Bionano Genomics Announces Publication of Study Evaluating Optical Genome Mapping for High Throughput Characterization of Cytogenomic Heterogeneity in MDS

December 8, 2021

SAN DIEGO, Dec. 08, 2021 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (BNGO), provider of optical genome mapping (OGM) solutions on the Saphyr® system and the leading software for genomic data visualization, interpretation and reporting, today announced the publication of a study of 76 subjects by authors at The University of Texas MD Anderson Cancer Center (MD Anderson), including Dr. Guillermo Garcia-Manero, Dr. Rashmi Kanagal-Shamanna and others. The study was published in *Blood*, the journal of the American Society of Hematology. The study evaluated the utility of OGM as an alternative to traditional cytogenomic methods for the characterization of structural variation (SV) in myelodysplastic syndrome (MDS). MDS refers to disorders of the bone marrow in which it does not produce enough healthy blood cells.

Dr. Rashmi Kanagal-Shamanna from MD Anderson commented: “The results of this study underscore the potential of optical genome mapping to become a single-platform cytogenetic tool for structural variant profiling in indications such as MDS. Structural variant profiling is as important as sequence variant or mutation profiling for proper characterization of MDS in research and patient management. Technical advances in structural variant profiling have lagged those for mutation profiling, despite the fact that large genomic aberrations have been shown to be critical for diagnosis and risk-stratification of MDS and a subset of them are therapeutic targets in clinical trials. We found that OGM provided a consolidated workflow that was simpler to perform and had a shorter turnaround time compared to the three standard methods karyotyping, CMA and FISH. Importantly, OGM was not only concordant with the traditional methods, it enabled us to see more variants in subjects at higher resolution compared to traditional workflows, which has the potential to help drive better outcomes as a result of better patient management. We are pleased with the outcome of this study and we plan to continue using OGM to help make it a standard method for structural variation profiling in the future."

In this study, 76 subjects were selected for analysis by OGM using fresh and frozen bone marrow. Compared to karyotyping, OGM results were 100% concordant. According to this study, OGM resolution was much higher than conventional karyotyping (CK) and enabled precise mapping of SVs at gene-level determining the status of clinically informative biomarkers such as *TET2, MECOM, TP53* and *KMT2A,* without the need for confirmatory assays, and facilitated detailed gene-level characterization of unknown fusions. Of significant interest, OGM identified 23 clinically significant SVs in 18% of the patients which eluded detection by CK. OGM also revealed a number of SVs with uncertain significance, which may be helpful in determining new algorithms for management of subjects after additional research is conducted.

“The work by this team illustrates the utility of OGM in a complex disorder that requires comprehensive SV analysis for proper management,” commented Erik Holmlin, PhD, president and chief executive officer of Bionano. “As an alternative to traditional methods like karyotyping, studies have shown that OGM is higher resolution, faster and reveals more variants than traditional methods alone. Each of these attributes is illustrated elegantly in this work and we congratulate Drs. Kanagal-Shamanna, Garcia-Manero and their colleagues on this publication.”

Dr. Rashmi Kanagal-Shamanna has been selected to deliver an oral presentation featuring the results from this study on December 11, 2021, at the 63rd annual American Society of Hematology (ASH) meeting. Below is a link to the abstract and presentation summary.

https://ash.confex.com/ash/2021/webprogram/Paper154005.html

About Bionano Genomics

Bionano 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 “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 expected benefits and significance of OGM as an alternative to traditional cytogenomic methods for the characterization of SV in MDS. 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 or improvements on existing methods, such as CK; failure of future study results to support those demonstrated in the study referenced in this press release; changes in our strategic and commercial plans; inability 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, 2020 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:
Amy Conrad
Juniper Point
+1 (858) 366-3243
amy@juniper-point.com

Media Relations:
Michael Sullivan
Seismic
+1 (503) 799-7520
michael@teamseismic.com

Source: Bionano Genomics