



Bionano Announces Peer-Reviewed Publication on the Utility of Combining OGM and a 523-gene NGS Panel for Standard Evaluation of Myeloid Cancers

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SAN DIEGO, June 20, 2023 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (BNGO), today announced the publication in *Cancers* of a peer-reviewed study from Augusta University on the utility of combining optical genome mapping (OGM) and a 523-gene next-generation sequencing (NGS) panel for the standard evaluation of myeloid cancers. Medical society guidelines recommend the use of karyotyping (KT), fluorescence *in-situ* hybridization (FISH) and sequencing to perform cytogenetic and molecular analysis of patients. The study describes myeloid cancers as posing a significant challenge to manage, with approximately 50% of cases displaying cytogenetically normal genomes, which can confound traditional analysis approaches.

In this blinded retrospective analysis of samples from 30 myeloid cancer subjects, the combination of OGM with the 523-gene NGS panel was compared to the common approach of KT and FISH combined with a 54-gene NGS panel. A pre-commercial version of Bionano's new NxClinical™ software enabled analysis of OGM and NGS data together, providing an integrated picture of genomic variation. Key findings on the performance of OGM combined with 523-gene panel compared to that of KT and FISH combined with the 54-gene panel are summarized below.

Key findings and their impact in this study	
OGM identified all SVs detected by KT and FISH	100% concordance
OGM found clinically relevant SVs in cases previously classified as normal by KT and FISH	4 out of 7 cases (57%)
OGM detected SVs listed in NCCN guidelines that were not identified by KT and FISH	5 out of 30 cases (16.6%)
OGM detected SVs listed in the NHS (UK) guidelines that were not identified by KT and FISH	4 out of 30 cases (13%)
The 523-gene panel identified sequence variants of potentially clinical relevance not identified by the 54-gene panel	6 out of 30 cases (20%)
OGM combined with 523-gene panel for MDS cases identified compound heterozygous events of clinical significance, including cases where the genes were listed on NCCN guidelines but missed by the KT/FISH and 54-gene panel	12 out of 30 cases (40%)
OGM results led to reclassification of cancer from simple to complex	5 out of 22 cases (23%)
OGM results with the 523-gene panel for MDS cases led to revisions in IPSS-R risk stratification from very good/good to very poor	2 out of 9 cases (22%)

SV = structural variations; NCCN = National Comprehensive Cancer Network; NHS (UK) = National Health Service, UK; MDS = myelodysplastic syndrome; IPSS-R = Revised International Prognostic Scoring System for MDS Risk Assessment

"This peer-reviewed publication outlines the potential utility of combining OGM with sequencing panels to evaluate myeloid cancer. I believe this research study shows that OGM can perform significantly better than KT and FISH, which can result in meaningful revisions to various risk classifications and disease stratifications, which are known to affect outcomes. The OGM and sequencing data were analyzed with the upcoming version of our NxClinical analysis software (commercially available as VIA™ analysis software). VIA analysis software will offer a powerful new workflow in cytogenomics and molecular pathology, especially for cancer" commented Erik Holmlin, president and chief executive officer of Bionano.

The publication can be viewed here <https://www.mdpi.com/2072-6694/15/12/3214> and a PDF of it can be downloaded here <https://www.mdpi.com/2072-6694/15/12/3214/pdf>

About Bionano

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, Inc. d/b/a Bionano Laboratories business, the Company also provides diagnostic testing for patients with clinical presentations consistent with autism spectrum disorder and other neurodevelopmental disabilities. 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. The Company additionally offers nucleic acid extraction and purification solutions using proprietary isotachopheresis (ITP) technology. For more information, visit www.bionano.com, www.bionanolaboratories.com or www.purigenbio.com.

Forward-Looking Statements of Bionano

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "can," "may," "potential," "will," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances and the negatives thereof) 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 performance of OGM compared to traditional cytogenetic methods including kT and FISH for the identification of SVs; the ability and utility of OGM to detect SVs in myeloid cancers; the ability and utility of combining OGM with a 523-gene panel for the analysis of myeloid cancers; the ability and utility of OGM to be adopted as a for analysis of myeloid cancers; and other statements that are not historical facts.

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 geopolitical and macroeconomic developments, such as recent and future bank failures, the ongoing Ukraine-Russia conflict, related sanctions, and

the COVID-19 pandemic, on our business and the global economy; challenges inherent in developing, manufacturing and commercializing products; our ability to further deploy new products and applications and expand the markets for our technology platforms; failure of our OGM solutions to be adopted for analysis of myeloid cancers; the failure of OGM to be combined with a 523-gene panel for the analysis of myeloid cancers; the failure of OGM to detect SVs consistent with the study results described in this press release; future study results that contradict the study results described in this press release; future study results that do not support the study results described in this press release; our expectations and beliefs regarding future growth of the business and the markets in which we operate; changes in our strategic and commercial plans; our ability to obtain sufficient financing to fund our strategic plans and commercialization efforts; and 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, 2022 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 are under no duty to update any of these forward-looking statements after the date they are made to conform these statements to actual results or revised expectations, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date the statements are made. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements contained in this press release.

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