Bionano Genomics Announces Publication of Landmark Research Study in Myelodysplastic Syndrome Showing OGM Data would Result in Revised Prognostic Risk Classification or Additional Actionable Variants in 28% of Study Participants

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SAN DIEGO, Aug. 01, 2022 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced the publication of the first study to evaluate the utility of optical genome mapping (OGM) for myelodysplastic syndrome (MDS) prognostication. In the peer-reviewed study, published in *Leukemia*, researchers from The University of Texas MD Anderson Cancer Center reported that when OGM was used instead of karyotyping, 17 to 21% of study subjects had different prognostic risk scores and in 13% of study subjects additional pathogenic variants were revealed. The OGM results were also compared to results of a next-generation sequencing (NGS) panel used for molecular pathology. The comparison to NGS showed that the utility of OGM above and beyond that of karyotyping is not provided by NGS.

Corresponding author, Dr. Rashmi Kanagal-Shamanna, from MD Anderson commented, “The results of this study demonstrate that we are grossly under-evaluating the degree of genomic aberrations. Most patients with high-risk MDS are not responsive to available therapies, pointing to the urgent need for new therapeutic alternatives that will improve the clinical outcomes of these patients and better tools to help in that pursuit. This study underscores the potential for OGM to become a single-platform cytogenetic tool for structural variant profiling in indications such as MDS, and shows that when OGM and NGS are combined, the success rate of finding pathogenic variants is higher than with any traditional methods in use today."

The study analyzed 101 consecutive, newly diagnosed MDS patients from a single center within MD Anderson. Multiple analysis methods, including OGM, karyotyping, fluorescence *in situ* hybridization (FISH), chromosomal microarray analysis (CMA) and an 81-gene NGS panel were used to detect pathogenic structural variants (SVs) and single nucleotide variants (SNVs) in the samples. The findings showed that OGM detected nearly twice the number of pathogenic SVs compared to traditional cytogenetic methods. When the OGM results were used to calculate prognostic risk scores by the comprehensive cytogenetic scoring system (CCSS), the risk scores were different for 21% of study subjects and when the international prognostic scoring system (IPSS) was used, the risk scores were different for 17% of study subjects. Prognostic risk is a component of disease management protocols outlined in treatment guidelines followed by oncologists on a global basis. Proper risk classification can help improve outcomes, including overall survival.

In addition to driving the reclassification of prognostic risk in up to 21% of subjects, the results showed that OGM detected pathogenic variants that traditional methods missed in 13% of subjects. The researchers suggest that these previously undetected SVs could provide additional information that oncologists could use to select therapies and to monitor therapeutic response and disease progression. Taken together, use of OGM resulted in a different cytogenetic analysis for 28% of subjects in the study.

The authors also evaluated the utility of combining OGM with NGS on the same MDS subjects and found that the combination of OGM and NGS resulted in the detection of at least one clinically significant clonal abnormality in 97 of 101 cases. In one subject, the researchers reported detecting a pathogenic SV that otherwise had no clinically relevant variants detected by NGS or traditional methods.

“We are thrilled to see the remarkable results from the study, which we believe illustrate the clinical utility of OGM in MDS. This study shows that OGM can have higher resolution, be faster and reveal far more variants than traditional methods alone, attributes that could impact people’s lives and play a role in disease management. It also shows that combining OGM with NGS can offer a workflow that reveals SVs and SNVs in a way that the standard combination of tools in use today cannot,” commented Erik Holmlin, PhD, president and chief executive officer of Bionano Genomics.

The publication is available at: https://www.nature.com/articles/s41375-022-01652-8

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,” “may,” “could, “potential,” “believe,” 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 OGM to complement next generation sequencing NGS in the detection of SVs and SNVs in MDS, the utility of OGM in determining prognostic scores for MDS, and the ability of OGM to detect clinically relevant SVs that traditional cytogenomic methods cannot. 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 to existing technologies; failure OGM to achieve useful complementarity with NGS or to be useful in determining prognostic scores for MDS; failure of future study results to support those demonstrated in the paper referenced in this press release; 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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