PRELUDE DX ™

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PRESIDENT & CEO
DANIEL FORCHE

Delivering Actionable Tools To Manage Early Stage Breast Cancer With The DCIS Test That Enables Personalized Treatment

PRELUDEDX

PreludeDx developed DCISionRT based on technology licensed from the University of California San Francisco and research that began with support from the National Cancer Institute.

DANIEL'S PERSONAL JOURNEY

Daniel Forche, President and CEO of PreludeDx, had early exposure to healthcare that sparked a desire to enter the field and make a positive impact. When Dan was 15 years old, his older brother had a diving accident and became a quadriplegic. He witnessed firsthand the challenges his brother faced and the opportunities to improve the patient experience within the healthcare system.

Dan says, "The fact that so many of my relatives have dealt with various cancers including breast cancer throughout the years motivated me to work in healthcare. I was first exposed to oncology early in my work with Abbott, while selling several tests for specialized markers like PSA, CEA, CA-125, and CA 15-3. When HER2/neu testing became the required test for Herceptin therapy for invasive breast cancer, that's when I really started to pay attention to targeted therapies and companion diagnostics. I am committed to the continual advancement of personalized medicine and precision testing to improve treatment decision-making and patient outcomes for physicians and their patients."

AN INTRODUCTION TO DCISIONRT AND THE UNMET MEDICAL NEED

Ductal carcinoma in situ (DCIS), also known as stage zero breast cancer, is characterized by the presence of abnormal cells inside a milk duct in the breast. According to the American Cancer Society, about 55,000 new cases of DCIS are diagnosed each year. After DCIS diagnosis, a patient's treatment decision is traditionally based on clinicopathologic factors including tumor size, grade, and margin, as well as the patient's age. Breast-conserving surgery (BCS)
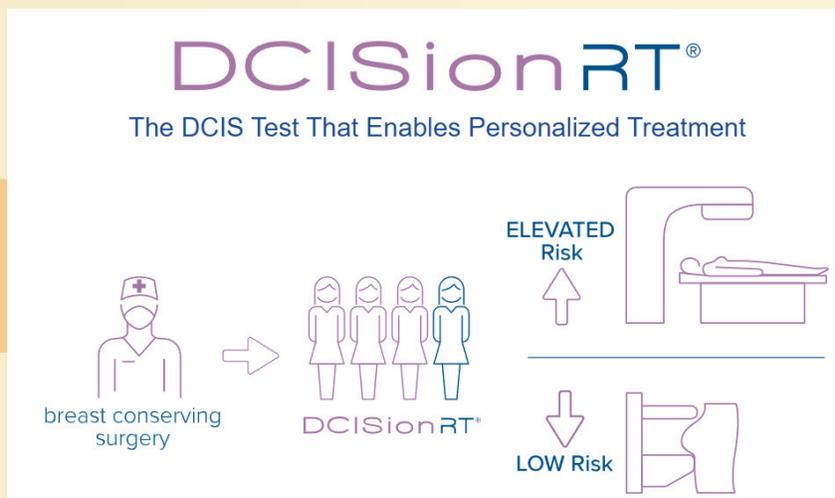
followed by radiation therapy (RT) is the standard treatment for DCIS. However, the majority of patients will not have a subsequent breast cancer recurrence after BCS alone while BCS and RT are standard treatment, many women do not want RT and fear receiving overtreatment with RT due to potential adverse side effects. The challenge lies in identifying the patient's individual risk of recurrence and benefit from radiation therapy, as every patient is different.

Unlike other risk assessment tools, the DCISionRT test provides patients with a personalized risk of recurrence after breast conserving surgery and also predicts if radiation therapy will or will not benefit the patient. Doctors use the test to make more informed treatment decisions and tailor treatment plans to the individual patient.. DCISionRT combines protein expression from seven biomarkers and four clinico-pathologic factors, using a non-linear algorithm to account for multiple interactions between individual factors to better interpret complex biological information, providing the patient and physician with actionable, personalized information.

DCISionRT test results gives patients:

• Their personal Decision Score (scale of 0-10)
• Their risk of recurrence over 10 years with surgery alone
• The benefit of radiation therapy
• Their risk of recurrence over 10 years with surgery plus radiation therapy

The DCISionRT test has impacted thousands of women and has been ordered by over 1,500 clinicians globally. A recent study published in Annals of Surgical Oncology, indicated that DCISionRT modified physicians' treatment recommendation for RT in 42% of DCIS patients. This critical information helps doctors and patients more confidently choose a personalized treatment path and avoid potentially under-over-treatment.

POSITIONING DCISIONRT IN THE CURRENT CLINICAL LANDSCAPE

In prior major clinical studies, pathological and clinical factors, including tumor grade, size, and margin status, failed to identify patients who could safely omit RT after BCS. DCISionRT predicts disease recurrence after surgery or surgery with RT based on a patient's own tumor biology. Quantitative and personalized test results help facilitate individualized treatment decisions. Precision medicine will help answer the "million-dollar question" –
who can safely omit radiation therapy after breast-conserving-surgery?

Precision medicine is booming. One projection by Strategic Market Research LLP, is $66.22 billion in 2021 to $175.6 billion in 2030. In 2020, roughly 40% of market revenue came from oncology.

ADVANCEMENT IN THE INDUSTRY

Our cutting-edge precision medicine test, DCISionRT integrates the most recent developments in molecular biology and was developed with artificial intelligence and machine learning. It is the only risk assessment test for individuals with DCIS that considers the patient's biology to estimate the probability of DCIS returning and forecast how much (if any) radiation therapy (RT) would lower the chance of recurrence.

In addition, DCISionRT is the most extensively published DCIS test and the only test verified by peer-reviewed published Level 1b evidence data.

DCISIONRT SERVICE EXPLANATION

A tissue sample taken after breast-conserving-surgery or from a core biopsy is used for the DCISionRT testing. The pathology report, medical notes, and a completed test-order-form are all sent to the PreludeDx lab by the physician. The PreludeDx customer care representative will then request the tissue sample from the pathology laboratory, making the process convenient for the doctor and patients. After receipt of the tissue specimen at the PreludeDx laboratory, DCISionRT results are typically available within 3-5 days.

HELPING CLIENTS OVERCOME THE CHALLENGES

It has been known that DCIS patients were diverse and needed personalized treatment, but until DCISionRT, there was no method to identify who would and would not benefit from RT after BCS, and who would still have elevated risk of disease recurrence even after BCS and RT.

Physicians want to minimize under and over-treating DCIS patients, but prior to DCISionRT, confidently identifying the risk and treatment decision for each patient was very difficult. Additionally, DCISionRT test results help facilitate collaboration between interdisciplinary medical care teams. Clinicians who use DCISionRT often say they can't imagine practicing without it, as it plays a critical role in shared-decision making with their patients.

NEWLY LAUNCHED

PreludeDx published new data demonstrating that DCISionRT can identify patients with a Residual Risk Subtype (RRt). Patients with this subtype have a high risk of recurrence even after the standard therapy of surgery and radiation. These patients may need closer follow-up and/or further treatment per their doctors' high risk protocol.

For the future, the company is developing a portfolio of precision medicine tests for invasive breast cancer and other cancer types.

CONCLUSION

DCISionRT is truly transforming DCIS directed therapy by providing actionable information to patients and their physicians. The test helps DCIS patients and their care team of surgeons, radiation oncologists, nurses and more, make a personalized and better shared decision regarding treatment which improves patient outcomes and quality of life.