Strong Analytical Validation Data Further Supports Use of DCISionRT® to Guide Shared Decision-Making for DCIS Therapeutic Management

DCISionRT Validated to Have ≥ 95% Sensitivity, Specificity and Accuracy/Reproducibility

LAGUNA HILLS, Calif., May 23, 2023 /PRNewswire/-- Prelude Corporation (PreludeDx™), a leader in molecular diagnostics and precision medicine for early-stage breast cancer, today announced that a paper titled *"Analytical Validation of the 7-gene Biosignature for Prediction of Recurrence Risk and Radiation Therapy Benefits for Breast Ductal Carcinoma in Situ"* was published in *Frontiers in Oncology.* The paper presents the results from analytical validation and summarizes the clinical validation for the DCISionRT® test. The analytical validation demonstrated that the DCISionRT assay has high sensitivity, specificity, and accuracy/reproducibility of ≥95%. These findings validate the continued increase in clinical adoption of the DCISionRT test to guide shared decision making for patients with ductal carcinoma in situ (DCIS), often referred to as Stage 0 breast cancer.

"The analytical validation results provide physicians greater confidence when making treatment recommendations based on DCISionRT Decision Scores (DS)," said Chirag Shah, MD, Co-Director of the Comprehensive Breast Program and Director of Clinical Research in the Department of Radiation Oncology, Taussig Cancer Institute, Cleveland Clinic Cleveland, OH. "The robust analytical validation of the DCISionRT test indicates that the test assays are highly accurate, and the test has a high level of reproducibility. This newly published data and validation studies support that the test should be considered as part of shared decision making for DCIS patients who are considering breast conserving surgery and radiation therapy."

DCIS, or Stage 0 breast cancer, represents 20 – 25% of breast cancer diagnoses in the US according to the National Institutes of Health. Current treatment options for DCIS include mastectomy or breast conserving surgery (BCS) with or without radiation therapy (RT). Historically, optimal risk-adjusted treatment selection was a primary challenge due to the inability to differentiate patients who do not benefit significantly from RT after BCS from those who do benefit from RT.

"We purposefully developed and validated DCISionRT to address the unmet need of personalized treatment in DCIS patient management," says Dan Forche, President and CEO of PreludeDx. "DCISionRT is the most published DCIS test and is the *only* DCIS test with peer-reviewed Level 1b clinical validation. Our data demonstrates the DCISionRT low risk group has a 99% negative predictive value for radiation therapy benefit for 10-yr invasive breast cancer

recurrence. In other words, you would need to treat 100 patients to prevent one invasive breast cancer recurrence. This analytical validation demonstrates the consistency and high precision of the DCISionRT assay."

The DCISionRT test has been adopted by top academic cancer centers and community centers through the US and world-wide to help guide personalized treatment for women diagnosed with DCIS. The test has been clinically validated with peer-reviewed publications on independent, randomized, and prospective studies in over 4,000 patients.

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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