

November 21, 2022



RaDaR(R) Assay Demonstrates Clinical Potential for Detecting Disease Recurrence Across All Types of Early Breast Cancer, Including Triple Negative Disease

Data presented at this year's San Antonio Breast Cancer Symposium builds on strong base of evidence supporting promise of RaDaR in helping prevent recurrence and improving outcomes

FT. MYERS, FL / ACCESSWIRE / November 21, 2022 / NeoGenomics, Inc. (NASDAQ:NEO), a leading provider of oncology testing and global contract research services, and its liquid biopsy-focused subsidiary, Inivata Limited ("Inivata") today announced that new data, being presented at the 45th Annual San Antonio Breast Cancer Symposium (SABCS) taking place on December 6-10, support the use of the RaDaR® [Assay](#) across all types of early breast cancer in both the adjuvant and surveillance settings.

RaDaR is a personalized, highly-sensitive sequencing test for the detection of minimal residual disease (MRD) and recurrence. MRD is the trace amounts of circulating tumor DNA (ctDNA) that remain after surgery or other cancer treatment.

"The data being presented at SABCS adds to the growing body of evidence demonstrating the accuracy of RaDaR in detecting minimal residual disease and early disease relapse," said Vishal Sikri, MBA, President and Chief Commercial Officer, Inivata, and President, Pharma Services, NeoGenomics. "We believe RaDaR offers great promise in breast cancer care as the detection of MRD and recurrence provides critical insights that can significantly impact patient care."

One study being presented is the c-TRAK TN trial, which compared the use of RaDaR to digital PCR (dPCR) in the surveillance setting in 161 patients with early-stage triple negative breast cancer (TNBC). Among ctDNA-positive patients, more than half (55.2%) were first detected by RaDaR versus 5.2% by dPCR. The use of RaDaR also was associated with a longer time between ctDNA detection and relapse (median lead time of 7.1 months with RaDaR vs 5.7 months with dPCR).

The c-TRAK TN study was selected as a spotlight poster presentation (Poster #PD5-03) and is being presented on December 7. Data presented in poster will be updated with analysis of additional patients from the study cohort.

The second study includes preliminary data from a long-term prospective cohort study called TRACER, investigating the use of RaDaR in patients with early breast cancer across multiple subtypes. Samples were measured at baseline, during neoadjuvant chemotherapy, during surgery, and during post-surgical follow up.

Among the first 43 of 145 patients enrolled, RaDaR was highly sensitive, detecting ctDNA in 88% (38/43) of patients prior to them receiving neoadjuvant therapy and allowing for monitoring ctDNA dynamics during treatment and surgical periods as well as identifying patients with persistent ctDNA after receiving curative-intent therapy. During neoadjuvant therapy, the majority of patients experienced a rapid decline in ctDNA levels from baseline to cycles 4 or 5. In the surgical period, 94% (17/18) of patients with available specimens prior to surgery and 96% (27/28) with available samples post-surgery demonstrated ctDNA clearance.

"The TRACER study is a long-term prospective study that has provided key insights into the potential of MRD detection by ctDNA for early-stage breast cancer" said David Cescon, MD, PhD, medical oncologist and clinical scientist in the division of Medical Oncology & Hematology, Department of Medicine, Princess Margaret Cancer Centre and University of Toronto. "Our research shows that the RaDaR Assay is able to help follow therapy response in the neoadjuvant setting as well as identify patients at high risk of recurrence. Together with other recent data from the CHiRP study, these will create opportunities to use RaDaR in interventional trials and develop new strategies to improve patient outcomes."

The TRACER study (poster #P6-01-16) will be presented on December 9 and will include data from additional patients in the cohort.

About RaDaR®

Inivata's RaDaR® assay is a personalized, tumor-informed, highly sensitive technology that tracks a set of up to 48 tumor-specific variants in cell-free DNA (cfDNA) within a cancer patient's blood plasma. Built on Inivata's proven InVision™ platform, the personalized RaDaR assay has been designed to detect MRD following curative intent or definitive treatment, and early signs of relapse, and has been validated for clinical use in lung, head and neck, and breast cancers. The RaDaR assay is a laboratory developed test (LDT) which has been granted Breakthrough Device Designation by the US FDA for use in the detection of MRD in early-stage cancer patients and has received the CE mark for the detection of MRD and recurrence.

NeoGenomics recently announced that it is prioritizing commercial and reimbursement efforts for RaDaR in breast cancer, with an accelerated commercial launch targeted for Q1 2023.

About NeoGenomics, Inc.

[NeoGenomics, Inc.](#) specializes in cancer genetics testing and information services, providing one of the most comprehensive oncology-focused testing menus in the world for physicians to help them diagnose and treat cancer. The Company's Pharma Services Division serves pharmaceutical clients in clinical trials and drug development.

NeoGenomics is committed to connecting patients with life altering therapies and trials. We

believe that, together, with our partners, we can help patients with cancer today and the next person diagnosed tomorrow. In carrying out these commitments, NeoGenomics adheres to all relevant data protection laws, provides transparency and choice to patients regarding the handling and use of their data through our [Notice of Privacy Practices](#), and has invested in leading technologies to ensure the data we maintain is secured at all times.

Headquartered in Fort Myers, FL, NeoGenomics operates CAP accredited and CLIA certified laboratories in Fort Myers and Tampa, Florida; Aliso Viejo and San Diego, California; Research Triangle Park, North Carolina; Houston, Texas; Atlanta, Georgia; Nashville, Tennessee; and CAP accredited laboratories in Rolle, Switzerland; and Singapore and China. NeoGenomics serves the needs of pathologists, oncologists, academic centers, hospital systems, pharmaceutical firms, integrated service delivery networks, and managed care organizations throughout the United States, and pharmaceutical firms in Europe and Asia.

About Inivata

[Inivata](#) is the liquid biopsy focused subsidiary of the NeoGenomics, Inc. (NASDAQ: NEO) Group. Inivata's proven InVision[®] liquid biopsy platform unlocks essential genomic information from a simple blood draw which may be used by clinicians to guide personalized cancer treatment, to monitor response to treatment and to detect relapse. The commercially available InVisionFirst[®]-Lung test offers highly sensitive testing and provides molecular insights that enable clinicians to make more informed treatment decisions for advanced NSCLC patients. Inivata's personalized RaDaR[™] assay allows the highly sensitive detection of residual disease and recurrence in certain cancers and has been granted Breakthrough Device Designation by the US FDA. Inivata is partnering with pharmaceutical, biotechnology companies and commercial entities in early through late-stage cancer development programs across a range of cancer types. The InVisionFirst[®]-Lung test and RaDaR are laboratory developed tests (LDTs) performed by Inivata's CLIA certified, CAP accredited laboratory in Research Triangle Park, North Carolina, USA. Inivata also has R&D laboratories in Cambridge, UK. Inivata's technology is based on pioneering research from the Cancer Research UK Cambridge Institute, University of Cambridge.

Forward Looking Statements

This press release includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "plan," "could," "would," "may," "will," "believe," "estimate," "forecast," "goal," "project," "guidance," "plan," "potential" and other words of similar meaning, although not all forward-looking statements include these words. These forward-looking statements address various matters, including statements regarding improving operational efficiency, returning to profitable growth and its ongoing executive recruitment process. Each forward-looking statement contained in this press release is subject to a number of risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the Company's ability to identify and implement appropriate financial and operational initiatives to improve performance, to identify and recruit executive candidates, to continue gaining new customers, respond to the effects of the COVID-19 outbreak, offer new types of tests, integrate its acquisitions and otherwise implement its business plan, and the risks identified under the heading "Risk

Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on February 25, 2022 as well as other information previously filed with the SEC.

We caution investors not to place undue reliance on the forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document (unless another date is indicated), and we undertake no obligation to update or revise any of these statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

For further information, please contact:

NeoGenomics, Inc.

William B. Bonello

Chief Financial Officer

T: 239.768.0600 x2426

bill.bonello@neogenomics.com

SOURCE: NeoGenomics, Inc.

View source version on accesswire.com:

<https://www.accesswire.com/727480/RaDaRR-Assay-Demonstrates-Clinical-Potential-for-Detecting-Disease-Recurrence-Across-All-Types-of-Early-Breast-Cancer-Including-Triple-Negative-Disease>