# FDA Approves New Targeted Therapy for Advanced Breast Cancer

Verzenio delayed disease progression among women with HR-positive/HER2-negative breast cancer.

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On September 28, the Food and Drug Administration (FDA) approved Verzenio (abemaciclib), a kinase inhibitor that disrupts cancer growth, for people with certain types of advanced or metastatic breast cancer that has progressed despite hormone therapy.

The approval was supported by data from a Phase III trial that showed that women who took Verzenio plus the estrogen blocker Faslodex (fulvestrant) after hormone therapy stopped working held off disease progression for nearly twice as long as those who took a placebo.

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). Estrogen and progesterone encourage the growth of HR-positive breast cancer, and treatment usually includes hormone-blocking drugs. Other tumors express a receptor called HER2 (human epidermal growth factor receptor 2). Triple-negative breast cancer doesn't express any of these receptors.

The FDA approved Verzenio for adults with HR-positive/HER2-negative advanced or metastatic (spread elsewhere in the body) breast cancer that has progressed after taking hormone blockers. More than 70 percent of all breast cancers are HR-positive and HER2-negative, according to the American Cancer Society.

Verzenio is taken by mouth twice daily. It can be given with Faslodex for patients whose cancer has progressed on hormone therapy or given alone for people previously treated with hormone therapy and chemotherapy after their cancer has spread.

Verzenio, made by Eli Lilly, 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), were previously approved for some types of breast cancer.

Results from MONARCH 2 were presented at the American Society of Clinical Oncology (ASCO) annual meeting in June. This study enrolled 669 women (median age about 60) with metastatic

breast cancer who experienced disease progression after taking hormone therapy. More than half had their cancer spread to internal organs and a quarter had bone metastases. Participants were randomly assigned to take either Verzenio or a placebo in combination with Faslodex.

Women who took Verzenio plus Faslodex were still alive without disease progression—known as progression-free survival—for a median of 16.4 months, compared with 9.3 months in the placebo plus Faslodex group. The median duration of response was 25.6 months in the placebo group but could not be determined in the Verzenio group because most patients were still responding. More than a third (35.2 percent) of women who took Verzenio had partial or complete tumor shrinkage, compared with 16.1 percent of those taking the placebo.

Another study, MONARCH 1, looked at Verzenio as a stand-alone treatment. This non-randomized trial included 132 patients with HR-positive/HER2-negative breast cancer that had progressed following treatment with hormone therapy and chemotherapy after metastasis. In this study, 19.7 percent experienced tumor shrinkage and responses lasted a median of 8.6 months.

Common side effects of Verzenio include diarrhea, low white blood cell counts, nausea, abdominal pain, loss of appetite and fatigue. In MONARCH 2, women treated with Verzenio plus Faslodex had more serious adverse events and early discontinuations due to side effects than those who took the placebo. In most cases, diarrhea could be managed with antidiarrheal medications or dose reduction.

“Verzenio provides a new targeted treatment option for certain patients with breast cancer who are not responding to treatment, and, unlike other drugs in the class, it can be given as a stand-alone treatment to patients who were previously treated with endocrine therapy and chemotherapy,” Richard Pazdur, MD, of the FDA’s Oncology Center of Excellence, said in an FDA press release.

Click here to read the FDA press release.

Click here to see the full prescribing information for Verzenio.

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