effects included nausea, vomiting, abdominal pain, loss of appetite, fatigue and hair loss. Serious adverse events occurred about twice as often among Verzenio recipients compared with placebo recipients.

"This approval is an important milestone, as it shows that Verzenio plus an aromatase inhibitor substantially reduced tumor size and delayed disease progression in women with HR-positive/HER2-negative metastatic breast cancer," Joyce O'Shaughnessy, MD, of Baylor University Medical Center in Dallas, said in an Eli Lilly press release. "This information will help inform treatment decisions for each patient, which can be complicated in advanced breast cancer."

Click here to read Eli Lilly's press release about Verzenio approval.

Click here to see the full prescribing information for Verzenio.
