

# NeoGenomics Liquid Biopsy Subsidiary Inivata and Collaborators Publish Positive Results from Prospective Clinical Study of RaDaR(TM) in Head and Neck Squamous Cell Carcinoma

RaDaR demonstrated 100% specificity in patients with no recurrence and 100% sensitivity in patients with clinical recurrence

FT MYERS, FL / ACCESSWIRE / February 11, 2022 / NeoGenomics, Inc. (NASDAQ:NEO), a leading provider of cancer-focused genetic testing services and global oncology contract research services, today announced that its liquid biopsy focused subsidiary Inivata Limited ("Inivata") has announced clinical validation data for its RaDaR<sup>TM</sup> liquid biopsy test in head and neck squamous cell carcinoma (HNSCC). The data from the Liquid BIOpsy for MiNimal RESidual DiSease Detection in Head and Neck Squamous Cell Carcinoma (LIONESS) study have been published in the British Journal of Cancer and can be viewed <a href="here.">here.</a>. The study was in collaboration with the Department of Otorhinolaryngology, Head and Neck Surgery (ORL-HNS), LMU Klinikum, and Institute of Pathology, Faculty of Medicine, LMU Munich.

In the LIONESS study, blood samples taken from 17 patients with stage III-IVB, p16-negative HNSCC who received curative-intent primary surgical treatment were tested using RaDaR to detect circulating tumor DNA (ctDNA) as evidence of minimal residual disease (MRD) and recurrence pre- and post-surgery. All patients had detectable ctDNA prior to surgery (100% clinical detection). In longitudinal monitoring after surgery, ctDNA was detected in five patients at levels as low as 0.0006% VAF (6 parts per million), consistent with previous studies utilizing RaDaR in breast and lung cancer.

Importantly, ctDNA was detected prior to progression in all five patients with clinical recurrence to date (clinical sensitivity of 100%), with lead times ahead of clinical confirmation ranging from 108 to 253 days. In the remaining 12 patients there was no recurrence detected, indicating a 100% clinical specificity of the RaDaR assay and confirming post-operative tumor clearance.

**David Eberhard MD, PhD, Chief Medical Officer, Inivata said:** "These data further highlight the clinical utility of our RaDaR assay in the detection of minimal residual disease across tumor types. The assay showed exceptionally high sensitivity, detecting ctDNA in every HNSCC patient who went on to recur, which along with its specificity demonstrates the potential of RaDaR to identify HNSCC patients at an increased risk of relapse, enabling

earlier intervention and personalized therapy planning."

**Professor Philipp Baumeister, ORL-HNS, LMU commented:** "The exciting data from this study highlight the potential of ctDNA as a reliable biomarker to facilitate monitoring and treatment of disease in HNSCC patients. Importantly, this method may spare our patients many unnecessary invasive examinations and imaging studies, and can guide our treatment recommendations in terms of de-escalation or intensification if needed."

#### **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 and San Diego, California; Research Triangle Park, North Carolina; Houston, Texas; Atlanta, Georgia; Nashville, Tennessee; and CAP accredited laboratories in Cambridge, United Kingdom; Rolle, Switzerland; and Singapore. 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 InVision® liquid biopsy platform unlocks essential genomic information from a simple blood draw to guide and personalize cancer treatment, monitor response and detect relapse. Inivata's technology is based on pioneering research from the Cancer Research UK Cambridge Institute, University of Cambridge. The personalized RaDaR™ assay allows the highly sensitive detection of residual disease and recurrence and has been granted Breakthrough Device Designation by the US FDA. The commercially available InVisionFirst®-Lung test offers best-in-class sensitivity and turnaround and provides molecular insights that enable clinicians to make more informed treatment decisions for advanced NSCLC patients. Inivata is partnering with pharmaceutical, biotechnology companies and commercial partners in a range of early and late-stage cancer development programs across a range of cancer types. Inivata has a CLIA certified, CAP accredited laboratory in Research Triangle Park, NC and R&D laboratories in Cambridge, UK.

# About RaDaR<sup>TM</sup>

RaDaR is Inivata's assay for the detection of molecular residual disease (MRD) and recurrence. Built on Inivata's proven InVision® liquid biopsy platform technology, RaDaR is a

highly sensitive personalized assay that tracks a set of up to 48 tumor-specific variants in a patient using a liquid biopsy, allowing both detection of residual disease following curative intent or definitive treatment, and early detection of relapse. RaDaR has been granted Breakthrough Device Designation by the US FDA.

## Forward Looking Statements

Certain information contained in this press release constitutes forward-looking statements for purposes of the safe harbor provisions of The Private Securities Litigation Reform Act of 1995. 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," "plan," "potential" and other words of similar meaning. These forward looking statements involve a number of risks and uncertainties that could cause actual future results to differ materially from those anticipated in the forward-looking statements as the result of the Company's ability to commercialize RaDaR successfully and obtain appropriate reimbursement thereof, 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, as well as additional factors discussed under the heading "Risk Factors" and elsewhere in the Company's Annual Report on Form 10-K filed with the SEC on February 25, 2021, as such information has been updated in subsequent SEC filings. As a result, this press release should be read in conjunction with the Company's periodic filings with the SEC. NeoGenomics routinely posts information that may be important to investors in the "Investor Relations" section of its website atwww.neogenomics.com. The Company encourages investors and potential investors to consult the NeoGenomics website regularly for important information about NeoGenomics.

Forward-looking statements speak only as of the date such statements are made (unless another date is indicated) and should not be relied upon as of any subsequent date. While the Company may elect to update forward-looking statements at some point in the future, it specifically disclaims any obligation to do so.

### For further information, please contact:

# NeoGenomics, Inc.

Doug Brown
Chief Strategy and Corporate Development Officer
T: 239.768.0600 x2539
M: 704.236.2064
doug.brown@neogenomics.com

Charlie Eidson
Director, Investor Relations and Corporate Development
T: 239.768.0600 x2726
M: 952.221.8816
<a href="mailto:charlie.eidson@neogenomics.com">charlie.eidson@neogenomics.com</a>

Karen Chandler-Smith
SVP Marketing and Communications
Inivata

+44 (0)7900 430235 karen.chandler-smith@inivata.com

#### **Inivata Media Contacts:**

Consilium Strategic Communications Chris Gardner/Angela Gray/Genevieve Wilson Alix Floyd (US) inivata@consilium-comms.com +44 (0)20 3709 5700

**SOURCE:** NeoGenomics, Inc.

View source version on accesswire.com:

https://www.accesswire.com/688258/NeoGenomics-Liquid-Biopsy-Subsidiary-Inivata-and-Collaborators-Publish-Positive-Results-from-Prospective-Clinical-Study-of-RaDaRTM-in-Head-and-Neck-Squamous-Cell-Carcinoma