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NeoGenomics' Liquid Biopsy Subsidiary Inivata Announces Clinical Collaboration With Princess Margaret Cancer Center for the Use of Its Liquid Biopsy Assays

Two clinical studies including interventional RaDaR™ study

FT. MYERS, FL / ACCESSWIRE / October 19, 2021 / 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 entered into a clinical collaboration with the Princess Margaret Cancer Center in Toronto, Canada, for the use of Inivata's liquid biopsy assays, InVisionFirst®-Lung and RaDaR™ in two separate studies.

The Accelerating Lung Cancer Diagnosis through Liquid Biopsy, ACCELERATE, study plans to compare time to treatment initiation in advanced non-small cell lung cancer (NSCLC) patients who have had a liquid biopsy, versus those patients referred in the previous 12 months who were treated based on tissue profiling. This prospective, single-arm study will use Inivata's InVisionFirst-Lung, a ctDNA next-generation sequencing (NGS) liquid biopsy, testing 37 genes relevant to the care of patients with advanced NSCLC and will assess the utility of blood-based NGS to accelerate time to treatment in patients awaiting their diagnostic tissue biopsy and molecular profiling. Patient recruitment has already started, with the aim to enroll a total of 150 patients with advanced NSCLC over the next 12 months.

The second study, ctDNA Lung, will use Inivata's RaDaR assay for ctDNA detection of minimal residual disease (MRD) to identify patients for curative therapy after lung cancer resection and will be split into two phases. The first phase, DETECT, will screen 360 early-stage lung cancer patients to assess the rate of pre- and post-operative ctDNA levels using RaDaR. Of the 360 patients, 66 participants with ctDNA detected at 3-6 weeks post-operatively will be referred to the second phase for a randomized controlled trial, RCT, investigating the benefit of intensified adjuvant treatment with chemo-immunotherapy.

Clive Morris, President of Inivata, said: *"Inivata is committed to building a robust body of evidence to support the use of its innovative liquid biopsy technologies and we are delighted to be collaborating with the Princess Margaret Cancer Center, which is one of the largest and most prestigious cancer centers in the world. The ctDNA lung trial is another important step in demonstrating the potential of our exceptionally sensitive RaDaR assay in the early detection of residual disease and informing treatment decisions which lead to better outcomes for patients."*

Dr. Natasha Leighl, Lung Site Lead, Medical Oncology, Princess Margaret Cancer Center, said: *"Liquid biopsy technologies have the potential to transform cancer treatment, getting patients to the right treatment faster and increasing the chances of a cure. We look forward to working with Inivata on these important studies."*

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; Houston, Texas; Atlanta, Georgia; Nashville, Tennessee; and CAP accredited laboratories in 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™

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 address various matters including management's expectations regarding Inivata's collaboration with the Princess Margaret Cancer Center and the enrollment, design and timing of the ACCELERATE and ctDNA Lung clinical studies. 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 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 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 at www.neogenomics.com . The Company encourages investors and potential investors to consult the NeoGenomics website regularly for important information about NeoGenomics.

Forward-looking statements represent the Company's estimates only as of the date such statements are made (unless another date is indicated) and should not be relied upon as representing the Company's estimates 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, even if its estimates change.

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
charlie.eidson@neogenomics.com

Karen Chandler-Smith
SVP Marketing and Communications
Inivata
karen.chandler-smith@inivata.com
+44 (0)7900 430235

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

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