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RaDaR® Assay Demonstrates Clinical Potential for Helping Oncologists Determine Whether or Not Muscle-Invasive Bladder Cancer Patients Undergo Radical Surgery

Newly-published data shows a strong link between tumor DNA circulating in blood and patient responses to investigational neoadjuvant treatment with immune therapies

FT. MYERS, FL / ACCESSWIRE / February 6, 2023 / NeoGenomics, Inc. (NASDAQ:NEO), a leading provider of oncology testing and global contract research services, today announced results of a new study of the RaDaR® assay in patients with muscle-invasive bladder cancer immediately following treatment with a combination of the immune checkpoint inhibitors in the neoadjuvant setting. Plasma and urine collected from the patients during treatment was analyzed.

The RaDaR assay is a personalized, highly-sensitive sequencing test for the detection of minimal residual disease (MRD) and recurrence. MRD is the trace amounts of circulating tumor DNA (ctDNA) that remain after surgery or other cancer treatment. The study, published in the journal *Nature Medicine*, found that the absence of ctDNA in plasma - as detected by RaDaR - was associated with patient responses to treatment prior to surgery offering the possibility of avoiding aggressive surgery that removes the patient's bladder (also known as a cystectomy).

"Most patients with muscle-invasive urothelial cancer are at a high risk for recurrence and most will undergo cystectomy that results in the removal of the bladder," said Vishal Sikri, President, Advanced Diagnostics, NeoGenomics. "If possible, preserving a patient's bladder is clearly an important outcome if new approaches to neoadjuvant treatments are successful. By determining if a patient has responded well to neoadjuvant treatment, RaDaR provides necessary insights to help oncologists decide whether a patient may be a candidate for bladder-sparing treatment strategies."

The new data are part of the second cohort of the Phase 1b/2a NABUCCO (**N**eo-**A**djuvant **B**ladder **U**rothelial **C**arcinoma **CO**mbination-immunotherapy) trial, which investigated patient responses to neoadjuvant treatment with a CTLA-4 inhibitor (ipilimumab) in combination with a PDL1 inhibitor (nivolumab) among patients with locoregionally-advanced urothelial cancer. In both cohorts, RaDaR assay was used before and during neoadjuvant therapy as well as pre-surgery to assessed ctDNA in urine and blood plasma to determine patient response to

treatment.

Cohort 1 (n=24) helped establish the feasibility of neoadjuvant therapy with ipilimumab 3 mg/kg plus nivolumab 1 mg/kg, demonstrating high pCR rates (a secondary endpoint). In Cohort 2 (n=30), patients received either ipilimumab 3 mg/kg plus nivolumab 1 mg/kg (cohort 2A) or ipilimumab 1 mg/kg plus nivolumab 3 mg/kg (cohort 2B), both for two cycles, followed by nivolumab 3 mg/kg.

Overall, 43 percent (6 patients) in cohort 2A and 7 percent (1 patient) in cohort 2B achieved a complete pathological response (pCR), the primary endpoint. The absence of ctDNA in blood plasma was highly associated with both pCR (odds ratio (OR): 45.0, 95% CI: 4.86-416.46) and PFS (hazard ratio (HR): 10.4, 95% CI: 2.86-37.50). In urine, the absence of ctDNA was linked to pCR but not PFS.

"Although cisplatin-based chemotherapy plus radical cystectomy remains the currently recommended treatment for muscle-invasive bladder cancer, there are some patients who are not eligible to receive chemotherapy and the prognosis for this patient population is poor," said Shashikant Kulkarni, Chief Scientific Officer, NeoGenomics. "The findings from the NABUCCO trial offer initial evidence in hopefully improving the outlook for these patients. Importantly, the research shows that the RaDaR assay can be used successfully to guide decision-making and help oncologists personalize patient care based on their risk of recurrence."

About RaDaR®

The 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 the 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 breast, colorectal, head and neck, as well as lung 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. RaDaR is also available for pharmaceutical, biotechnology companies and commercial entities in early through late-stage cancer development programs across a range of cancer types.

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.

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 San Diego, California; Research Triangle Park, North Carolina; Houston, Texas; Atlanta, Georgia; Nashville, Tennessee; and CAP accredited laboratories in Cambridge, UK, Rolle, Switzerland, 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.

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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