

## **DCISionRT<sup>®</sup> by PreludeDx<sup>™</sup> Receives Advanced Diagnostic Laboratory Test (ADLT) Status Approval from the Centers for Medicare & Medicaid Services**

LAGUNA HILLS, Calif., March 28, 2023 /PRNewswire/-- Prelude Corporation (PreludeDx<sup>™</sup>), a leader in molecular diagnostics and precision medicine for early-stage breast cancer, today announced that the Centers for Medicare & Medicaid Services (CMS) has approved Advanced Diagnostic Laboratory Test (ADLT) status effective April 1, 2023, for the DCISionRT<sup>®</sup> test.

“Receiving ADLT status is a major milestone for PreludeDx and confirms the clinical value and unique nature of the DCISionRT test,” says Dan Forche, President and CEO of PreludeDx. “We are committed to working closely with CMS to ensure that patients and physicians have access to our test and the ability to improve patient outcomes and quality of life through more informed, personalized treatment decisions.”

ADLT status is reserved for innovative products with Medicare coverage that provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests, among other criteria. The announcement of the ADLT approval for DCISionRT confirms that the test meets these criteria established by CMS for laboratory tests under the Protecting Access to Medicare Act of 2014 (PAMA). The DCISionRT test is the only test that can predict radiation therapy benefit for women diagnosed with DCIS and this new information improves shared decision making between patients and their treating physicians. PreludeDx is only the eighth company to receive Advanced Diagnostic Laboratory Test distinction.

The DCISionRT test has been adopted by top academic cancer centers and community centers through the US and world-wide to help guide personalized treatment for women diagnosed with DCIS. The test has been clinically validated with peer-reviewed publications on independent, randomized, and prospective studies in over 4,000 patients.

### **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<sup>™</sup> that identifies a woman’s risk as low or elevated. Unlike other risk assessment tools, the DCISionRT test combines protein expression from seven biomarkers and four clinicopathologic

factors, using 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™. 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.

PreludeDx, the PreludeDx logo, DCISionRT, the DCISionRT logo, DecisionTree, Decision Score, The DCIS Test, Know Your Risk and Your Biology, Your Decision are trademarks of Prelude Corporation or its wholly owned subsidiaries in the United States and foreign countries.

#### **Media Contact**

Cory Dunn  
760.705.7464

[cdunn@preludedx.com](mailto:cdunn@preludedx.com)

#### **Investor Contact**

Andrew Wade  
949.600.8925

[awade@preludedx.com](mailto:awade@preludedx.com)