PreludeDx™ DCISionRT® Predicts Radiation Benefit in Landmark Randomized SweDCIS Clinical Trial

The Only DCIS Test Validated with Peer-reviewed Published Level 1b Evidence

LAGUNA HILLS, Calif., December 7, 2021 /PRNewswire/-- Prelude Corporation (PreludeDx™), a leader in molecular diagnostics and precision medicine for early-stage breast cancer, announced the publication of SweDCIS randomized clinical trial data in the *Special Issue*: *Updates on Breast Cancer* edition of *Cancers.* The randomized study demonstrates that the DCISionRT test predicts radiation benefit for reducing 10-year local invasive breast cancer risk. The peer-reviewed article entitled "Prognostic Risk Assessment and Prediction of Radiotherapy Benefit for Women with Ductal Carcinoma in Situ (DCIS) of the Breast in a Randomized Clinical Trial (SweDCIS)" is available online at https://www.mdpi.com/2072-6694/13/23/6103.

"In this study, DCISionRT demonstrated statistically significant radiation therapy (RT) benefit in patients with higher Decision Scores (DS), and minimal benefit in lower scores," said principal investigator, Fredrik Wärnberg, MD, PhD, Professor in the Department of Surgery, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Sweden. "This was a highly valuable use of bio-banked tissue from the landmark SweDCIS patient cohort as no other randomized studies have been able to identify DCIS patients who can omit RT."

The study assessed 10-yr outcomes in 504 women treated with breast conserving surgery (BCS) and randomized into RT or no RT arms. Patients in the DCISionRT elevated risk group had a 9% significant reduction in invasive risk from radiation therapy. While women in the low risk group had a 1% non-significant difference after receiving radiation therapy. The results are highly consistent with three prior DCISionRT studies, further validating the predictive value of the assay.

"DCISionRT represents a significant advancement in the current standard of care for DCIS patients in deciding who will or who will not benefit from radiation therapry following breast conserving surgery," said study investigator Chirag Shah, MD, Director of Breast Radiation Oncology, Department of Radiation Oncology, Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH. "These comprehensive study results will provide the highest level of confidence among physicians to fully adopt and implement DCISionRT to guide their treatment recommendations for patients with DCIS."

"We are thrilled to publish this latest data on DCISionRT, the *only* DCIS test validated with peer-reviewed published Level 1b clinical evidence. The results confirm the power of the DCISionRT assay to predict RT benefit and enabling personalized treatment decisions," said Dan Forche, President and CEO of PreludeDx. "The consistency of results with prior validations studies substantiates the robustness and reliable performance of DCISionRT. We believe these much-anticipated results will have a significant impact on clinical practice for DCIS patient management."

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. 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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