January 11, 2022

NeoGenomics Announces RaDaR(TM) Assay Receives CE Mark and is Submitted for US Reimbursement via the MolDX Program

FT. MYERS, FL / ACCESSWIRE / January 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 received the CE mark for its RaDaR™ assay for the detection of molecular residual disease (MRD) and recurrence, having met the requirements of the European In-Vitro Diagnostics Directive (98/79/EC). In addition, Inivata has submitted to the MolDX program in the US for the reimbursement of RaDaR for clinical testing.

The achievement of both milestones supports the commercialization of RaDaR in a clinical setting, both in collaboration with biopharma partners and other collaborators, as well as Inivata's own clinical development program. Medical devices require the CE mark for use in clinical applications in several key territories including the UK and the EU, and receipt of the designation therefore supports increasing clinical use of the assay.

RaDaR is an innovative, personalized liquid biopsy assay that tracks a set of up to 48 tumor specific variants in a patient using a simple blood draw, allowing both the detection of residual disease following curative intent or definitive treatment, and early detection of relapse. RaDaR has demonstrated exceptionally high sensitivity and specificity in detecting circulating cancer DNA. Analytical validation data for Clinical Laboratory Improvement Amendments (CLIA) certification in December 2020 demonstrated 95% sensitivity and 100% specificity at circulating tumor DNA concentration levels as low as 0.0011% variant allele frequency or 11 parts per million.

Clive Morris, President of Inivata, said: *"Receiving CE marking for RaDaR is a testament to the quality of our technology and the robustness of our processes. The certification should strengthen both our ability to support clinical trials in Europe and the future commercialization of the MRD assay. In the US, submitting to the MolDX program for the reimbursement of RaDaR represents our continuing efforts to accelerate access to our vital technology."*

Mark Mallon, CEO of NeoGenomics Laboratories, said: *"The achievement of these key milestones reflects the exciting work that is ongoing at Inivata and the quality of its science, as well as instilling further confidence in the RaDaR technology to provide meaningful molecular information to help guide clinical decisions and make clinical trials more efficient. We look forward to seeing continued regulatory progress with RaDaR, supporting its future*

success in a commercial setting."

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™

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 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 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.

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SOURCE: NeoGenomics, Inc.

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