The DCISionRT® Test Result is the Most Important Factor Determining Clinician Treatment Recommendations – Findings from Multicenter PREDICT Study of 2,007 Patients

LAGUNA HILLS, Calif., June 26, 2024 /PRNewswire/-- Prelude Corporation (PreludeDx®), a leader in precision diagnostics for early-stage breast cancer, announced an important advancement in the field of breast cancer care with the publication of the PREDICT study in the Annals of Surgical Oncology (ASO). This comprehensive study evaluated the clinical utility of PreludeDx's DCISionRT® test, a genomic biosignature designed to assess each patient's unique tumor biology in order to guide personalized treatment decisions for women with ductal carcinoma in situ (DCIS).

Historically, DCIS has presented a unique challenge in both overtreatment and undertreatment of women with DCIS. The PREDICT study was designed to address the impact of the DCISionRT test on radiotherapy (RT) recommendations. The study enrolled more than 2,000 women diagnosed with DCIS at 63 academic and community centers across the U.S. Patients were offered the DCISionRT test as part of their standard of care, and clinicians reported their treatment recommendations both before and after receiving the test results. Importantly, the DCISionRT test result influenced a change in RT treatment recommendations in 38% of patients, and emerged as the strongest predictor of post-test RT guidance from physicians.

"The PREDICT study represents a significant milestone in our understanding of how to personalize treatment for DCIS," said Dan Forche, President and CEO of PreludeDx. "The publication of this study in the Annals of Surgical Oncology further establishes the DCISionRT test as a valuable tool for clinicians and patients alike, providing essential information to guide treatment decisions and improve outcomes for women facing this diagnosis."

"This decision-impact study confirms that leading breast care doctors recognize that the DCISionRT molecular profile reliably identifies patients who do and who do not benefit from adjuvant radiation, and that utilization of traditional clinicopathologic factors alone will often lead to undertreatment or overtreatment," said Chirag Shah, MD, Co-Director of the Comprehensive Breast Program and Director of Breast Radiation Oncology at the Cleveland Clinic. "The publication of this study is practice-changing and is the standard for clinicians seeking to empower patients diagnosed with DCIS with critical information for shared decision-making."

5 key study findings

- **Significant impact on treatment decisions:** DCISionRT test results led to a change in pre-test to post-test RT recommendations for 38% of women, highlighting its clinical utility in optimizing treatment plans based on individual patient risk profiles.
- **Net reduction in RT recommendations:** Overall, the test contributed to a 20% net reduction in the number of women recommended for RT, potentially sparing many from unnecessary treatment and associated side effects.
- **Identification of elevated risk patients:** Importantly, the test identified 31% of women initially not recommended for RT who were subsequently recommended RT after receiving their DCISionRT results, ensuring those at elevated risk receive appropriate therapy to reduce their risk of recurrence.
- **Strongest predictor of RT recommendation:** The DCISionRT Decision Score, a continuous risk score generated by the test, emerged as the strongest predictor of post-test RT recommendation, even surpassing traditional clinicopathologic factors such as tumor size and grade.
- **Impact across risk categories:** The test significantly influenced treatment recommendations for both clinicopathologic “low-risk” and “high-risk” patient groups, demonstrating its ability to refine risk assessment beyond traditional methods.

Implications for clinical practice

- The PREDICT study adds to the growing body of evidence supporting the clinical utility of the DCISionRT test in routine clinical practice. By integrating this test into the decision-making process, clinicians can confidently tailor treatment plans to each individual patient's unique risk profile.
- The test's ability to identify women who are unlikely to benefit from RT can help prevent overtreatment, reducing unnecessary exposure to radiation and its associated risks.
- Conversely, the test's ability to identify women at high risk of recurrence can help ensure that these patients receive appropriate therapy, potentially improving their long-term outcomes.
- The study reinforces the importance of shared decision-making in DCIS treatment, incorporating both clinical factors and informed patient preferences alongside DCISionRT results to create individualized treatment plans.

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 provide 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'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 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 with technology licensed from University of California San Francisco, 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.

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