# PreludeDx Receives FDA Breakthrough Device Designation for AidaBREAST® - Early-Stage Invasive Breast Cancer Assay

## AidaBREAST designation marks PreludeDx's second FDA Breakthrough Device, following DCISionRT®

LAGUNA HILLS, CA – April 29, 2026- Prelude Corporation (PreludeDx™), a leader in precision diagnostics for early-stage breast cancer, announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device designation for the AidaBREAST® test.

AidaBREAST provides individualized prognostic risk assessment and predicts the benefit of radiation therapy (RT) for women diagnosed with early-stage invasive breast cancer. The test integrates multi-omic data to generate a patient-specific assessment of 10-year locoregional recurrence risk and benefit from adjuvant radiation therapy, supporting more personalized treatment decisions following breast-conserving surgery.

"AidaBREAST addresses an important need in early-stage invasive breast cancer by providing both recurrence risk assessment and insight into which patients are most likely to benefit from radiation therapy," said Dan Forche, President and CEO of PreludeDx. "With Breakthrough Device designations for both DCISionRT and AidaBREAST, we are continuing to advance precision diagnostics that support more informed treatment decisions for patients and physicians."

**The test is designed for women with early-stage (I,IIa) invasive breast cancer and:**

- **Predicts the benefit of radiation therapy after breast-conserving surgery (BCS)**
- **Is prognostic for 10-year risk of locoregional breast cancer recurrence**
- **Aids in preventing the over- and undertreatment of early-stage disease**

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 receive priority review by the FDA, which can significantly shorten the time it takes to bring new technologies to patients.

Forche continued, "We look forward to working closely with the FDA as we advance AidaBREAST through the regulatory process and remain committed to expanding access to precision diagnostic tools that improve outcomes for patients with early-stage breast cancer."

### About AidaBREAST for Early-Stage Breast Cancer

AidaBREAST is the *only* risk assessment test for patients with stage I,IIa breast cancer that predicts radiation therapy benefit. The next-generation multi-omic assay developed by PreludeDx uses advanced spatial biology technology combining multiplex protein expression with targeted next-generation RNA sequencing to provide a comprehensive assessment of a

patient's tumor biology. Leveraging the power of artificial intelligence, the assay integrates these complex data to generate a patient's individualized risk assessment for 10-year locoregional recurrence and predict their benefit from radiation therapy. This innovative approach enables physicians to move beyond traditional measures offering patients personalized results with new insights into recurrence risk and radiation therapy benefit. This new information helps patients and their physicians to make more informed treatment decisions.

**About PreludeDx**

PreludeDx is a leading personalized breast cancer diagnostics company serving patients and physicians worldwide. Founded in 2009 with technology from the University of California San Francisco, PreludeDx is dedicated to developing precision breast cancer tools that impact treatment decisions. The company's mission is to provide innovative technologies that improve patient outcomes and reduce healthcare costs. Before making a treatment decision, Know Your Risk™, Know Your Benefit. 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 X, LinkedIn, Instagram and Facebook.

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