



PreludeDx™ Presents New Data at SABCS Spotlight Session Re-Classifying Patients Meeting RTOG 9804 Low Risk Criteria as Elevated Risk Using DCISionRT®

New data Is Consistent with the Previously Published Independent Validation in Kaiser Permanente Northwest Cohort

LAGUNA HILLS, Calif., 2020 /PRNewswire/-- Prelude Corporation (PreludeDx™), a leader in molecular diagnostics and precision medicine for early stage breast cancer, presented clinical outcomes data last week at the San Antonio Breast Cancer Symposium (SABCS) that further validates the DCISionRT® test results of an independent study by Kaiser Permanente Northwest published earlier this year in [Clinical Cancer Research](#). DCISionRT is a biologic risk signature that assesses the 10-yr risk of a subsequent breast cancer recurrence. A Spotlight Poster presented at SABCS, showed that the DCISionRT test reclassified 45% of patients meeting RTOG 9804 low risk or 'good risk' criteria for Ductal Carcinoma In Situ (DCIS) as Decision Score (DS) Elevated Risk. These patients who were reclassified by the DCISionRT test to DS Elevated Risk had clinically elevated 10-year breast cancer rates when treated without radiation therapy (RT) and demonstrated an 84% relative benefit with RT.

The company's Spotlight Poster, entitled [DCIS biosignature reclassified patients, who met RTOG 9804 or ECOG-ACRIN E5194 low-risk clinicopathologic criteria into an elevated invasive risk group who benefited significantly from radiation therapy](#), was presented on Thursday, December 10 by Dr. Chirag Shah, Director of Breast Radiation Oncology and Director of Clinical Research – Radiation Oncology at Cleveland Clinic.

RTOG 9804 criteria is based on traditional clinical and pathological features and is used to identify low risk or 'good risk' DCIS patients. In this study, complete biomarker data was available for 535 women meeting 'good risk' clinicopathologic RTOG 9804-like criteria. In the DCISionRT DS Low Risk group there was no significant reduction from RT. However, in the DCISionRT DS Elevated Risk group, RT significantly reduced invasive breast cancer risk by 84%.

"In this study we examined the utility of the DCISionRT test to identify patients who otherwise met traditional 'good-risk' criteria but remained at an elevated invasive risk after lumpectomy," said Dr. Shah. "The study supports the use of DCISionRT, which provides a ten-year breast event risk with and without radiation therapy after lumpectomy, as compared to traditional clinical and pathological features when making radiation therapy decisions following breast conserving surgery in patients with DCIS."

Similar results were previously reported by an independent validation of DCISionRT conducted by Kaiser Permanente Northwest (KPNW), which included a 455 patient cohort. DCISionRT reclassified approximately 50% of patients meeting 'good risk' criteria like RTOG 9804 as DS Elevated Risk. Women in the DS Elevated Risk category in the KPNW cohort had a 21% 10-yr invasive recurrence rate when treated with lumpectomy and without RT, and a 6% rate when receiving radiation therapy.

"We appreciate the opportunity to have worked alongside such esteemed physicians and organizations and are thrilled to announce another strong data set supporting the integration of DCISionRT into

clinical practice management for DCIS,” said Daniel Forche, President and CEO of PreludeDx. “Women and their physicians contemplating the next treatment steps now can make a personalized decision for radiation therapy that includes their individual tumor biology to add or omit radiation therapy after breast conserving surgery.”

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. In the US, over 60,000 women are newly diagnosed with DCIS each year. DCISionRT, developed by PreludeDx 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 artificial intelligence and machine learning to assess a woman’s individual tumor biology along with other risk factors and provide a personalized recurrence risk. The test provides a Decision Score™ that identifies a woman’s risk as low or elevated. 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™.

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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