DCISionRT® by PreludeDx™ Identifies Subset of RTOG 9804 Low Risk Criteria DCIS Patients Who Experienced 84% Relative Benefit with Radiation

PreludeDx to Present Clinical Outcomes Data at 2020 San Antonio Breast Cancer Symposium

LAGUNA HILLS, Calif., December 8, 2020 /PRNewswire/-- Prelude Corporation (PreludeDx™), a leader in molecular diagnostics and precision medicine for early stage breast cancer, will present clinical outcomes data on the company's commercially available test, DCISionRT® at the 2020 San Antonio Breast Cancer Symposium (SABCS), which is being held virtually December 8 – 11. PreludeDx will present a Spotlight Poster discussing clinical outcomes of DCISionRT, a biologic signature, to assess Ductal Carcinoma In Situ (DCIS) in patients meeting 'low-risk' criteria by RTOG 9804 or ECOG-ACRIN E5194, which are considered the current traditional gold standards for assessing recurrence risk and guiding treatment.

SABCS Spotlight Poster #PD5-04, 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*, will be presented in a Spotlight Poster discussion on December 10 from 2:15 – 3:30 pm CT.

The study included complete biomarker and clinical data for 535 women meeting RTOG 9804 'low risk' clinicopathologic criteria and 660 women meeting ECOG-ACRIN E5194 grade 1 or 2 criteria similarly identified as 'low risk'. The greatest variance occurred when DCISionRT identified patients from four cohorts who met 'low risk' clinicopathologic criteria from traditional methods, yet were re-classified to be in the Decision Score (DS) Elevated Risk group with elevated 10-year risk for invasive breast occurrence after breast conserving surgery (BCS). These particular patients experienced a substantial 84% relative risk reduction benefit of invasive breast cancer from radiation therapy (RT) . In contrast, the biosignature also identified a DS Low Risk group of patients which had minimal (1-2%) risk reduction from RT. In comparison with traditional clinicopathologic features used to guide RT recommendations, the DCISionRT score was dramatically associated with RT therapy benefit.

"The goal of therapy for DCIS is to prevent invasive breast cancer. However, there remains a significant need for prognostic and preventive tools to enable physicians to design individual and appropriate treatment plans for women diagnosed with DCIS," says Dan Forche, President and CEO of PreludeDx. "We are excited to present this data that further validates the utility of

DCISionRT in the clinical-decision making process to enable clinicians and patients to identify optimal treatments while preventing over- or under-treatment."

SABCS Poster #P56-17, will be available December 9, at 8:00 am CT. The poster is entitled *Clinical utility of a biologic signature to assess DCIS recurrence risk in patients with good-risk criteria (RTOG 9804, ECOG E3194): interim analysis of the DCISionRT PREDICT study*. The purpose was to investigate the change in adjuvant RT recommendation by physicians based on DCISionRT. The study included 513 patients from 32 sites in the U.S. with DCISionRT testing completed after treatment with BCS, but prior to RT decision.

This poster represents the second PREDICT study interim analysis to demonstrate a significant net change in radiation therapy recommendation in patients with 'good-risk' clinicopathology based on DCISionRT. Overall DCISionRT demonstrated high clinical utility by impacting RT recommendations in up to 46% of women post-test, thus helping to reduce overtreatment and minimize undertreatment of DCIS.

SABCS Poster #OT-08-01, will be available December 9, at 8:00 am CT. The poster is entitled *The PREDICT registry: A prospective registry to evaluate the effect of a predictive assay on treatment decisions in patients with DCIS following breast conserving therapy*.

This is an ongoing prospective cohort study for patients diagnosed with DCIS of the breast. The primary objective of the study is to create a de-identified database of patients, test results, treatment decisions and outcomes that can be queried to determine the utility of the DCISionRT test in the diagnosis and treatment of DCIS of the breast. The resulting data set will identify the percent of cases in which treatment recommendations are changed after the test results become available.

The PREDICT Study has consented 1,230 women with 586 consented in 2020 to date. There are 56 sites enrolled and an additional 28 sites pending activation. The goal is to activate up to 100 sites and consent 2,500 patients diagnosed with DCIS.

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, accounting for an estimated 18 – 25% of the total number of newly diagnosed breast tumors. Current treatment strategies include BCS with radiotherapy, BCS alone, mastectomy or observation. A recent study demonstrated that 53% of DCIS patients' risk scores were under classified and 34% were overclassified using traditional methods, resulting in overtreatment or undertreatment. 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: www.preludedx.com

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