Bionano Genomics Announces Release of Version 6.2 of its NxClinical Software with Significant New Capabilities for Cancer Research Applications Including HRD Analysis

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Version includes a powerful capability for genomic scar analysis for assessments of homologous recombination deficiency (HRD) that provides an efficient, consistent approach for analysis of tumor biomarkers used in pharmacogenomics and other cancer research

SAN DIEGO, April 07, 2022 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (BNGO), pioneer of optical genome mapping (OGM) solutions on the Saphyr® system and provider of N_XClinical™ software, the leading solution for visualization, interpretation and reporting of genomic data, today announced the launch of an integrated genomic scar analysis for homologous recombination deficiency (HRD) in the version 6.2 software release of N_XClinical. This feature provides a comprehensive, consistent, and automated analysis of biomarkers from next-generation sequencing (NGS) and microarray data that can help clinical researchers stratify therapeutic response across multiple tumor types.

Integrated HRD genomic scarring has been introduced into this latest version of N_XClinical software, developed by BioDiscovery, to measure genomic instability in a platform-agnostic way. This analysis allows cancer researchers to gain important insights from genetic data they are already generating from widely available array and sequencing assays, including several from Illumina, ThermoFisher, and Agilent.

HRD represents a disruption to the normal cellular pathway that repairs double-stranded DNA breaks, which consequentially results in acquired chromosomal breakage. Clinical research has shown that cells with HRD are more sensitive to certain therapies, like Poly(ADP-Ribose) Polymerase (PARP) inhibitors and other DNA repair-targeting drugs; therefore, a measurement of HRD may be an effective pharmacogenetic biomarker across various tumor types.

N_XClinical software includes measurement of three genomic scars – Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-Scale State Transitions (LST) – that signal large-scale genomic instability. The automation of genomic scar analysis can simplify and expand access to HRD status assessment of cancer samples and enhance the clarity and transparency of tumor profiles. This analysis has the potential to drive improved stratification for clinical trials and provide pharmacogenomic-driven decisions in a precise manner that is relevant to the underlying biology of the cancer under investigation.

Current tools for assessing HRD status are limited to targeted detection of point mutations in HR genes predicted to be causative of HRD or cannot detect abnormalities across the entire genome. N_XClinical software can help resolve this limitation by providing a genome-wide scarring approach coupled with integrated SNV analysis of HR genes that may reveal critical insights to tumor biology. The proprietary analysis method assesses copy number and allelic changes across the genome to identify specific quantifiable signatures of HRD genomic instability.

Related to this new functionality, Bionano is participating as an industry partner with the nonprofit organization Friends of Cancer Research on a research project to harmonize the use of HRD as a biomarker to guide certain treatment types. Diagnostic Laboratory Services (Hawaii) will serve as the collaborator and laboratory testing site, leveraging the HRD measurement capabilities of N_XClinical software.

“Scientific interest in tumor HRD status is high, given its potential to serve as a routine and effective biomarker for a wide range of cancer types,” stated Soheil Shams, PhD and chief informatics officer of Bionano. “We believe N_XClinical 6.2 software offers an unparalleled visualization of the consequences of HRD and can streamline HRD analysis across different platforms and clinical research settings. Our goal is ultimately to improve cancer care by providing clinical researchers better tools to confidently adopt HRD analysis into their practice, without disruption to their current workflows.”

Erik Holmlin, PhD, president and chief executive officer of Bionano, commented, “With this release of N_XClinical 6.2 software, we are significantly expanding the genome analysis capabilities available to the clinical and translational research communities. One of the key steps towards eliminating cancer is for researchers to better identify targeted treatments based on tumor biology, and having an automated, consistent, and comprehensive HRD analysis may unlock new insights and treatments for elevating human health. Once we have successfully integrated OGM data capabilities into N_XClinical software, we expect structural variants uniquely identified by OGM to enhance the performance of our HRD analysis capabilities.”

About Bionano Genomics

Bionano Genomics is a provider of genome analysis solutions that can enable researchers and clinicians to reveal answers to challenging questions in biology and medicine. The Company’s mission is to transform the way the world sees the genome through OGM solutions, diagnostic services and software. The Company offers OGM solutions for applications across basic, translational and clinical research. Through its Lineagen business, the Company also provides diagnostic testing for patients with clinical presentations consistent with autism spectrum disorder and other neurodevelopmental disabilities. Through its BioDiscovery business, the Company also offers an industry-leading, platform-agnostic software solution, which integrates next-generation sequencing and microarray data designed to provide analysis, visualization, interpretation and reporting of copy number variants, single-nucleotide variants and absence of heterozygosity across the genome in one consolidated view. For more information, visit www.bionanogenomics.com, www.lineagen.com or www.biodiscovery.com

Forward-Looking Statements of Bionano Genomics

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “can,” “could,” “potential,” “may,” “expect,” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) convey uncertainty of future events or outcomes and are intended to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the ability and utility of N_XClinical 6.2 software to detect and identify HRD status, and resolve current limitations of tools for assessing HRD status;

potential of HRD to serve as a routine and effective biomarker for a wide range of cancer types; ability of HRD analysis to unlock new insights and treatments for elevating human health; and expected enhancement of the performance of our HRD capabilities once we are able to integrate OGM data capabilities into N_XClinical software. Each of these forward-looking statements involves risks and uncertainties. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include the risks and uncertainties associated with: the impact of the COVID-19 pandemic on our business and the global economy; general market conditions; changes in the competitive landscape and the introduction of competitive technologies or improvements in existing technologies, including with respect to HRD analysis; changes in our strategic and commercial plans; our ability to obtain sufficient financing to fund our strategic plans and commercialization efforts; the ability of medical and research institutions to obtain funding to support adoption or continued use of our technologies; and the risks and uncertainties associated with our business and financial condition in general, including the risks and uncertainties described in our filings with the Securities and Exchange Commission, including, without limitation, our Annual Report on Form 10-K for the year ended December 31, 2021 and in other filings subsequently made by us with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise.

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