

# NeoGenomics Provides Update on MoIDX Submission for CRC and RaDaR(TM) Commercial Launch

### FORT MYERS, FL / ACCESSWIRE / October 28, 2022 / NeoGenomics, Inc.

(NASDAQ:NEO) (the "Company"), a leading provider of cancer-focused genetics testing services and global oncology contract research services, is providing an update on its discussions with MoIDX and on its commercial launch activities for **RaDaR<sup>TM</sup>**, its proprietary assay for the detection of minimal residual disease (MRD) and recurrence.

Late last week, MoIDX informed the Company that additional clinical evidence is needed in order to secure Medicare coverage for **RaDaR<sup>TM</sup>** for Colorectal Cancer (CRC). Specifically, MoIDX asked for a direct comparison with other MRD tests being utilized or a full clinical study.

Therefore, due to the strength of published clinical data, the Company will prioritize commercial and reimbursement efforts in breast cancer, with an accelerated commercial launch of **RaDaR**<sup>TM</sup> for breast cancer targeted for Q1, 2023. Clinical data supporting the use of **RaDaR**<sup>TM</sup> in early stage breast cancer have been presented in both published papers and through presentations at professional meetings<sup>1,2,3,4,5</sup>. In addition, NeoGenomics will launch **RaDaR**<sup>TM</sup> for CRC in the first quarter, while also expanding clinical research studies to support reimbursement from Medicare and other payors.

Our precision medicine team is fully trained on **RaDaR<sup>TM</sup>** and excited to get this technology in the hands of oncologists and surgeons in the US for both breast cancer and CRC applications. Moreover, the Company continues to see strong demand from Pharmaceutical companies for **RaDaR<sup>TM</sup>** across all cancer types and will increase the **RaDaR<sup>TM</sup>** capacity in the US and UK to meet this need.

"We believe that **RaDaR<sup>TM</sup>** is a powerful tool for detection of minimal residual disease and cancer recurrence and look forward to promoting the assay through a controlled launch for both breast and colorectal cancer early next year," said Chris Smith, Chief Executive Officer. "We are confident that we can generate the additional clinical evidence necessary to secure Medicare and commercial payor reimbursement."

#### References:

- 1. Janni W, et al. San Antonio Breast Cancer Symposium 2021
- 2. Janni W, et al. European Society of Medical Oncology Annual Conference 2021
- 3. Cutts R, et al. American Association for Cancer Research Annual Conference 2021

- 4. Lipsyc-Sharf M, et al. J of Clin Oncol. 2022
- 5. Lynce F et al. San Antonio Breast Cancer Symposium 2021

#### 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 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. Inivata's proven InVision<sup>™</sup> 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<sup>™</sup>-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<sup>™</sup> 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<sup>TM</sup> assay

Inivata's RaDaR<sup>™</sup> 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<sup>™</sup> 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.

# For further information, please contact:

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