Verzenio Improves Outcomes for People With Early Breast Cancer

The oral targeted therapy Verzenio reduced relapse risk in extended follow-up from a recent study.

December 21, 2020 By Caroline Tien

For people with high-risk HR-positive/HER2-negative early breast cancer, the oral medication Verzenio (abemaciclib) reduces the likelihood of recurrence by 29% when combined with adjuvant hormone therapy after surgery, researchers reported at the virtual San Antonio Breast Cancer Symposium.

This figure marks a 4% increase from results presented earlier this year and is based on extended follow-up data from the Phase III monarchE study.

In a press release, senior author Priya Rastogi, MD, an associate professor at the University of Pittsburgh School of Medicine and the medical director of the National Surgical Adjuvant Breast and Bowel Project Foundation, said, “These results may mark a notable treatment advance in the last two decades” for this patient population.

Breast cancer is classified according to the types of receptors it expresses. A majority of breast tumors express estrogen or progesterone hormone receptors (HR) 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/HER2 negative. In total, breast cancer claims about half a million lives each year, including about 42,000 in the United States alone.

Although HR-positive/HER2-negative breast cancer can often be treated successfully—typically with a combination of surgery, radiation and adjuvant, or post-surgery, chemotherapy—the disease can recur. About 20% of people with this common form of breast cancer experience recurrence within 10 years, according to Rastogi. The risk is higher for people with larger tumors, cancer that has spread to nearby lymph nodes or biomarkers of cell proliferation.

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, the study recruited 5,637 people with high-risk HR-

positive/HR-negative early breast cancer from 38 countries. 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 surgery as well as, in a majority of cases, receiving chemotherapy, half of the participants were randomly assigned to a regimen of Verzenio twice daily for up to two years plus standard adjuvant hormone therapy, while the other half were assigned to hormone therapy alone. Both will continue on hormone therapy for five to 10 years, as recommended for high-risk early breast cancer.

The researchers looked at both invasive disease-free survival, meaning the time until cancer recurrence in the remaining tissue on the same side, in nearby lymph nodes, in the other breast or elsewhere in the body, as well as distant relapse-free survival, meaning the time until metastasis, or spread, to other parts of the body.

The earlier analysis, presented at the European Society of Medical Oncology (ESMO) Virtual Congress in September and published in the Journal of Clinical Oncology, found that Verzenio reduced the likelihood of recurrence after a median follow-up period of 15.5 months. At the two-year mark, 7.8% of the participants taking Verzenio had experienced a recurrence compared with 11.3% of those not taking Verzenio, representing a 25% reduction in risk. Verzenio also improved distant relapse-free survival.

The follow-up data confirmed these results after a median follow-up of 19.1 months. Rastogi reported that 7.7% of the participants taking Verzenio had experienced a recurrence, compared with 10.7% of those not taking Verzenio, representing a 28.7% reduction in risk. In addition, 6.2% of the participants taking Verzenio and 9.2% of those not taking the drug had experienced distant metastasis, representing a 31.3% reduction in risk.

Among patients with a biomarker (Ki-67) that signals aggressive tumors that are more likely to recur, the risk of recurrence fell by 30.9%, and the risk of metastasis also decreased.

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, according to Rastogi.

“Across the spectrum of data for abemaciclib, we have observed a consistent benefit in all subgroups,” she said.

Treatment was found to be generally safe. Common adverse events included diarrhea, fatigue and neutropenia (low white blood cell count), which can increase susceptibility to infections. About 17% of study participants discontinued Verzenio due to side effects, typically diarrhea.

Even though the study has not yet been completed—final results are projected for delivery in June 2027—Rastogi is optimistic about the medication’s future.

“These clinically meaningful results have the potential to change how high-risk, HR-positive, HER2-negative early breast cancer is treated,” she said.

So what do cancer patients and those 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 about the ESMO presentation. “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.”

To learn more about breast cancer, click here.

To see a list of breast cancer medications, click here.

© 2026 Smart + Strong All Rights Reserved.
http://beta.docker.cancerhealth.com/article/verzenio-improves-outcomes-early-breast-cancer-patients