

MEDIA RELEASE

GenesisCare and PreludeDx™ present compelling Australian-first DCISionRT Study Interim Analysis during Breast Cancer Awareness Month**45% change in treatment recommendations when using DCISionRT**

Sydney, Australia/California, United States – October 27, 2022 - GenesisCare, a leading provider of integrated cancer care globally, and Prelude Corporation (PreludeDx™), a leader in molecular diagnostics and precision medicine, today announced interim results from the AUS-PREDICT registry. Data presented at the Australasian International Breast Congress demonstrates a significant (45%) change in radiation therapy treatment recommendations¹ when using the DCISionRT test, optimising management to prevent over and under treatment of Australian women with Ductal Carcinoma In Situ (DCIS).

DCIS is a pre-invasive disease of the breast that may lead to invasive breast cancer if untreated.² After breast conserving surgery (BCS) for DCIS, radiation therapy is often used to minimise the risk of recurrence. DCISionRT® is a novel molecular test that assesses the 10-year risk of recurrence after BCS and if there would be a benefit to treating with radiation therapy. GenesisCare and PreludeDx formed a strategic partnership in 2021 to bring DCISionRT to Australia for the first time and establish the AUS-PREDICT registry to collect real-world data to further the development of precision medicine and decision tools globally.

The presentation, entitled *Interim Analysis of the PREDICT Registry Australia: Changes in Treatment Recommendation for a Biologic Signature Predictive of Radiation Therapy (RT) Benefit in Patients with DCIS*, studied 232 patients from Australia who had received the DCISionRT test following breast-conserving surgery. Radiation therapy recommendation decreased by 70% in patients with a low risk DCISionRT score and increased 29% in patients with elevated risk scores.¹

Leading Specialist Breast Surgeon and Director of Breast Cancer Services for Royal Melbourne and Royal Women's Hospital, Melbourne, Professor Bruce Mann, said: "Historically, we have relied on clinical pathology, such as tumour grade and size, to determine treatment plans for patients with DCIS. This data demonstrates the integration of DCISionRT into clinical decision making has a substantial impact on RT recommendations and has the ability to prevent over and under treatment of DCIS patients."

Principal Investigator and GenesisCare Radiation Oncologist, Dr Yvonne Zissiadis, said the interim results "demonstrate the critical role of DCISionRT in the clinical treatment pathway for DCIS patients, ensuring women receive the right treatment at the right time. Our study highlights that DCISionRT is a promising predictive tool, arming clinicians and patients with the information to make informed decisions about treatment options based on a patient's individual biological risk profile."

"GenesisCare, in partnership with PreludeDx, is thrilled to present the interim findings from our Australian-first study," continued Dr Zissiadis.

"The first interim analysis of AUS-PREDICT is highly consistent with the US-PREDICT registry³ that has completed enrollment of 2,500 patients," said Troy Bremer, PhD, Chief Scientific Officer of PreludeDx.

“In the registry studies in both countries, DCISionRT was the most impactful single factor for changing treatment recommendations regarding radiation therapy following breast conserving surgery,” continued Dr. Bremer.

“We are delighted to bring precision medicine to Australian women diagnosed with DCIS and further enrollment in the AUS-PREDICT registry. We look forward to the continued expansion of our global data network and clinical evidence for DCISionRT,” said Dan Forche, CEO of PreludeDx.

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References

1. Zisiadis et al. Interim Analysis of the PREDICT Registry Australia: Changes in Treatment Recommendation for a Biologic Signature Predictive of Radiation Therapy (RT) Benefit in Patients with DCIS [abstract]. In: Australasian International Breast Congress.; October 13-15 2022; Brisbane, Australia.
2. Breast Cancer Network Australia. *Understanding breast cancer: Ductal Carcinoma In Situ*. viewed 11 October 2022. < <https://www.bcna.org.au/understanding-breast-cancer/what-is-breast-cancer/ductal-carcinoma-in-situ/>>
3. Shah *et al.* The Clinical Utility of DCISionRT[®] on Radiation Therapy Decision Making in Patients with Ductal Carcinoma In Situ Following Breast-Conserving Surgery. *Ann Surg Oncol* **28**, 5974–5984 (2021).

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About GenesisCare

Headquartered in Sydney, Australia, GenesisCare is a global healthcare company and one of the world’s largest integrated oncology organisations. The company’s purpose is to design care experiences that get the best possible life outcomes. This is grounded in the belief that care should be focused on the individual, not the condition.

GenesisCare is the world’s largest provider of radiotherapy – a vital treatment option for cancer patients – and provides patients with access to diagnostics, medical oncology, surgical oncology, radiotherapy, and novel therapies alongside the ability to participate in the latest clinical trials. With a growing research and trials program numbering more than 150 clinical trials, a contract research

organisation, and global innovation programs focused on precision medicine and novel therapies, GenesisCare aims to bring new therapies to more patients in need in a more affordable way.

Every year, GenesisCare clinical teams see more than 400,000 people across 440+ locations, including more than 300 locations in the U.S., 40 in Australia, 14 in the UK, and 17 in Spain. A further 30 new centres are also under development. The organisation employs more than 6,000 highly trained physicians, healthcare professionals and support staff across Australia, Europe, and the U.S. For more information, visit www.genescare.com

About AUS-PREDICT Registry

AUS-PREDICT is a prospective registry study designed to evaluate the effect of the DCISionRT test on treatment decisions in patients with DCIS following breast conserving therapy. The study will enrol 1500 women across Australia onto the registry, who have accessed DCISionRT following surgery.

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 personalised 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.

Disclaimer: As the test has only recently launched in Australia, it is not currently on the Medicare Benefits Scheme or listed on the Therapeutic Goods Association (TGA) in Australia. Instead, the patient's tissue sample is sent offshore to California to a Prelude's CAP/CLIA-approved lab for analysis. The test is frequently used in the USA and many insurers fund the test there.

Globally, the test is validated by Level 1b clinical evidence which is considered to be one of the highest levels of evidence. Health care practitioners can access extensive research and findings [here](#).

About PreludeDx

PreludeDx is a leading personalised 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. PreludeDx, the PreludeDx logo, DCISionRT, the DCISionRT logo, Decision Score, The DCIS Test, Know

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