Fourth Validation of DCISionRT by PreludeDx Predicts Risk of Breast Cancer Recurrence and Radiation Benefit for DCIS Patients after Surgery

Data presented in plenary session at Society of Surgical Oncology 2021

LAGUNA HILLS, CA., March 18, 2021 /PRNewswire/-- Prelude Corporation (PreludeDx™), a leader in molecular diagnostics and precision medicine for early stage breast cancer, presented data at the Society of Surgical Oncology (SSO) 2021 International Conference on Surgical Cancer Care. The study validated the clinical utility of the DCISionRT® biosignature to assess ipsilateral breast event (IBE) risk after breast conserving surgery (BCS) and the benefit of radiation therapy (RT). Women with ductal carcinoma in situ (DCIS) and Elevated Decision Scores™ (DS) had a significantly higher risk of IBE and a greater relative benefit from RT compared to women with lower DS.

The use of adjuvant RT varies widely due to limited risk assessment factors. Current recommendations for adjuvant DCIS treatment are based on clinicopathological factors such as tumor grade, size and patient age.

"Relying solely on clinicopathological factors to guide adjuvant BCS treatment has been proven to be largely ineffective. Precise assessment of adjuvant RT benefit is needed to guide physicians and patients in making more individualized treatment decisions for DCIS," said Dr. Bruce Mann, MBBS, PhD, FRACS, The Royal Melbourne Hospital and Women's Hospital, Victoria, Australia and principal investigator of the study. "This validation in a contemporary cohort, supports previous findings that DCISionRT provides prognostic and predictive information enabling personalized treatment decisions."

The SSO Presentation, entitled *DCIS Biologic Risk Signature Predicts Risk of Recurrence and RT Benefit after BCS,* studied 183 women from Australia with DCIS. After BCS, those with a Low DS had a non-significant 2% difference in outcome with and without RT, while those with Elevated DS had a significant 27% benefit from RT. Consistent with prior validation studies, DCISionRT upstaged 43% of patients to elevated risk who were previously identified as "low risk" by individual clinical pathology factors (Grade 1/2, size ≤25mm). The results also demonstrated that women at DS elevated risk received more than a 70% relative benefit from RT.

"This fourth validation study further confirms that DCISionRT is a powerful tool for clinicians to accurately assess DCIS risk and personalize adjuvant therapy," said Dan Forche, President and CEO of PreludeDx. "The biosignature fills an unmet need in DCIS by enabling patients to confidently make more informed decisions about their care and treatment options."

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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