



Multi-Center Research Study Illustrates How OGM Can Potentially Result in More Patients Qualifying for Treatments in Leukemia

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- *Researchers from eight research institutes recommend OGM as first-line analysis for AML due to its ability to perform better and cost less than analysis with karyotyping, FISH, and CMA*
- *OGM identified pathogenic variants in 12% of cases that altered ELN risk-level or identified eligibility for clinical trials*
- *OGM had 100% concordance with traditional cytogenetic methods and added new relevant information in 13% of cases*

SAN DIEGO, Dec. 09, 2022 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced the publication of a multi-institutional peer-reviewed study initiated by the Cancer Genomics Consortium evaluating the performance of optical genome mapping (OGM) for detection of cytogenetic abnormalities in acute myeloid leukemia (AML) samples. OGM identified structural variants (SVs) and copy number variants (CNVs) with 100% concordance to traditional cytogenetic methods, added important pathogenic findings in 13% of findings, and uncovered additional genomic events in 12% of samples that may change risk stratification and alter recommended clinical care, including access to clinical trials.

Given the consistent correlation of clinical outcomes with specific genomic aberration classes, the World Health Organization (WHO), National Comprehensive Cancer Network (NCCN) and European Leukemia Net (ELN) have developed recommendations for diagnosis and management of AML in adults based on the spectrum of CNVs, SVs and somatic single nucleotide variants (SNVs) detected by traditional cytogenetic methods. In the study published in *Blood Advances*, researchers used OGM to evaluate its performance in the detection of cytogenetic abnormalities in 100 AML samples that had previously been analyzed using methods including karyotyping (KT), fluorescence in situ hybridization (FISH) and chromosomal microarray analysis (CMA).

Key findings were:

- In five subjects, analysis by OGM resulted in a change in risk stratification score compared to the scores determined by KT
- In eight subjects, OGM identified additional genomic events that would have rendered those subjects eligible to participate in research studies evaluating the effectiveness of experimental treatments
- In three of the subjects that would be eligible to participate in research studies evaluating the effectiveness of experimental treatments, OGM also showed that potential adverse risks would be independent of *TP53*, which may allow for them to be safely enrolled in multiple trials with known *TP53*-related adverse effects

Overall, the research study supports the view that OGM analysis may be useful to assemble a more accurate and complete karyotype by refining cytogenetic breakpoints, resolving unknown cytogenomic elements and detecting additional significant variants.

"We are excited to see the findings from this study, which was conducted by a multi-site consortium led by renowned pathologists who, through their memberships in various medical societies, are responsible for defining standards of care and testing throughout pathology. We are gratified to see the authors' recommendation of OGM as a methodology with the potential to become standard-of-care for cytogenomic evaluation of AML samples," commented Erik Holmlin, PhD, president and chief executive officer of Bionano Genomics.

The publication is available [here](#).

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

Bionano's OGM products are for research use only and not for use in diagnostic procedures.

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," "potential," "would" 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 detect cytogenetic abnormalities, including SVs and CNVs, in AML samples, the ability of OGM to produce concordant results with

traditional cytogenetic methods or to uncover additional genomic events, the ability and utility of OGM to analyze genomes and reveal answers in genetic disease and cancer research, and the potential for OGM to become the standard of care. 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: global and macroeconomic events, such as the impact of the COVID-19 pandemic and the ongoing Ukraine-Russian conflict and related sanctions, 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 of future study results to support those reported in the publication referenced in this press release; future study results that contradict the results reported in the publication referenced in this press release; failure of OGM to produce concordant results with traditional cytogenetic methods; failure of OGM to uncover additional genomic events when compared to traditional cytogenetic methods; failure of OGM to be adopted as a standard of care for cytogenomic evaluation of AML samples; 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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