DCISionRT by PreludeDx Identifies Women with DCIS with Unacceptably High Rates of Local Recurrence after Breast Conserving Surgery and Radiation Therapy

Data presented in breast cancer discussion session at 2021 ASCO

LAGUNA HILLS, CA., June 4, 2021 /PRNewswire/-- Prelude Corporation (PreludeDx™), a leader in molecular diagnostics and precision medicine for early stage breast cancer, presented data at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting. The study demonstrated additional clinical utility of DCISionRT® to identify those ductal carcinoma in situ (DCIS) patients who will remain at elevated recurrence risk even after treatment with breast conserving surgery (BCS) plus radiation therapy (RT).

The ASCO Presentation is entitled 'A Novel Biosignature Identified DCIS Patients with a Poor Biologic Subtype with Unacceptably High Rates of Local Recurrence after Breast Conserving Surgery and Radiotherapy'. The study was comprised of 485 women diagnosed with DCIS from previous DCISionRT validation cohorts in Sweden, Australia and the U.S.

Following BCS, these patients were classified by DCISionRT into three distinct risk groups—Low Risk, Elevated Risk with good Response Subtype (Rst), and Elevated Risk with poor Rst—and ipsilateral breast tumor recurrence (IBTR) and invasive breast cancer (IBC) risks were assessed.

"In this study we examined the utility of DCISionRT and its additional response subtype to stratify DCIS patients following breast conserving surgery who could potentially omit radiation therapy, who would likely benefit significantly from radiation therapy, and who would still remain at a high recurrence rate even after radiation," said Dr. Frank Vicini, Radiation Oncologist at GenesisCare, member of NRG Oncology, and principal investigator of the study. "In the DCISionRT Elevated Risk group, RT was associated with significantly reduced recurrence rates, but only for those patients with a good Response Subtype."

For Elevated Risk group patients with a poor Rst, no benefit to RT was noted. Those with a poor Rst had significant 25%/15% 10-year IBTR/IBC rates, irrespective of RT, which were much higher than rates of 6.6%/4.5% for women with a good Rst who received RT. For patients in the Low Risk group, there was no significant difference in 10-year IBTR/IBC rates with and without RT.

Clinicopathologic risk factors, such as age, grade, and size were ineffective at identifying poor versus good response subtypes, further validating the need for a novel biosignature to guide treatment decisions.

"We are excited about the growing body of research for expanded clinical utility of DCISionRT in identifying patients who have unacceptably high recurrence rates after standard breast conserving surgery and adjuvant RT," said Dan Forche, President and CEO of PreludeDx. "For the

first time, physicians and patients will have personalized data to make more informed treatment decisions, especially for these particular patients who are often the most concerning for physicians."

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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