Verzenio Prevents Recurrence and Metastasis of Early Breast Cancer

The oral targeted therapy lowered the risk of relapse in a late-stage study.

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For people with high-risk HR-positive/HER2-negative early breast cancer, the oral medication Verzenio (abemaciclib) reduced the likelihood of recurrence by 25% when combined with adjuvant (post-surgery) hormone therapy, researchers reported at the European Society for Medical Oncology's ESMO Virtual Congress 2020 and in the Journal of Clinical Oncology.

If approved for this indication, Verzenio has the potential to set a new standard of care, according to lead study investigator Stephen Johnston, MD, PhD, a professor of breast cancer medicine at the Royal Marsden NHS Foundation Trust in London. It is "potentially one of the most notable treatment advances in the last two decades for this population of breast cancer patients," he said in a press release.

Breast cancer is classified according to the types of receptors it expresses. A majority of breast tumors carry estrogen or progesterone hormone receptors (HR positive) and can be treated with hormone therapy. Others express a receptor called HER2 and can be treated with HER2 inhibitors. Roughly 70% of all breast cancers are HR positive/HR negative, making it by far the most common breast cancer diagnosis. Breast cancer claims about half a million lives each year, including about 42,170 in the United States alone.

Although many people with HR-positive/HR-negative breast cancer can be cured with surgery, radiation and adjuvant chemotherapy, cancer can be difficult to eliminate completely. In a 2015 study, researchers found that 30% of people with this type of breast cancer were at risk for recurrence.

Developed and manufactured by the pharmaceutical giant Eli Lilly and Company, Verzenio is a CDK4/6 inhibitor that targets two cyclin-dependent kinases, proteins that play a role in cell division. It is currently approved for the treatment of advanced or metastatic breast cancer.

Between July 2017 and August 2019, Johnston and colleagues recruited 5,637 people with high-risk HR-positive/HR-negative early breast cancer from 38 countries for a Phase III study known as MonarchE. Notably, the study included men—over 2,000 of whom are diagnosed with breast cancer in the United States each year—as well as women. Risk was assessed based on factors

such as tumor size and the number of involved lymph nodes.

After undergoing initial treatment with surgery, as well as chemotherapy in a majority of cases, half of the participants were randomly assigned to a regimen of Verzenio plus standard adjuvant hormone therapy and half to hormone therapy alone. Verzenio was taken twice daily for up to two years. Both groups will continue on hormone therapy for five to 10 years, as recommended for high-risk early breast cancer.

At the two-year mark, 7.8% of the participants taking Verzenio had experienced a recurrence compared with 11.3% of the participants not taking Verzenio—a 25% reduction in risk.

Verzenio plus hormone therapy also improved distant relapse-free survival, a measure of the time to metastasis to another part of the body. At the two-year mark, 6.4% of the participants taking Verzenio and 9.7% of the participants not taking the drug had experienced metastasis—a 28% risk reduction.

Verzenio is the first CDK4/6 inhibitor to demonstrate a statistically significant reduction in the risk of recurrence for people with high-risk HR-positive/HER2-negative early breast cancer, the researchers concluded. Another drug in this class, Ibrance (palbociclib), has not shown a significant reduction in recurrence risk compared with chemotherapy alone for this population.

Verzenio was generally safe. Common adverse events included diarrhea, fatigue and neutropenia (low white blood cell count), which can increase susceptibility to infections. About 16% of study participants discontinued Verzenio due to side effects, mostly because of diarrhea.

Even though the study has not yet been completed—final results are projected for delivery in June 2027—Giuseppe Curigliano, MD, PhD, the chair of ESMO's guidelines committee, is optimistic. "This is a very important trial, and the findings will change practice," he said in an ESMO press release.However, he added, "The safety data are important, particularly the number of patients treated with [Verzenio] who had to discontinue or required dose reductions due to side effects."

So what do cancer patients and those who who work closely with them think about taking Verzenio and the potential trade-off between cancer recurrence and chronic gastrointestinal distress?

"The results of MonarchE are welcome news for our community," Jean Sachs, the CEO of the national nonprofit Living Beyond Breast Cancer, said in a Lilly press release. "Up to 30% of people with hormone receptor–positive early breast cancer may have a recurrence, so this finding is an exciting development for those with high risk [HR-positive/HR-negative] early breast cancer, especially because the trial included women of any menopausal status as well as men."

Click here to read the study abstract.

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http://beta.docker.cancerhealth.com/article/verzenio-prevents-recurrence-metastasis-early-breast-cancer