

## **PreludeDx™ Presents New Data at the 40<sup>th</sup> Annual Miami Breast Cancer Conference Identifying Which Patients with DCIS May Be Undertreated Based on Clinicopathologic Factors Alone**

*Using 10-yr Outcomes Data, DCISionRT Reclassified Nearly 70% of CP Model Low-Risk Patients to Elevated Risk*

LAGUNA HILLS, Calif., March 2, 2023 /PRNewswire/-- Prelude Corporation (PreludeDx™), a leader in molecular diagnostics and precision medicine for early-stage breast cancer, today announced it will be presenting data comparing risk stratification and radiation benefit (RT) for patients with ductal carcinoma in situ (DCIS) using DCISionRT® with a clinicopathologic (CP) model similar to the Memorial Sloan Kettering Cancer Center (MSKCC) DCIS nomogram at the 40<sup>th</sup> Annual Miami Breast Cancer Conference (MBCC), being held on March 2 – 5, 2023 at the Fontainebleau Miami Beach.

The poster entitled, ['Comparing Risk Stratification and Radiotherapy Benefit for Patients with DCIS Using a 7-gene Biosignature as Compared to a Clinicopathologic Nomogram'](#) will be available for viewing during the duration of the conference and available during the in-person poster receptions on March 2<sup>nd</sup> and 3<sup>rd</sup>. The study included 926 DCIS patients from four cohorts who were treated with breast conserving surgery (BCS) or BCS + radiation therapy (RT). The study compared MSKCC DCIS nomogram-like model with the DCISionRT 7-gene biosignature.

DCISionRT re-classified nearly two-thirds of patients in the Low-Risk MSKCC nomogram-like group as Elevated Risk, which had elevated 10-yr IBR rates and an 80% relative benefit from RT.

“It is important for clinicians to follow the clinical evidence to enable the best treatment decisions for their patients,” said Julie Margenthaler, MD, FACS, Siteman Cancer Center, Washington University School of Medicine. “In this study, we demonstrated the ability of DCISionRT to better risk-stratify DCIS patients following BCS and identify patients with low-risk CP who may benefit from RT, avoiding potential undertreatment.”

“Previously we were limited to clinicopathologic criteria, such as nomograms, to guide DCIS treatment decisions,” said Chirag Shah, MD, Co-Director of Comprehensive Breast Program and Director of Clinical Research in the Department of Radiation Oncology, Taussig Cancer Institute, Cleveland Clinic Cleveland OH. “DCISionRT provides us the clinical evidence to identify which DCIS patients, despite having low-risk clinicopathologic features, can actually benefit from RT and which patients may safely omit RT.”

“We are pleased to share our latest data demonstrating the clinical significance of DCISionRT,” says Dan Forche, President and CEO of PreludeDx. “We have been able to consistently demonstrate that the integration of DCISionRT into clinical decision processes has substantial impact on recommendations aimed at optimal patient management to prevent over-or under treatment of DCIS patients.”

#### **Additional MBCC Poster Presentations Include:**

Posters will be available for viewing during the duration of the conference and available during the in-person poster receptions on March 2<sup>nd</sup> and 3<sup>rd</sup>.

*Characterization of Recurrence Risk After Lumpectomy and Radiotherapy in HER2-Positive Ductal Carcinoma In Situ of the Breast Using a 7-gene Predictive Biosignature: Implications for the NSABp-B43 Trial Results*

*A 7-Genes Predictive Biosignature Improves Risk Stratification for Breast Ductal Carcinoma in Situ Patients Compared to Clinicopathologic Criteria, Identifying a Low Risk Group Not Clinically Benefiting from Adjuvant Radiotherapy*

*Changes in Treatment Recommendation for Patients with Ductal Carcinoma In Situ Using a 7-gene Predictive Biosignature: Analysis of the PREDICT Study*

The PREDICT study is a prospective, multi-institutional registry for patients who received DCISionRT testing as part of their routine care. The registry includes females 26 and older who are diagnosed with DCIS and are candidates for BCS and eligible for RT. The analysis demonstrates RT recommendations to add or omit RT based on the 7-gene predictive biosignature in 2,308 patients was changed in 38% of women after testing and hormonal treatment (HT) recommendations was changed in 11%.

#### **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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