



## Landmark OPTIMA Trial Delivers Practice-Changing Evidence that Veracyte's Prosigna Test Identifies Patients with High-Risk Breast Cancer Who Can Safely Avoid Chemotherapy

May 29, 2026

*Highest level of prospective evidence supports test-directed chemotherapy decisions in broadest high-risk population to-date, including premenopausal women and patients with extensive lymph node involvement*

*Study shows for the first time, based on the Prosigna test results, that more than two-thirds of patients could be spared chemotherapy without compromising outcomes*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 29, 2026-- Veracyte, Inc. (Nasdaq: VCYT), a leading cancer diagnostics company, announced today results from the independent [OPTIMA](#) (Optimal Personalised Treatment of early breast cancer using Multi-parameter Analysis) trial, led by University College London (UCL). The results, which will be presented at the ASCO Annual Meeting, conclude that the Prosigna® Breast Risk of Recurrence (ROR) test safely guides adjuvant chemotherapy decisions in patients with early-stage, ER-positive HER2-negative breast cancer.

"Behind every breast cancer treatment decision is a patient asking, 'Do I really need chemotherapy?'" said Prof. Robert Stein, Lead Investigator, University College London. "OPTIMA answers this question with robust evidence. These study results can be practice-changing – we can now use the Prosigna test to predict which high-risk patients can safely avoid chemotherapy and its lasting side effects without compromising outcomes. That is a profound shift for patients and the clinicians who care for them."

The Phase III prospective, randomized controlled trial compared standard of care – chemotherapy followed by hormone therapy – to treatment guided by Prosigna test results: patients with high ROR scores (>60) received chemotherapy followed by hormone therapy while those with low ROR scores (≤60) received hormone therapy alone.

### Key Trial Findings

The OPTIMA trial results demonstrate:

- **Chemotherapy can be safely avoided for many patients:** The Prosigna test identified that 68% of patients with clinically high-risk node-positive breast cancer, who previously would have received chemotherapy, could safely forgo it entirely. These patients achieved 5-year cancer-free survival rates of 93.7% -- statistically noninferior to the 94.9% achieved with chemotherapy -- demonstrating that omitting treatment for these patients does not compromise outcomes or increase recurrence risk.
- **Robust results across broadest range of high-risk subgroups:** Non-inferiority was confirmed in previously understudied populations where treatment guidance has been most uncertain, demonstrating that tumor biology, vs clinical factors alone, can guide chemotherapy decisions for:
  - Premenopausal women treated with ovarian function suppression (HR 1.04; 90% CI 0.60–1.80)
  - Patients with extensive nodal involvement (4–9 positive nodes, or pN2 disease) (HR 1.19; 95% CI 0.62–2.29)
- **Highest level of prospective evidence:** With 4,429 patients and 4.0-year median follow-up, OPTIMA provides Level 1A evidence, showing that the Prosigna test can accurately predict chemotherapy benefit and guide safe de-escalation across patient populations.

### The Impact on Patients with Breast Cancer

Breast cancer remains the most commonly diagnosed cancer worldwide, affecting 1 in 8 women in the U.S.,<sup>1</sup> with over 225,000 new HR+/HER2- breast cancer cases diagnosed annually.<sup>2</sup> Treatment decisions play a critical role in preventing recurrence and improving long-term outcomes.

For many of these patients, chemotherapy decisions have historically been driven by clinical factors alone – age, tumor size, and lymph node status – and its potential for multiple, severe side effects. Up to 43% of breast cancer survivors experience persistent nerve damage years after chemotherapy, with studies showing a broader range of treatment-related side effects impacting the majority of patients during and after care.<sup>3</sup>

The Prosigna test is a genomic test that uniquely combines intrinsic subtypes and proliferation score with clinical pathological factors to calculate a patient's Risk of Recurrence (ROR) score. In OPTIMA, an ROR score ≤60 enabled clinicians to identify patients who could safely avoid chemotherapy. The results from the OPTIMA trial are in a position to transform how clinicians approach breast cancer treatment decisions using the Prosigna ROR score to confidently de-escalate therapy in a high percentage of high-risk patients.

"OPTIMA sets a new standard for how chemotherapy decisions are made in breast cancer," said Phillip Febbo, M.D., Chief Scientific and Medical Officer, Veracyte. "Prosigna now has the strongest prospective evidence of any genomic test to predict which patients with clinically high-risk hormone-receptor positive breast cancer can safely avoid chemotherapy. For patients, that means the option to choose a treatment with fewer unnecessary side effects, and for clinicians, the confidence to act on it."

### ASCO Annual Meeting Presentation

The OPTIMA trial results are being presented this Saturday, May 30 at the 2026 ASCO Annual Meeting during the Breast Cancer—Local/Regional /Adjuvant Oral Abstract Session (1:15 PM CDT, Hall B1, Abstract 500). Prof. Robert C. Stein from University College London is presenting the findings, which will also be livestreamed via the ASCO conference platform.

### About the OPTIMA Trial

OPTIMA (Optimal Personalised Treatment of early breast cancer using Multi-parameter Analysis) is an international, multicenter randomized controlled trial led by University College London and funded by U.K. National Institute for Health and Care Research. The independent study enrolled 4,429 women and men aged  $\geq 40$  years with ER-positive HER2-negative early breast cancer and 0–9 involved axillary lymph nodes. Participants were randomly assigned to either the control arm for standard chemotherapy followed by hormone therapy or to the Prosigna test-directed arm of standard chemotherapy followed by hormone therapy for patients with Prosigna high ROR test results ( $>60$ ), versus hormone therapy alone for patients with Prosigna low ROR test results ( $\leq 60$ ). All premenopausal women were required to have ovarian function suppression.

### About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company with a vision to transform cancer care for patients around the world. The company's molecular tests assess the unique biology of each patient's tumor to help clinicians answer essential questions about cancer care. [Veracyte's Diagnostics Platform](#) combines broad genomic and clinical data, advanced bioinformatics and AI, and a powerful evidence-generation engine to support continued [innovation and pipeline development](#). The company's portfolio includes the [Afirma® Genomic Sequencing Classifier test](#), [Decipher® Bladder Genomic Classifier test](#), [Decipher® Prostate Genomic Classifier test](#), [Prosigna® Breast Risk of Recurrence test](#), and the [TrueMRD™ Monitoring Test for MIBC](#). For more information, visit Veracyte's [website](#) or follow the company on [LinkedIn](#) or [X \(Twitter\)](#).

### Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to statements regarding the potential clinical utility, impact, and benefits of Veracyte's Prosigna Breast Risk of Recurrence (ROR) test; the ability of the Prosigna Breast Test to guide adjuvant chemotherapy decisions in early-stage, ER-positive HER2-negative breast cancer patients, including identifying patients who may safely avoid chemotherapy and its side effects without compromising outcomes; the extent to which the results of the OPTIMA trial may be considered practice-changing or influence clinical decision-making; the potential for molecular testing to inform treatment decisions based on tumor biology rather than clinical factors alone; and the adoption and use of the Prosigna Breast Test in clinical practice across patient population. Forward-looking statements can be identified by words such as: "appears," "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will," "enable," "positioned," "offers," "designed," "ultimately," and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions. Additional factors that may impact these forward-looking statements can be found under the caption "Risk Factors" in our Annual Report on Form 10-K filed on February 26, 2026, as well as in other documents that we may file from time to time with the Securities and Exchange Commission. Copies of these documents, when available, may be found in the Investors section of our website at [investor.veracyte.com](#). These forward-looking statements speak only as of the date hereof and, except as required by law, we specifically disclaim any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise.

### References:

1. <https://www.nationalbreastcancer.org/breast-cancer-facts/>
2. <https://seer.cancer.gov/statfacts/html/breast-subtypes.html>
3. <https://onlinelibrary.wiley.com/doi/10.1002/cam4.4202?utm>

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