Multi-Center Evaluation of Bionano Optical Genome Mapping by Cytogenetics Thought Leaders in the US Leads to Recommendation for Bionano's Saphyr to Replace Karyotyping as First-Line Test for Detection and Identification of Structural and Copy Number Variants in Leukemia Patients

November 11, 2020

- *Saphyr detected all clinically relevant structural variants (SVs) and copy number variants (CNVs) in 100 AML samples making it 100% concordant with standard of care*
- *Saphyr also detected additional clinically relevant SVs above and beyond standard of care in 11% of cases and refined the genomic structure analysis in another 13% of cases, which means Optical Genome Mapping (OGM) with Saphyr has the potential to change prognosis and patient management*
- *Study authors are from leading institutions in the United States, including Augusta University, Columbia University, Fred Hutchinson Cancer Research Center, Mayo Clinic, MD Anderson Cancer Center and, Penn State University*

SAN DIEGO, Nov. 11, 2020 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) announced the publication of a study led by cytogenetics experts from the nation's top clinical and cancer centers in which they recommended that optical genome mapping (OGM) using Bionano's Saphyr System be considered as a first-line test for detection and identification of clinically relevant structural variants and copy number variants in leukemias. The paper, published this week in medRxiv, describes detection and identification of structural variants and copy number variants in 100 patients with acute myeloid leukemia (AML). This study is the largest to-date in leukemia for Bionano and the first published study from the United States comparing Bionano's OGM to karyotyping, the current standard of care in leukemia testing.

The authors, who are cytogenetic leaders from prestigious institutions including Augusta University, Columbia University, Fred Hutchinson Cancer Center, Mayo Clinic, MD Anderson and Penn State University, reported that Saphyr detected 100% of all clinically relevant SVs and CNVs previously detected by standard of care methods and that Saphyr provided additional actionable data in 24% of the cases.

Karyotyping, which provides a whole genome analysis of single cells, has been the standard of care for AML patients for decades. This study demonstrated several advantages of OGM over karyotyping with no obvious deficiencies in performance. The authors reported that the performance of OGM surpassed even the performance of karyotyping combined with other tests, such as fluorescence in situ hybridization (FISH) and chromosomal microarray, in a more refined and simplified workflow that was more cost effective than current methods.

Erik Holmlin, Ph.D., CEO of Bionano Genomics commented, "This study is our flagship study in the United States. The authors come from leading institutions across the country and belong to the groups that influence what technologies are included in medical guidelines. While their finding of 100% concordance with standard of care is an important benchmark, the finding of incremental diagnostic information above and beyond the standard of care is what makes Saphyr compelling as a potential new standard in testing leukemia patients. We believe the authors' recommendation to make Saphyr a first-line test for the detection and identification of clinically relevant genomic variants in AML and other leukemias indicates that Saphyr is ready for broad clinical adoption. We further believe that this study and others published like it form the basis of an important dossier that shows the clinical utility and validity of Bionano optical genome mapping, which we will be able use in connection with assays developed through our Lineagen business to outline a potential path to reimbursement of laboratory developed tests that are performed on Saphyr."

The publication is available at: https://www.medrxiv.org/content/10.1101/2020.11.07.20227728v1

About Bionano Genomics
Bionano is a genome analysis company providing tools and services based on its Saphyr system to scientists and clinicians conducting genetic research and patient testing, and providing diagnostic testing for those with autism spectrum disorder (ASD) and other neurodevelopmental disabilities through its Lineagen business. Bionano's Saphyr system is a platform for ultra-sensitive and ultra-specific structural variation detection that enables researchers and clinicians to accelerate the search for new diagnostics and therapeutic targets and to streamline the study of changes in chromosomes, which is known as cytogenetics. The Saphyr system is comprised of an instrument, chip consumables, reagents and a suite of data analysis tools, and genome analysis services to provide access to data generated by the Saphyr system for researchers who prefer not to adopt the Saphyr system in their labs. Lineagen has been providing genetic testing services to families and their healthcare providers for over nine years and has performed over 65,000 tests for those with neurodevelopmental concerns. For more information, visit www.bionanogenomics.com or www.lineagen.com.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" 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 contribution of Bionano's OGM technology to the improved detection of diagnostic information in patients with leukemia and other genetic diseases; the capabilities of Bionano's OGM technology in comparison to other genome analysis technologies; Bionano's beliefs regarding Saphyr's readiness for broad clinical adoption; the ability of this study's authors to influence what technologies are included in medical guidelines; our expectations regarding the utilization of Bionano OGM technology with assays developed through our Lineagen business; and Bionano's strategic plans. 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 products; 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; the loss of key members of management and our commercial team; 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, 2019 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.

CONTACTS

Company Contact:
Erik Holmlin, CEO
Bionano Genomics, Inc.
+1 (858) 888-7610
eholmlin@bionanogenomics.com

Investor Relations Contact:
Ashley R. Robinson
LifeSci Advisors, LLC
+1 (617) 430-7577
arr@lifesciadvisors.com

Media Contact:
Darren Opland, PhD
LifeSci Communications
+1 (617) 733-7668
darren@lifescicomms.com

Source: Bionano Genomics