PreludeDx PREDICT Study Demonstrates High Clinical Utility of DCISionRT for DCIS Breast Cancer Patients

42% change in treatment recommendations when using DCISionRT

LAGUNA HILLS, Calif., April 21, 2021 /PRNewswire/-- Prelude Corporation (PreludeDx™), a leader in molecular diagnostics and precision medicine for early stage breast cancer, announced results for a prospective study in 44 U.S. academic and community cancer centers that evaluated the impact of DCISionRT on clinicians' recommendations to administer or omit adjuvant radiotherapy (RT) in patients with DCIS (ductal carcinoma in situ) following breast conserving surgery (BCS). Data published today in the *Annals of Surgical Oncology* demonstrates that utilization of DCISionRT® led to a change in recommendation for adjuvant RT in 42% of patients with DCIS, also known as stage 0 breast cancer. The peer-reviewed article entitled "The Clinical Utility of DCISionRT on Radiation Therapy Decision Making in Patients with Ductal Carcinoma In Situ following Breast Conserving Surgery" is available online at https://preludedx.com/wp-content/uploads/2021/04/PREDICT-Registry-Publication_Ann-Surg-Oncol.pdf

"In the PREDICT Registry Study, utilization of DCISionRT demonstrated a substantial overall change in the recommendation for RT for DCIS patients undergoing breast conserving surgery," said study investigator Chirag Shah, MD, Department of Radiation Oncology, Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH. "Of particular interest, compared to traditional clinical and pathological features such as tumor grade, tumor size and margin status, the DCISionRT result was viewed as the most impactful factor in making adjuvant RT recommendations following surgery. Surgeons and radiation oncologists now have a biologicially driven tool to make individualized radiation treatment recommendations for DCIS patients. "

The primary endpoint of the study was to identify the percent of all women for whom DCISionRT led to a change in physician treatment recommendations regarding adjuvant RT. The study included 539 patients at 44 study sites. DCISionRT changed recommendations both to add or omit radiation treatment, demonstrating the benefits of precision medicine across all clinical and pathology factors.

"The uncertainty associated with subsequent breast cancer has historically complicated DCIS treatment decisions, leading to the broad utilization of RT following BCS. This collective data will be instrumental in providing more informed treatment decisions to help prevent over and under treatment of our patients," said co-lead investigator Pat Whitworth, MD, Breast, Surgical Oncologist, Director, Nashville Breast Center.

"We are delighted to present this data that clearly demonstrates DCISionRT is differentiating and compelling for doctors to change their treatment recommendations for their DCIS patients following breast surgery," said Dan Forche, President and CEO of PreludeDx. "Women and their physicians contemplating the next treatment steps now can now have greater peace of mind when making a personalized decision to add or omit radiation therapy after breast conserving surgery that includes their individual tumor biology."

The PREDICT study is an observational, ongoing prospective cohort study for patients diagnosed with DCIS of the breast. The primary objective of the study is to determine the utility of the DCISionRT test in 2,500 women diagnosed with DCIS, and then to assess prospective 10 year outcomes.

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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