PreludeDx Receives FDA Breakthrough Device Designation for DCISionRT® Test for DCIS Breast Cancer Patients

LAGUNA HILLS, Calif., January 16, 2025 /PRNewswire/-- Prelude Corporation (PreludeDx®), a leader in precision diagnostics for early-stage breast cancer, announced today that the U.S. Food and Drug Administration (FDA) granted Breakthrough Device designation for its DCISionRT® test.

DCISionRT provides individualized risk assessment and predicts the benefit of radiation therapy (RT) for women diagnosed with ductal carcinoma in situ (DCIS), also known as Stage 0 breast cancer. DCISionRT represents a significant advancement in DCIS patient care by combining tumor biology with clinicopathologic factors to deliver personalized results. The test analyzes seven protein biomarkers and four clinical factors to generate a Decision Score that helps physicians identify which patients are most likely to benefit from RT and can help reduce over- and under-treatment.

“DCISionRT addresses an unmet need for DCIS patients by answering the questions, ‘Do I need radiation therapy?’, and ‘will I benefit?’. DCISionRT helps patients and their physicians to make a better and more informed treatment decision.” says Dan Forche, President and CEO of PreludeDx.

The test is designed for women aged 30-85 with DCIS and:

- Predicts the benefit of radiation therapy after breast conserving surgery (BCS)
- Is Prognostic for 10-year risk of breast cancer recurrence
- Identifies patients with residual risk even after BCS and radiation therapy

The FDA’s Breakthrough Device designation is reserved for medical devices that provide for more effective treatment or diagnosis, and offer significant advantages over existing approved or cleared alternatives. Breakthrough Devices will receive priority review by the FDA, which can significantly shorten the time it takes to get approval.

Forche continued, “We will continue to work closely with the FDA and we remain committed to providing access to advanced precision diagnostics in breast cancer care that improve patient outcomes through new and innovative tools.”

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. The test provides a DecisionScore™ that identifies a woman's risk as low, elevated, or residual risk. Unlike other risk assessment tools, the DCISionRT test combines protein expression from seven biomarkers and four clinicopathologic factors, and uses a non-linear algorithm to account for multiple interactions between individual factors in order to better interpret complex biological information. 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: https://preludedx.com and follow us on Twitter @PreludeDx, Facebook, Instagram and LinkedIn.

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