

Clinical Trials Connected, aims to connect you with crucial research updates and clinical trials to help you stay informed about the latest advancements in breast cancer care. In this edition, we bring you the latest news from ASCO and CBCS 2025.

Use our blog <u>on Understanding Common Research Terms</u> as a guide for some of the terms we reference.

The 2025 ASCO Annual Meeting showcased important advances in breast cancer research and treatment. Below are some of the key trial results presented this year, highlighting promising new therapies and improvements in disease management across different breast cancer subtypes.

ASCO 2025 Highlights

ASCENT-04/KEYNOTE-D19 Phase 3: Sacituzumab Govitecan Delays Progression in Advanced PD-L1-Positive TNBC

Combining the anti-body drug conjugate saciituzumab govitecan (SG) with pembrolizumab helped people with advanced PD-L1-positive triple negative breast cancer (TNBC) stay stable longer than those who received standard chemotherapy with pembrolizumab. On average, people receiving the new combination went 11.2 months without their cancer getting worse (called progression-free survival), compared to 7.8 months with chemotherapy. Among those whose cancer responded to treatment, the response lasted longer for an average of 16.5 months (known as duration of response), compared to 9.2 months with chemotherapy. These results suggest that this drug combination may become a new first-line option for this type of breast cancer.

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DESTINY-Breast09 Phase 3: T-DXd plus Pertuzumab Delays Cancer Progression in Metastatic HER2-Positive Breast Cancer This drug combination significantly delayed cancer progression in people with metastatic HER2-positive breast cancer. Patients who received fam-trastuzumab deruxtecan (T-DXd) plus pertuzumab had longer disease control (measured as progression-free survival) compared to those on the current standard treatment. On average, the time before the cancer worsened was about 41 months with the new combination, compared to 27 months with standard therapy. At two years, more patients receiving T-DXd plus pertuzumab were still progression-free, and the response to treatment lasted longer. Side effects were generally similar between the groups, though lung and heart-related issues occurred slightly more often with T-DXd, and doctors say the findings suggest this combination could become a new first-line option.

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SERENA-6 Phase 3: Camizestrant Plus CDK4/6 Inhibitor Slows Breast Cancer Progression with Early Mutation Detection

A new study found that switching to the drug camizestrant, after detecting specific ESR1 mutations in a blood test, helped people with metastatic HR-positive, HER2-negative breast cancer stay on treatment longer without their cancer worsening. In the SERENA-6 trial, people who switched to camizestrant while continuing their CDK4/6 inhibitor stayed progression-free nearly 7 months longer compared to those who stayed on standard hormone therapy. This benefit was seen before tumours showed growth on scans, thanks to regular blood testing (called ctDNA) that detected mutations early. Two years after starting treatment, nearly 30% of people on camizestrant were still progression-free compared to just 5% on standard therapy. The treatment was well tolerated, with few side effects causing people to stop therapy, showing that early action based on blood test results could improve care for many people.

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VERITAC-2 Phase 3: New Drug Vepdegestrant Slows Cancer Growth in Certain Advanced Breast Cancers

A new drug called vepdegestrant helped slow the growth of advanced ER-positive, HER2-negative breast cancer in people whose cancer had a specific biomarker called an ESR1 gene mutation, according to results from the VERITAC-2 trial. Compared to the standard treatment fulvestrant, vepdegestrant nearly doubled the time it took for cancer to worsen (known as progression free survival) in patients with this mutation. The benefit was not seen in people without the ESR1 biomarker, meaning the drug may work best in a select group. Side effects like fatigue and changes in liver enzymes were manageable, and very few people needed to stop treatment due to side effects. These results suggest that vepdegestrant may offer a new option for people with previously treated, ESR1-mutated advanced breast cancer who have not yet received chemotherapy.

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INAVO120 Phase 3: Inavolisib Combination Extends Survival and Delays Chemotherapy in Advanced Breast Cancer

The targeted drug called inavolisib, when combined with palbociclib and fulvestrant, helped people with HR-positive, HER2-negative, endocrine-resistant advanced breast cancer live longer (known as overall survival), according to final results from the INAVO120 study. Patients who received this three-drug combination lived a median of 7 months longer than those on standard treatment and were able to

delay the start of chemotherapy by nearly two years. Inavolisib works by targeting a specific mutation found in about 40% of these breast cancers (PIK3CA), and it appears to be more precise and better tolerated than older drugs in its class. Side effects like high blood sugar and diarrhea did occur, but they were generally manageable, and very few patients had to stop treatment because of them. These results suggest this combination could become a new standard treatment option for patients whose cancer has stopped responding to hormone therapy.

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OptiTROP-Breast05 Trial Phase 2: Sacituzumab Tirumotecan Shows Strong Results for Untreated Metastatic Triple Negative Breast Cancer

A new drug called sacituzumab tirumotecan may help treat people with advanced triple negative breast cancer (TNBC) who haven't had any previous treatment for their advanced disease. In a clinical trial with 41 participants, over 70% responded to the treatment (known as objective response rate), and nearly all had their cancer controlled for a period of time. The drug worked well even in people with low levels of PD-L1. On average, the treatment kept the cancer from getting worse for about 13 months (known as progression-free survival). While all patients experienced some side effects (mostly low blood counts) most were manageable.

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Canadian Breast Cancer Symposium Highlights

We had the opportunity to attend the 2025 Canadian Breast Cancer Symposium, held in Toronto on June 19 and 20. During this national event, we hosted a booth showcasing CBCN's patient education resources to oncologists from across the country. We were also honoured to participate in a panel discussion "Patient Groups: Your Partners on the Ground" facilitated by Dr. Fahima Osman, a surgical oncologist. Rebecca Armstrong, Director of Patient Education and Engagement, spoke about the importance of education for people with breast cancer. She highlighted how CBCN's tools support newly diagnosed individuals in becoming active participants in their care, and how our patient navigation program helps individuals advocate for themselves and navigate difficult conversations with their care team.

Keep reading to discover how this conference put the spotlight on lobular breast cancer.

Spotlight on Lobular Breast Cancer

A powerful morning session focused on invasive lobular carcinoma (ILC), a less common but important type of breast cancer that can be hard to detect.

Brenda Cunnington, a patient advocate and board member of the <u>Lobular Breast Cancer Alliance</u>, opened the session by sharing her personal story of how long it took to receive an ILC diagnosis, despite years of close monitoring via mammography. Her experience highlighted the unique challenges of detecting lobular breast cancer early.

Dr. Nancy Nixon followed with an overview of what we know about ILC and how it is treated. ILC makes up about 15% of breast cancer cases and is usually hormone receptor-positive (HR+). It's often missing a key protein called E-cadherin, which normally helps cells stick together. Without it, cancer cells spread in

a line rather than forming a lump, making them harder to spot on traditional imaging. ILC can also spread to less common areas like the bowel, peritoneum, or around the eyes.

Dr. Nixon explained that ILC doesn't always respond well to chemotherapy, and some people may not benefit from it after surgery. However, for people with higher-risk disease—often identified by a high Oncotype DX recurrence score, which predicts the likelihood of cancer returning and whether chemotherapy may help—chemo may still be beneficial. Hormonal therapy plays a key role in treatment, with aromatase inhibitors (like letrozole or anastrozole) preferred over tamoxifen, especially when combined with ovarian suppression for younger women. She also noted that in the metastatic setting, CDK4/6 inhibitors are appropriate in people with lobular breast cancer, though more data is needed to understand how well ILC responds compared to other types. Importantly, while major clinical trials included participants with lobular breast cancer, the results have not yet been analyzed separately for this group. This highlights a gap in evidence that could help guide treatment decisions.

Dr. Andrea Covelli then discussed the challenges of imaging and surgery for ILC. These cancers are often missed or underestimated by mammograms and ultrasounds. Breast MRIs can help find additional disease in about 1 in 5 patients but can sometimes overestimate tumour size. PET/CT scans may be more accurate for staging than other scans, though ILC can still be harder to detect this way than other breast cancer types.

Surgically, the approach to treating ILC is similar to other breast cancers: remove the tumour with clear margins while preserving the look of the breast when possible. However, ILC has a higher chance of needing repeat surgery due to positive margins, and new surgical techniques like oncoplastic surgery may help reduce this risk. Neoadjuvant chemotherapy (chemo before surgery) is generally less effective at shrinking ILC tumors, but it may still help in some advanced cases.

Finally, Dr. David Lim presented on emerging research highlighting a new Canadian study called LOBCAN. This prospective pan-Canadian cohort study aims to better understand invasive lobular breast cancer and improve outcomes for those diagnosed. The study will collect and analyze data specifically from patients with ILC. This is an important step toward filling the current research gaps. Read more about it <u>here</u>.

The session made it clear that more awareness, better imaging, and dedicated research are urgently needed to improve outcomes for people diagnosed with lobular breast cancer.