PreludeDx Study Demonstrates Superiority of DCISionRT® Over Clinicopathology Factors and Criteria for DCIS Treatment Management

LAGUNA HILLS, Calif., July 31, 2025 — PreludeDx™, a leader in breast cancer precision diagnostics, today announced the publication of new groundbreaking data in the *International Journal of Radiation Oncology· Biology· Physics* ("Red Journal").

The study demonstrated that clinicopathology (CP) based risk assessment frequently fails to accurately assess recurrence risk and radiation therapy benefit for patients diagnosed with DCIS. Consequently, treatment decisions based on CP alone may result in over 40% of women being over- or undertreated with radiation therapy when compared to the molecular-based test DCISionRT®.

This study, titled "Limitations in the Application of Clinicopathologic Factors Alone in Predicting Radiation Benefit for Women with Low-Risk Ductal Carcinoma in Situ after Breast Conserving Surgery: The Impact of a 7-gene Biosignature based on 10-Year Ipsilateral Breast Recurrence (IBR) Rates" evaluated 10-year recurrence risk in 926 women diagnosed with DCIS and treated with BCS with or without radiation therapy (RT). The recurrence risk and treatment benefit for patients with low and high CP risk were compared to the risk assessment by DCISionRT.

"The study underscores the utility of DCISionRT to enhance shared decision-making and deliver more personalized RT guidance in the management of DCIS," said Frank Vicini, MD, first author and nationally recognized radiation oncologist from Michigan Healthcare Professionals.

Key Findings

- Over 50% of patients initially classified low-risk by CP criteria were actually High Risk, based on their molecular tumor biology assessed by DCISionRT. These reclassified patients had significant benefit from radiation therapy.
    - 63% of patients considered low-risk based on criteria like the MSKCC nomogram were biologically High Risk by DCISionRT and had a significant benefit from radiation therapy.
    - 57% of VNPI-like patients were reclassified to molecular High Risk and benefited from radiation therapy.
    - 51% of patients considered low-risk based on RTOG-9804 trial criteria had elevated recurrence risk and had a significant benefit from radiation therapy.
- 28% of CP high-risk patients were reclassified to molecular Low Risk.
- Women classified as low-risk by CP and Low Risk by DCISionRT had low 10-year recurrence risks and no significant benefit from RT.

Please see Figure 1 in the Red Journal Link Below:

Dr. Patrick Borgen, Chair of the Department of Surgery, Maimonides Medical Center shared, "This observational study further supports optimizing de-escalation and escalation treatment strategies using DCISionRT." Dr. Borgen continued, "The national randomized clinical trial (NRG CC-016) will

soon be underway to further define the utility of DCISionRT to identify important subsets of patients with low recurrence risk and minimal to no benefit from radiation therapy."

"This latest publication continues to support our mission to bring precision medicine to early-stage breast cancer patients," said Dan Forche, President and CEO of PreludeDx. "The data clearly demonstrates that DCISionRT provides guidance above and beyond all the CP criteria reviewed in the study. We believe this will further empower women and their clinicians to make better and more informed shared treatment decisions. I also want to personally thank the outstanding group of authors from NCCN and leading cancer centers, as well as the Red Journal editors and reviewers for their time and dedication to getting this critical data in the hands of treating physicians and their patients." DOI: 10.1016/j.ijrobp.2025.07.1411

Importance for Patients and Physicians

The novel information provided by DCISionRT is vital for improving shared decision-making and personalizing RT recommendations in the management of ductal carcinoma in situ (DCIS). DCISionRT differs from CP-based risk assessments in that it incorporates 7 biomarkers and 4 CP factors using a non-linear algorithm rather than a simple linear combination of factors. By integrating molecular biology, DCISionRT enables more accurate risk assessment, leading to better patient outcomes.

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. 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 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, 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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