

June 21, 2022



NeoGenomics Liquid Biopsy Subsidiary Inivata Announces New Data Demonstrating Clinical Potential of the RaDaR(TM) MRD Test in HR+ HER2- Breast Cancer

FT. MYERS, FL / ACCESSWIRE / June 21, 2022 / NeoGenomics, Inc. (NASDAQ:NEO), a leading provider of cancer-focused genetic testing services and global oncology contract research services, today confirms that its liquid biopsy focused subsidiary Inivata Limited ("Inivata") has announced new data in support of its RaDaR™ assay for the detection of minimal residual disease (MRD) and recurrence in patients with high-risk hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer.

The data, from the CHiRP study (Circulating tumor DNA (ctDNA) and late recurrence in high-risk, hormone receptor-positive, HER2-negative breast cancer), has been published in the [*Journal of Clinical Oncology*](#) and was presented in part at the 2022 ASCO® Annual Meeting which took place 3-7 June 2022 in Chicago, IL.

In collaboration with the Dana-Farber Cancer Institute, the AstraZeneca supported study used Inivata's RaDaR personalized MRD assay to examine ctDNA and its association with metastatic recurrence in patients with high-risk, early-stage HR+ HER2- breast cancer at least five years after diagnosis - when over half of metastatic recurrences are known to occur.

The RaDaR assay used patient-specific primer panels to analyze ctDNA in blood samples of the 83-patient cohort. Samples were collected every 6-12 months, starting at a median time of 8.4 years (range, 4.9 - 20 years) after initial diagnosis, and followed for clinical tumor recurrence. Median follow-up time was 2 years from the first blood sample.

Ten percent of the patients had positive MRD results during the study. In all 6 cases of distant metastasis in the cohort, ctDNA was previously identified using the RaDaR assay with a median lead time of one year. None of the patients with positive MRD testing - which included an additional two patients who have not yet experienced recurrence - had known metastatic recurrence at the time of first plasma sample.

The data highlight the potential of the RaDaR assay to provide an early predictor of tumor recurrence which, in turn, may allow for earlier intervention, and demonstrates that tumor-informed ctDNA assays can be used successfully several years after diagnosis and treatment of the original tumor.

David Eberhard MD PhD, Chief Medical Officer at Inivata, commented: *"To our knowledge, this is the first data to be released on plasma ctDNA analysis for MRD detection in late adjuvant HR+ breast cancer patients, building on our existing evidence base in breast cancer as well as other indications. These results support the potential benefits of the clinical utility of the RaDaR assay in improving patient outcomes. The data will be useful in informing the future study of liquid biopsy to personalize treatment and prevent, or delay, late recurrence of early-stage breast cancer."*

Marla Lipsyc-Sharf, MD, Clinical Oncology Fellow at the Dana-Farber Cancer Institute, said: *"The results of the CHiRP study mark an important step in helping us understand the baseline prevalence and role of ctDNA in the late adjuvant setting of HR+ breast cancer. The data demonstrate how important targeting multiple variants using an individualized assay, such as the RaDaR assay, can be in identifying MRD-positive patients. It is exciting to see this data highlighting the promise of this method and I am hopeful that, with further studies, earlier detection of disease may enable earlier intervention and more positive outcomes for patients at greater risk."*

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, Carlsbad, California; Research Triangle Park, North Carolina; Houston, Texas; Atlanta, Georgia; Nashville, Tennessee; and CAP accredited laboratories in Rolle, Switzerland; 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 NeoGenomics Laboratories (NASDAQ: NEO). 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.

About the RaDaR™ assay

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.

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.

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SOURCE: NeoGenomics, Inc.

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