Interim Analysis of DCISionRT PREDICT Study Shows Impact on DCIS Patients

Laguna Hills, CA—May 8, 2019—Prelude Corporation (PreludeDx), a leader in molecular diagnostics and personalized medicine for early stage breast cancer, presented interim results from its large PREDICT study during a poster presentation (Abstract ID: 581643), titled “Interim Analysis of the DCISionRT PREDICT Study: Clinical Utility of a Biologic Signature Predictive of Radiation Therapy (RT) Benefit in Patients with DCIS”, at the American Society of Breast Surgeons (ASBrS) Annual Meeting in Dallas, TX, on Friday, May 3.

The PREDICT study evaluates the impact of DCISionRT—the only predictive and prognostic DCIS test—on clinical management of patients with ductal carcinoma *in situ* (DCIS) as compared to traditional clinical and pathologic risk factors. The study will enroll up to 2,500 patients at 100 sites to demonstrate the impact DCISionRT has on DCIS treatment. The study includes large health systems and many of the nation’s top cancer centers. Once completed, it will be the largest clinical utility study performed for DCIS patients.

The interim analysis of the PREDICT study, which included approximately 200 DCIS patients, concluded that inclusion of DCISionRT changed 51% of radiation therapy recommendations for patients with DCIS. In the DCISionRT low risk group, 62% of patients had a change in their treatment recommendations; in the DCISionRT elevated risk group, 35% of patients had a change in their treatment recommendations. In all cases, the decision change was statistically significant and the impact did not differ by clinicopathologic group.

According to one of the PREDICT Study’s lead investigators Charles Cox, MD, Professor of Surgery at University of South Florida, “The impact of DCISionRT on management of DCIS is clearly very large and points to the enormous need for a test that is not only prognostic but predicts radiation therapy benefit. These results have widespread implications on personalizing treatment for DCIS patients.”

Daniel Forche, President and CEO of PreludeDx, said, “We are pleased that the decision impact of DCISionRT is consistent with how the test reclassifies patients compared to traditional clinicopathologic methods. The results of the PREDICT study to date demonstrate the importance of integrating DCISionRT into clinical decision-making.” He continued, “DCISionRT is great news for DCIS patients and their physicians. It represents a paradigm shift in DCIS management and the arrival of precision medicine.”

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: https://preludedx.com and follow us on Twitter @PreludeDx, Facebook, Instagram and LinkedIn.

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