



Bionano Genomics Announces Publication of Prospective Study Demonstrating Performance Improvements from OGM in the Analysis of AML and MDS Compared to Traditional Methods

February 22, 2022

SAN DIEGO, Feb. 22, 2022 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. ([BNGO](#)), pioneer of optical genome mapping (OGM) solutions on the Saphyr® system and provider of NxClinical™, the leading software solution for visualization, interpretation and reporting of genomic data, today announced the publication of a peer-reviewed, prospective study comparing OGM to traditional methods and demonstrating improved sensitivity and lower cost of OGM in the analysis of acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) compared to karyotyping and fluorescence *in situ* hybridization (FISH). This research provides scientific and practical support for the use of OGM workflows as a potential alternative to karyotype and FISH testing for certain hematologic malignancies, while also identifying novel structural variants (SVs) that can impact disease stratification or serve as therapeutic targets.

In the study, published in the *International Journal of Cancer*, 27 samples from subjects with AML or MDS underwent routine cytogenetic diagnostics (karyotype, FISH and RT-PCR when indicated), as well as OGM. The authors describe how OGM detected 31% more European Leukemia Net (ELN) and recurrent myeloid abnormalities compared to karyotyping and FISH. OGM also found abnormalities in 35% more cases than karyotyping and FISH, and in 67% of samples, the karyotype could be redefined by OGM. OGM refinement of the karyotype results resulted in putative changes the ELN risk classifications. These classifications are typically used as part of the process of determining treatment plans.

The authors also found the cost-efficiency of using a single OGM analysis, with OGM cost comparable to two FISH probes.

"We believe this research demonstrates the usability of OGM for analysis of AML and MDS. Based on OGM's performance observed in this study, we believe that OGM can be used in routine cytogenetic diagnostics and has the potential to provide improved clinical diagnosis for hematologic malignancies, which we would expect to establish in more research," commented authors Wanda Gerding, PhD and Professor Huu Phuc Nguyen from the University of Bochum, Germany.

Erik Holmlin, PhD, president and chief executive officer of Bionano commented, "Results from this peer-reviewed research study demonstrate some key benefits of OGM for accurately identifying clinically relevant and actionable SVs related to hematologic malignancies. Studies to date have consistently shown that OGM has superior sensitivity for detecting SVs and can be run at lower costs compared to existing workflows, which rely on multiple different technologies."

This publication is available at: <https://onlinelibrary.wiley.com/doi/abs/10.1002/ijc.33942>

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 bionanogenomics.com, lineagen.com or 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 use of OGM as a potential alternative workflow for identification of hematologic malignancies; OGM's performance in future applications and cost-effectiveness as compared to other methods; the ability of OGM to influence ELN risk classification; and the anticipated superior performance of OGM in routine cytogenetic diagnostics. 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; failure of future study results to support those demonstrated during the presentations referenced in this press release; changes in the competitive landscape, including the introduction of competitive technologies or improvements in existing technologies; 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, 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.

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Source: Bionano Genomics