FDA Green-Lights Five New Treatment Options for Breast Cancer

The approvals include new indications for triple-negative, double-positive and HER2-negative breast cancer.

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The Food and Drug Administration (FDA) recently approved several new therapies for breast cancer, including for patients with metastatic (Stage IV) cancer and hard-to-treat triple-negative breast cancer (TNBC). Because treatment is continually evolving, it is often possible to move on to new medications if current ones stop working.

Breast cancer, classified by the type of receptors or proteins on tumors, is not a single disease. Around 75% carry estrogen or progesterone receptors, known as HR-positive. HR-positive breast cancer is typically treated with hormone, or endocrine, therapy. Around 15% to 20% of tumors have high expression of HER2, a protein that promotes cell growth. However, a majority of tumors historically classified as HER2-negative have some HER2 expression; with more precise testing, they are now classified as HER2-low or HER2-ultralow. TNBC, accounting for about 15%, does not express any of these receptors, so it has fewer treatment options and poorer prognosis.

Datroway for TNBC

In May, the FDA approved Datroway (datopotamab deruxtecan), from AstraZeneca and Daiichi Sankyo, as a new option for previously untreated patients with inoperable or metastatic TNBC who are not candidates for PD-1 or PD-L1 checkpoint inhibitor immunotherapy. Datroway is an antibody-drug conjugate (ADC) that uses a monoclonal antibody targeting TROP-2—a protein on tumors that spurs cell growth—to deliver potent chemotherapy directly to cancer cells.

Results from the Phase III TROPION-Breast02 trial, presented at last year's European Society for Medical Oncology Congress (ESMO 2025) and published in Annals of Oncology, showed that first-line Datroway prolonged overall survival by a median of five months compared with chemotherapy for this patient population (23.7 versus 18.7 months)—a 21% improvement—with an "unprecedented" median overall survival of approximately two years, according to a company news release. The FDA previously approved Datroway for people with inoperable or metastatic HR-positive/HER2-negative breast cancer.

"For seven out of 10 patients with metastatic triple-negative breast cancer who are not candidates

for immunotherapy, chemotherapy has remained the only treatment option," said Arlene Brothers, executive director of the Triple Negative Breast Cancer Foundation, The approval of Datroway "means that for the first time, these patients will have a new standard of care beyond traditional chemotherapy at the outset of their treatment."

Trodelvy for TNBC

In June, the FDA gave the nod to Gilead Sciences' TROP-2 ADC, Trodelvy (sacituzumab govitecan), as an initial treatment option for people with inoperable locally advanced or metastatic TNBC.

Based on findings from the Phase III ASCENT-03 trial, Trodelvy was approved as a solo drug for patients who are not eligible for PD-1 or PD-L1 checkpoint inhibitors. In that setting, first-line Trodelvy monotherapy reduced the risk of disease progression or death by 38% versus chemotherapy (median progression-free survival 9.7 versus 6.9 months). Further data presented at the American Society of Clinical Oncology Annual Meeting (ASCO 2026) showed that at 12 months, the second progression-free survival rates were 71% and 59%, respectively.

Trodelvy was also approved as initial treatment in combination with the checkpoint inhibitor Keytruda (pembrolizumab) for people whose tumors express PD-L1, suggesting they're likely to respond to the immunotherapy. In the Phase III ASCENT-04/KEYNOTE-D19, Trodelvy plus Keytruda reduced the risk of disease progression or death by 35% compared with Keytruda and chemotherapy (median progression-free survival 11.2 versus 7.8 months). The second progression-free survival rates were 72% and 53%, respectively. In both trials, overall survival data are not yet mature.

Trodelvy was already approved for previously treated patients with TNBC or HR-positive/HER2-negative breast cancer. Another similar candidate, sacituzumab tirumotecan, from the Chines company Kelun-Biotech, also shows promise.

"For patients with metastatic TNBC, a new first-line treatment option offers optimism to a community with historically few choices," Ricki Fairley, cofounder and CEO of TOUCH, the Black Breast Cancer Alliance, said in a news release. "TNBC disproportionately affects younger women—many in the prime of their lives—and often leads to poorer outcomes. Because so many patients may never receive subsequent lines of therapy, the ability to start with a promising option like Trodelvy with or without Keytruda is critical."

Ibrance for HR-Positive/HER2-Positive Breast Cancer

During the same busy week, the FDA approved Ibrance (palbociclib) as maintenance therapy for people with locally advanced or metastatic HR-positive/HER2-positive—so-called double-positive—breast cancer. Ibrance is a CDK4/6 inhibitor that blocks proteins that promote malignant cell growth.

The new indication is for Ibrance plus hormone therapy and Herceptin, with or without Perjeta,

following induction therapy. Ibrance was previously approved for patients with HR-positive/HER2-negative advanced breast cancer.

In the Phase III PATINA trial, adding Ibrance to anti-HER2 and endocrine therapy reduced the risk of disease progression or death by 24%. Study results were previously presented at the 2024 San Antonio Breast Cancer Symposium and published in The New England Journal of Medicine. Overall survival data are not yet mature.

“Resistance to dual anti-HER2 and endocrine therapy remains a central clinical challenge for patients with HR-positive/HER2-positive metastatic breast cancer—even after an excellent response to initial treatment,” lead investigator Otto Metzger, MD, of Dana-Farber Cancer Institute, said in a news release. “Based on the results from the PATINA study, the addition of IBRANCE in the maintenance phase can meaningfully extend the time patients go without their disease progressing.”

Enhertu for Earlier HER2-Positive Breast Cancer

In May, the FDA approved two new indications for AstraZeneca and Daiichi Sankyo’s Enhertu (trastuzumab deruxtecan), an ADC that uses the HER2-targeted monoclonal antibody trastuzumab to deliver chemotherapy to cancer cells. Enhertu is now approved for use before surgery (neoadjuvant therapy) and after surgery (adjuvant therapy) in patients with high-risk but potentially curable breast cancer.

The FDA initially approved Enhertu in December 2019 for patients with inoperable or metastatic HER2-positive breast cancer after hormone therapy. Approval was extended to advanced HER2-low breast cancer in August 2022 and HER2-ultralow tumors in January 2025. Now, approval has been expanded to include people with earlier-stage disease.

The Phase III DESTINY-Breast11 trial evaluated neoadjuvant Enhertu in patients with Stage II or III HER2-positive breast cancer, followed by chemotherapy, Herceptin (trastuzumab) and Perjeta (pertuzumab). As reported at ESMO 2025 and in Annals of Oncology, 67% had a pathologic complete response (no cancer found in removed tissue), compared with 56% of those who started with intensive chemotherapy.

The Phase III DESTINY-Breast05 trial tested adjuvant Enhertu for people with early HER2-positive cancer who had residual invasive disease despite neoadjuvant treatment. Enhertu reduced the risk of invasive disease recurrence or death by 53% compared to the ADC Kadcyla (trastuzumab emtansine), researchers reported at ESMO 2025 and in The New England Journal of Medicine. Both HR-positive and HR-negative patients saw a benefit.

“HER2-positive breast cancer is an aggressive disease, and our goal is to reduce the risk of recurrence for patients as early as possible to achieve the best long-term outcomes,” Shanu Modi, MD, of Memorial Sloan Kettering Cancer Center, said in a news release. “The neoadjuvant setting offers the earliest opportunity to improve outcomes, while the adjuvant setting provides another

important chance to prevent recurrence for patients with residual disease after surgery."

Revtorpyk for HR-Positive/HER2-Negative Patients

Finally, in July, the FDA approved a brand-new drug, Revtorpyk (gedatolisib), for people with HR-positive/HER2-negative locally advanced or metastatic breast cancer without a PIK3CA gene mutation. Revtorpyk, from Celcuity, is a pan-PI3K/mTOR inhibitor that interferes with a signaling pathway that promotes cancer cell growth.

The indication is for Revtorpyk plus Faslodex (fulvestrant), with or without Ibrance, for patients who have experienced disease progression during or after endocrine therapy. As described at ESMO 2025, findings from a cohort of patients with wild-type, or nonmutated, PIK3CA in the Phase III VIKTORIA-1 trial, Revtorpyk plus Faslodex and Ibrance reduced the risk of disease progression or death by 76%, and Revtorpyk plus and Faslodex lowered the risk by 67%, compared with Faslodex alone (median progression-free survival 9.3, 7.4 and 2.0 months, respectively). Study results were published in the Journal of Clinical Oncology.

The company intends to also request FDA approval of Revtorpyk for previously treated breast cancer with the PIK3CA mutation. The drug is also being studied for first-line treatment.

"For patients with HR-positive/HER2-negtaive locally advanced or metastatic breast cancer, there is an urgent need for new treatment options that can meaningfully increase the likelihood of survival without disease progression or death," investigator Sara Hurvitz, MD, of Fred Hutchinson Cancer Center and the University of Washington School of Medicine, said in a news release. "With the approval of REVTORPYK, oncologists now have an effective new treatment option for these patients."

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