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NeoGenomics and German Breast Group Announce New Data Demonstrating Clinical Potential of the RaDaR MRD Assay in HR+/HER2- Breast Cancer

FT. MYERS, FL / ACCESSWIRE / June 5, 2023 / NeoGenomics, Inc. (NASDAQ:NEO), a leading provider of oncology testing and global contract research services, today announced new data in support of its RaDaR® assay for the detection of molecular residual disease (MRD) and recurrence in patients with high-risk hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer.

Data from a retrospective analysis of the Phase 3 PENELOPE-B study was presented in part at the 2023 ASCO® Annual Meeting on Friday, June 2nd in Chicago, IL.

In collaboration with the trial sponsor, German Breast Group (GBG), the study used NeoGenomics' RaDaR personalized MRD assay to assess the potential of circulating tumor DNA (ctDNA) analysis to predict future clinical relapse of patients enrolled in the PENELOPE-B trial.

"We are delighted that the development of liquid biopsies for the early detection of circulating tumor DNA is moving forward. There is an unmet need for early response evaluation in plenty of clinical situations, and these results support the potential benefits of the clinical utility of individualized assays, such as the RaDaR assay." said Professor Sibylle Loibl, MD, Chief Executive Officer of German Breast Group. "Prognostic and predictive implications of circulating tumor DNA assays still need to be validated on a broader basis. Nevertheless, we are confident that prospective investigations on ctDNA will lead to their clinical application and ultimately improve patient outcomes."

Patients in the trial had already completed neoadjuvant therapy and surgery, with or without radiation. The RaDaR assay analyzed ctDNA in blood samples from 78 patients collected at three points: prior to initiation of standard of care endocrine therapy with either palbociclib or placebo, during therapy, and at the end of treatment. ctDNA positivity was compared to patient outcomes.

Nine percent of the patients had ctDNA detected at baseline (prior to the start of endocrine plus palbociclib or placebo). Of patients undetected at baseline, 4% had ctDNA detected in later samples and of patients detected at baseline, 29% became undetected in later samples, indicating that ctDNA positive patients may benefit from palbociclib. Detection of ctDNA following neoadjuvant chemotherapy, and surgery, is associated with a very high risk of early relapse suggesting clinical imaging and experimental therapy may be warranted for

these patients.

The data highlight the potential of the RaDaR assay to provide an early predictor of efficacy of adjuvant endocrine therapy and assess on treatment dynamics, and demonstrates that highly sensitive tumor-informed ctDNA assays can be used successfully after diagnosis and treatment of the original tumor to risk stratify patients.

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 minimal residual disease (MRD) and recurrence 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. MRD is the trace amounts of circulating tumor DNA (ctDNA) that remain after surgery or other cancer treatment.

The RaDaR workflow leverages proprietary algorithms to both create personalized RaDaR panels for each patient and analyze results of a RaDaR test, all culminating in an exceptionally sensitive test with one of the industry's leading limit of detections (LODs) down to 0.001%.

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 companies, 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. 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.

About GBG

GBG Forschungs GmbH (GBG) represents a professional institute of academic breast cancer research dedicated to continuously improving the treatment of breast cancer patients for over 20 years. GBG is led by Professor Sibylle Loibl, MD, CEO and, as the largest German academic breast cancer study group, can build on the scientific experience gained from more than 110 clinical trials and enrolling over 67,000 patients. The clinical trial

program focuses on the investigation of advanced therapy options and new drugs in all stages of breast cancer. Our mission: Healing through innovation, competence and partnership.

Forward Looking Statements

This press release includes forward-looking statements. 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, 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, 2022 filed with the SEC on February 23, 2023 as well as other information previously filed with the SEC. 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.

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