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Journal of Clinical Cancer Research Publication Demonstrates that DCISionRT® Provides Prognostic and Predictive Power for Assessing a Patient's DCIS Risk

LAGUNA HILLS, CA, August 2, 2018 (PR NEWSWIRE) -- Prelude Corporation (PreludeDx), a leader in molecular diagnostics and personalized medicine for early stage breast cancer, announced today that Clinical Cancer Research published results from a large cross validation study of DCISionRT® in patients with DCIS (ductal carcinoma in situ), also referred to as stage 0 breast cancer. The multi-site study demonstrated that DCISionRT—***The DCIS Test***™—was a strong predictor of radiation benefit and was able to identify patients with significantly elevated recurrence risk that would be considered low risk by traditional clinical assessment. The peer-reviewed publication entitled "A biologic signature for breast ductal carcinoma in situ to predict radiation therapy (RT) benefit and assess recurrence risk" is available online in Clinical Cancer Research.

According to lead Investigator Fredrik Wärnberg, MD, PhD, Associate Professor of Surgery at Uppsala University and member of the Swedish Breast Cancer Group, "The study analyzed the biology and clinical factors of 526 patients using DCISionRT and demonstrated that the biologic signature was excellent at identifying which patients would have a DCIS or invasive breast cancer recurrence within 10 years, but—importantly—also distinguished the patients most likely to have clinically meaningful radiation therapy benefit from those that would not." This is in contrast to previous studies that consistently showed a 50% risk reduction for all patients receiving radiation therapy, whereas the DCISionRT Score identified a group of patients that had nearly twice the risk reduction typically expected (risk reduction of 70% or more).

This data is the first to show a tool that is able to predict radiation therapy benefit for DCIS patients. The DCISionRT Score identified patients with 10-year invasive breast cancer risks from 3% to 40% with surgery alone, or 3% to 10% with surgery and radiation therapy. The study also showed that DCISionRT distinguishes risk independent of clinicopathologic factors, where the test found that 42% of clinicopathologically low-risk patients were in the DCISionRT elevated risk group and had a substantial 10-year total recurrence risk of 31%.

"This study of DCISionRT represents an important step forward in the management of DCIS and brings treatment of this disease fully into the age of personalized medicine," stated Pat Whitworth, MD, Director of Nashville Breast Center and Chief Science Officer of TME Breast Care Network. "Radiation oncologists and breast surgeons have long been searching for a tool to help us identify patients that do or do not benefit from radiation therapy. This study indicates that DCISionRT identifies DCIS patients at low risk for invasive recurrence with no significant reduction in risk from radiation. We can now help the patient decide on treatment with the confidence that the choice is being made based on her individual biology."

Daniel Forche, President and CEO of PreludeDx, stated, "Our breakthrough validation shows that DCISionRT accurately assess a woman's risk of her DCIS recurring and provides a personalized approach to properly assess her own biology. We are at a time where precision medicine can now truly personalize testing to each woman's unique biology and provide information for a better decision and better patient outcome. We believe it is important to have the best information available and for each woman to know her DCIS risk as well as therapeutic benefit."

In an oral presentation at the December 2017 San Antonio Breast Cancer Symposium, Dr. Wärnberg presented predictive data from the landmark SweDCIS trial that demonstrated that the DCISionRT test was able to accurately stratify patients into a low risk group with a non-significant risk reduction of 1% from radiation therapy and an elevated risk group that received a significant 9% absolute benefit from radiation therapy. According to Rakesh Patel, MD, a leading breast cancer radiation oncologist and Medical Director of Breast Cancer Services at Good Samaritan Hospital in Los Gatos, CA, "The validation of DCISionRT in this randomized trial demonstrated the test identified a group of patients that had twice the benefit of radiation compared to all other previous trials; this is big news to radiation oncologists and surgeons worldwide and will impact the way DCIS is managed moving forward."

Why This Matters to Patients
DCISionRT empowers women and their breast cancer doctors with new information, which was not previously available from traditional clinical or pathologic assessments. This new technology assesses a woman's individual biology and predicts the risk of her DCIS coming back. With DCISionRT, patients and their physicians are now equipped with the power of biology to guide treatment decisions. Before making a decision, we hope that each woman and her physician will use DCISionRT to ***Know Her Risk***™.

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. The test was developed by PreludeDx and built on research that began with funding from the National Cancer Institute to better understand the biology of DCIS. DCISionRT assesses a woman's individual tumor biology along with other risk factors to 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 and follow us on Twitter @PreludeDx, Facebook and LinkedIn.

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