PreludeDx Announces First Independent Validation of AidaBreast™, the Only Multi-Omic Test to Predict Locoregional Recurrence Risk and Radiation Therapy Benefit in Early-Stage Invasive Breast Cancer

LAGUNA HILLS, CA - December 10, 2025 - Prelude Corporation (PreludeDx®), a leader in precision diagnostics for early-stage breast cancer, today announced results from the first independent validation of AidaBreast™, a novel multi-omic biosignature developed to predict a woman's 10-year risk of locoregional recurrence (LRR) and her individualized benefit from adjuvant radiation therapy (RT) following breast-conserving surgery.

The findings will be presented at the San Antonio Breast Cancer Symposium (SABCS) 2025 by Dr. Bruce Mann, Director of Research at Breast Cancer Trials, Head of Breast Surgical Research at Royal Melbourne Hospital, Professor of Surgery at The University of Melbourne, and Principal Investigator of the study, together with Troy Bremer, PhD, Chief Scientific Officer of PreludeDx.

The validation study, conducted at Royal Melbourne Hospital (RMH) in Australia, evaluated more than 400 women with early-stage HR+ / HER2- invasive breast cancer who underwent breast-conserving surgery and endocrine therapy, with or without radiation therapy. The results confirmed and strengthened PreludeDx's initial validation:

- AidaBreast stratifies women into Low Risk and Elevated Risk groups based on underlying tumor biology.
- Within the Elevated Risk group, the test identifies which women are likely to experience significant therapeutic benefit from RT, and which show minimal benefit from RT, despite elevated recurrence risk.
- Women in the Low Risk group demonstrated very low 10-year recurrence rates whether or not they received radiation therapy.

"This independent blinded validation confirms the prior results, demonstrating that AidaBreast is prognostic for LRR risk and predictive for RT benefit. The results demonstrated that the test identified patients who are good candidates for the omission of RT and patients who would significantly benefit from radiation therapy," said Dr. Bruce Mann, Principal Investigator of the study. "AidaBreast provides information that cannot be determined from clinicopathology alone and offers a major advance in early-stage invasive breast cancer treatment."

AidaBreast: The First and Only Test Providing Both Prognostic and Predictive Insight for Radiation Therapy

AidaBreast uses multi-omic technology by analyzing RNA and protein expression together with spatial biology, providing a more complete assessment of a patient's tumor biology.

“AidaBreast provides a new level of clarity for women with early-stage invasive breast cancer,” said Dan Forche, President and CEO of PreludeDx. “For the first time, patients and physicians have a tool for Stage I and IIa breast cancer that supports shared treatment decisions, helping women make more confident and informed choices on radiation therapy.”

AidaBreast™: The Next Generation of Insight for Early-Stage Breast Cancer

AidaBreast assessment of RT benefit is the first in a comprehensive approach for early-stage invasive breast cancer. Future plans include evaluation of endocrine therapy and chemotherapy benefit, enabling a unified, integrated decision-support tool.

“This is the first and only commercially available test developed specifically for RT in Stage I and IIa breast cancer”, said Dr. Troy Bremer, CSO. “Prior tests were focused on metastatic risk and chemotherapy benefit. AidaBreast incorporates both RNA and functional proteins that drive tumor biology, giving patients and clinicians the first tool for assessing both recurrence risk and predicting radiation therapy benefit.”

Extending the Proven Impact of DCISionRT®

AidaBreast builds on PreludeDx’s leadership established with DCISionRT®, the widely adopted test that transformed radiation therapy decision-making for women diagnosed with ductal carcinoma in situ (DCIS).

“With AidaBreast, we are bringing the same level of precision and biological insight to early-stage invasive breast cancer,” added Forche. “Our goal is to ensure women have the clearest possible understanding of their treatment options so they can make the best decision for their health and quality of life.”

About DCISionRT®

DCISionRT is the *only* risk assessment test for patients with ductal carcinoma in situ (DCIS) that predicts radiation therapy benefit. Patients with DCIS have cancerous cells lining the milk ducts of the breast, but they have not spread into surrounding breast tissue. In the US, over 60,000 women are newly diagnosed with DCIS each year. DCISionRT, developed by PreludeDx on technology licensed from the University of California San Francisco, and built on research that began with funding from the National Cancer Institute, enables physicians to better understand the biology of DCIS. The test provides a Decision Score that identifies a woman’s risk as low, elevated, or residual risk. Unlike other risk assessment tools, the DCISionRT test combines protein expression from seven biomarkers and four clinicopathologic factors, using a non-linear algorithm to account for multiple interactions between individual factors to better interpret complex biological information. DCISionRT’s intelligent reporting provides a woman’s recurrence risk after breast conserving surgery alone and with the addition of radiation therapy. In turn, this new information may help patients and their physicians to make more informed, personalized treatment decisions.

About PreludeDx

PreludeDx is a leading personalized breast cancer diagnostics company serving patients and physicians worldwide. Founded in 2009 with technology from the University of California San Francisco, PreludeDx is dedicated to developing precision breast cancer tools that impact treatment decisions. The company's mission is to provide innovative technologies that improve patient outcomes and reduce healthcare costs. Before making a treatment decision, Know Your Risk™, Know Your Benefit. For more information on how PreludeDx is making a difference for patients, please visit the Company's website: https://preludedx.com and follow us on X, LinkedIn, Instagram and Facebook.

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