

PreludeDx Announces Groundbreaking Study Results on HER2-Positive DCIS Patients

LAGUNA HILLS, Calif., October 2, 2024/PRNewswire/— Prelude Corporation (PreludeDx®), a leader in precision diagnostics for early-stage breast cancer, today announced results of a cutting-edge study in Clinical Breast Cancer. The study, marks a significant advancement in personalized treatment for DCIS patients.

The study evaluated HER2-positive patients treated with breast conserving surgery (BCS) plus radiation therapy (RT) to determine if the DCISIONRT test could identify those patients with elevated residual risk remaining after treatment. The study showed that patients with the DCISIONRT Residual Risk subtype had significantly higher in-breast recurrence (IBR) rates compared to those without the Residual Risk subtype (16.2% vs 1.6%, p=.01).

Dr. Frank Vicini, a leading investigator on this study said, “The identification of this residual risk subtype opens new avenues for tailored treatments. It particularly highlights the possible benefit of Trastuzumab in this subset of patients, as we’ve been investigating in the NSABP-B43 trial. These results could significantly impact how we approach treatment for HER2-positive DCIS patients moving forward.”

“We’re very encouraged by the latest publication,” says Dan Forche, President and CEO of PreludeDx. “This study represents a significant opportunity to bring companion diagnostics and targeted treatment into the area of DCIS, marking a pivotal step in PreludeDx’s commitment to advancing personalized medicine in breast cancer treatment.”

By enabling more precise risk stratification and predicting which women will benefit from RT, DCISIONRT empowers physicians and patients to make more informed shared decisions about treatment plans, potentially improving outcomes and quality of life for women diagnosed with DCIS.

Key findings of the study “A 7-gene biosignature for ductal carcinoma in situ of the breast identifies distinct subpopulations of HER2-positive patients with varying response to radiation therapy after breast-conserving surgery” are shown below:

- DCISIONRT successfully identified two distinct groups of HER2(3+) DCIS patients treated with breast-conserving surgery (BCS) plus radiation therapy (RT) that could not be identified using traditional clinicopathologic factors.
- 63% of HER2(3+) patients had the Residual Risk subtype and remained at elevated risk even after BCS + RT, suggesting an opportunity to refine treatment strategies for these patients.

About DCISionRT for Breast DCIS

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. DCISionRT combines the latest innovations in molecular biology with risk-based assessment scores to assess a woman's individual tumor biology along with other pathologic risk factors and provides a personalized recurrence risk. The test provides a Decision Score™ that identifies a woman's risk as low or elevated. 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 in order to better interpret complex biological information. DCISionRT 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 treatment decisions.

About PreludeDx

PreludeDx is a leading personalized breast cancer diagnostics company dedicated to serving breast cancer patients and physicians worldwide. Founded in 2009, PreludeDx has focused on developing precision breast cancer tools that will impact a patient's treatment decision. Our mission is to provide patients and physicians with innovative technologies that improve patient outcomes and reduce the overall cost burden to the healthcare system. Before making a treatment decision, Know Your Risk™. PreludeDx is a Fjord Ventures portfolio company.

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 Twitter @PreludeDx, Facebook, Instagram and LinkedIn.

PreludeDx, the PreludeDx logo, DCISionRT, the DCISionRT logo, DecisionTree, Decision Score, The DCIS Test, Know Your Risk and Your Biology, Your Decision are trademarks of Prelude Corporation or its wholly owned subsidiaries in the United States and foreign countries.

Media Contact

Chris Emery

cemery@preludedx.com

Investor Contact

Andrew Wade

awade@preludedx.com