

PreludeDx™ Presents Risk Assessments for DCIS Patients Using Clinicopathologic-Based Models Like RTOG 9804 and MSKCC Compared to DCISionRT®

Results Show DCISionRT® Identified DCIS Patients at “Low Risk” Based on RTOG-9804 or MSKCC- Like Models Who Benefited Significantly from Radiotherapy

LAGUNA HILLS, Calif., October 2, 2023 /GlobeNewswire/-- Prelude Corporation (PreludeDx™), a leader in molecular diagnostics and precision medicine for early-stage breast cancer, today announced study results of 926 women demonstrating that DCISionRT®, the 7-gene biosignature for patients with ductal carcinoma in situ (DCIS), reclassified Clinical Pathologic (CP) Low-Risk patients defined by RTOG-9804 and MSKCC-like DCIS models as DCISionRT High-Risk. These DCISionRT High-Risk patients had high 10-year ipsilateral breast recurrence (IBR) rates and significant radiation therapy (RT) benefit. In contrast, the corresponding DCISionRT Low-Risk patients had low 10-yr IBR rates and no significant RT benefit. The data was presented in an oral presentation at the 2023 American Society for Radiation Oncology (ASTRO) Annual Meeting, held on October 1 – 4, 2023 at the San Diego Convention Center, San Diego, CA.

“Prior to DCISionRT, we relied primarily on traditional clinicopathologic factors to make treatment decisions. We now recognize that those methods are not always accurate at classifying DCIS patients into Low or High-Risk groups,” said Frank A. Vicini, MD, Radiation Oncologist at Michigan Healthcare Professionals, member of NRG Oncology, and first author of the study. “DCISionRT is a powerful tool that enables physicians to help identify which patients may have a significant or minimal benefit from radiation therapy based on the patient’s individual tumor biology, thus optimizing cross-specialty collaboration, particularly with surgeons, and eliminating unnecessary over- or under-treatment for DCIS patients.”

Dan Forche, President and CEO of PreludeDx stated, “We are excited to present this data at ASTRO demonstrating the value of our biosignature to identify which patients will benefit from radiation therapy who may have been at low risk by traditional clinicopathologic factors. This data further establishes DCISionRT’s substantial impact in clinical practice, empowering patients and their physicians to confidently make a personalized and shared treatment decision that is best for them.”

The oral presentation, [‘Limitations in the Application of Clinicopathologic Factors Alone in Predicting Radiation Benefit for Women with Low-Risk DCIS after Breast Conserving Surgery: The Impact of a 7-gene Biosignature based on 10-year Ipsilateral Breast Recurrence \(IBR\) Rates’](#) demonstrated that patients reclassified into the DCISionRT Low-Risk group had a 10-yr IBR risk of 5.6% after breast conserving surgery (BCS) and no significant RT benefit (0.8% absolute RT

benefit, p=0.70), demonstrating a 99% negative predictive value (NPV) for RT benefit. Conversely, the study also demonstrated patients reclassified into the DCISionRT High-Risk groups had higher IBR rates without RT (20% and 12%) and significant absolute IBR rate reductions (13% and 8%) from RT.

PreludeDx Additional Poster Presentations at ASTRO 2023:

Posters will be available for viewing during the duration of the conference in the Poster Hall and online via the Virtual Poster Library.

[*A Biosignature Integrating Immune and Metabolic Signaling Axes to Assess Limited Radiation Therapy Response in Early-Stage Cancer from a Low-Risk Cohort*](#)

[*Impact on Radiation Therapy Recommendation and Treatment Modality for Patients with Ductal Carcinoma in Situ Using the 7-gene Biosignature: Analysis of the Predict Study*](#)

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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