Bionano Announces Three Publications Demonstrating OGM's Utility for Hematological Malignancy Research

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- Three peer-reviewed publications collectively illustrate the building support in Europe for optical genome mapping (OGM) as a powerful alternative to traditional methods of cytogenetic analysis for hematological malignancies
- Taken together, the publications, a review paper and two independent studies, illustrate that OGM is not only comparable to traditional methods of cytogenetic analysis for hematological malignancies but is potentially more sensitive in the detection of relevant aberrations

SAN DIEGO, April 26, 2023 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (BNGO), today announced the publication of three studies which collectively illustrate the continued development of data supporting optical genome mapping (OGM) as an alternative to traditional cytogenetic methods for the analysis of hematological malignancies. The studies confirm OGM's high level of concordance and ability to identify relevant variants that are not detected by traditional methods but that could have an impact on clinical research, potentially leading to improved patient management, including therapy selection and overall risk assessment.

Key Findings and Takeaways

The publication from Ruhr-University Bochum (Nilius-Eliliwi *et al*.) is a combined review of 11 peer-reviewed papers covering 509 samples from subjects in acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS) research studies, including the authors' own independent study of 42 AML and MDS samples. The authors concluded that OGM offers unbiased genome-wide analysis of structural variants (SVs) with high resolution. The authors noted that, in a single workflow, OGM can combine most of the current diagnostic yield of traditional cytogenetic methods with substantial additional information regarding unseen SVs and the clarification of previously unclear findings. The authors also noted OGM's ability to detect currently unknown variants, which might give insight into disease biology and refine risk stratification.

The researchers' independent study used OGM to analyze 35 AML samples and 7 MDS samples and reported:

- OGM had a 91% concordance rate with traditional cytogenetic methods for AML cases with additional information detected in 64% of samples
- OGM had an 83% concordance rate with traditional methods for MDS cases with additional information detected in 50% of samples
- OGM's threshold for detection could be reduced to a variant allele fraction (VAF) of 1-2% with a 600x coverage protocol
- OGM offers a simplified workflow, with results able to be generated in 4 days without the need for cell culture and other complexities found in traditional cytogenetic methods

The publication from University Hospital of Clermont-Ferrand (Soler *et al*.) evaluated the performance of OGM against traditional cytogenetic methods in 29 samples characterized as AML or ALL. Overall, OGM had high concordance with traditional cytogenetic methods and detected a number of additional findings that could be confirmed to be pathogenic or likely pathogenic and that would play a significant role in influencing disease management.

- OGM was 100% concordant with prognostic classification conducted with traditional cytogenetic methods
- OGM detected additional cytogenetic and molecular abnormalities not described by standard techniques including aberrations cryptic at the karyotype level in 6 samples
- OGM identified the involvement of candidate genes with a known or putative role in leukemogenesis or as therapeutic targets, including *TP53*, *TCL1A*, *KMT2A*, *CDK6*, or *BCL11B*

The publication from University of Oulu (Valkama *et al*.) is one of the first studies to evaluate the utility of OGM in chronic lymphocytic leukemia (CLL) samples. OGM was fully concordant to a four-probe fluorescence *in situ* hybridization (FISH) panel in 18 samples and was also able to detect additional genetic variations, including both unbalanced and balanced SVs. Importantly, OGM also enabled the detection of prognostically significant complex karyotypes, undetectable by FISH, in three samples, which are associated with shorter survival and advanced disease. The authors concluded that OGM is a powerful tool for genome-wide SV analysis and has the potential to serve as a first-tier cytogenetic test for CLL.

- OGM was 100% concordant with traditional cytogenetic methods
- Additional chromosomal aberrations were detected in 78% of the samples, including complex karyotypes, which are undetectable by FISH
- The authors reported high sensitivity in complex samples where pathogenic variants were present in very low abundance, at a 3-9% VAF

"We have seen a significant increase in the number of peer-reviewed studies showing OGM's utility for hematological malignancy research. These three new publications from European sites underline those positive results and confirm OGM's potential to serve as a first-tier cytogenetic method for analysis, due to its ability to perform, in a single assay what today requires multiple technologies, with effective and reliable results," commented Erik Holmlin, PhD, president and chief executive officer of Bionano.

The publication from Nilius-Eliliwi *et al.* is available at https://www.mdpi.com/2072-6694/15/6/1684; the publication from Soler *et al.* is available at

https://www.mdpi.com/2072-6694/15/7/2131; the publication from Valkama *et al.* is available at https://www.mdpi.com/2072-6694/15/4/1294.

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, 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. 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.bionano.com, www.bionanolaboratories.com or www.biodiscovery.com

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "can," "could," "may," "potential," "would," 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 karyotyping and FISH for the identification of SVs; the ability and utility of OGM to detect SVs in hematologic malignancies including AML, ALL, CLL, and MDS samples; the ability and utility of OGM to be adopted as a first-tier test for the identification of SVs in hematologic malignancies including AML, ALL, CLL, and MDS samples; 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 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 hematologic malignancies including AML, ALL, CLL, and MDS samples; the failure of OGM to be adopted as a first-tier test for the identification of SVs in hematologic malignancies including AML, ALL, CLL, and MDS samples; 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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