



Bionano Announces Peer-Reviewed Publication on the Utility of Combining OGM and WES for Evaluation of Pediatric Leukemia

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SAN DIEGO, Sept. 06, 2023 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced a peer-reviewed publication from researchers at the German Cancer Consortium (DKTK) showing the utility of optical genome mapping (OGM) and whole-exome sequencing (WES) in better understanding the mutational landscape of pediatric B-cell precursor acute lymphoblastic leukemia (BCP-ALL). Researchers compared the analysis of 60 pediatric BCP-ALL samples using traditional cytogenetic methods against OGM and WES, finding that OGM and WES may provide novel insights into disease development and progression.

Key Takeaways

- OGM and WES identified 19 recurrently altered regions with novel potential leukemic drivers
- OGM and WES identified double hits of structural variants (SVs) and single-nucleotide variants (SNVs) (*ETV6*, *BTG1*, *STAG2*, *MANBA*, *TBL1XR1*, *NSD2*) in the same sample, demonstrating the power of the combined approach of OGM and WES to identify compound events relevant to risk stratification and treatment of hematological malignancies
- OGM identified 95% of SVs (526 out of 552) detected by karyotyping (KT), fluorescence *in situ* hybridization (FISH) and/or single nucleotide polymorphism (SNP) array, including all hallmark translocations and chromosomal gains in hyperdiploid (HD) BCP-ALL
- OGM identified 677 additional SVs of potential clinical relevance not identified by traditional methods, including SVs in known leukemia development genes and subclonal *IKZF1* deletions missed by SNP-array
- Overall, OGM detected three times more deletions than were detected by a SNP-array at a 50kb detection limit
- OGM identified 3 novel fusion genes (*SFMBT2::DGKD*, *PDS5B::STAG2*, and *TDRD5::LPCAT2*)
- PacBio long-read sequencing was performed on 11 tumor samples where sufficient material was available to validate selected SVs that were newly detected by OGM
- The combination of KT, FISH and SNP-array detected only 43% of SVs that OGM detected

"This peer-reviewed publication from a leading German cancer consortium outlines the utility of OGM for detecting SVs that current methods identify and for revealing ones that current methods miss. It also shows the potential of combining OGM with WES to identify double hits, which are highly significant. It's noteworthy that long-read sequencing confirmed the fusions detected by OGM once OGM revealed the regions in which to look for them, highlighting the possibility that OGM can be a primary tool used alongside short-read next-generation sequencing (NGS). Altogether, the findings may result in meaningful revisions to various risk classifications and disease stratifications, which are known to affect outcomes," commented Erik Holmlin, president and chief executive officer of Bionano.

The publication can be viewed here: https://journals.lww.com/hemasphere/fulltext/2023/08000/optical_genome_mapping_identifies_novel_recurrent.4.aspx

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 technology. For more information, visit www.bionano.com, www.bionanolaboratories.com or www.purigenbio.com.

Unless specifically noted otherwise, Bionano's OGM products are for research use only and not for use in diagnostic procedures.

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 "can," "may," "potential," 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 ability of OGM and WES to provide novel insights into disease development and progression; the performance of OGM compared to traditional cytogenetic methods including KT, FISH, and SNP-arrays for the identification of SVs; the ability and utility of OGM to detect SVs in BCP-ALL samples; the potential of combining OGM with WES to identify double hits; the ability and utility of combining OGM with WES for the analysis of BCP-ALL samples; the ability and utility of OGM to be adopted as an analysis method for BCP-ALL samples; the

possibility that OGM can be a primary tool used alongside NGS; whether the findings discussed in this press release will result in meaningful revisions to various risk classifications and disease stratifications; 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 any global pandemics, 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 OGM and WES to provide novel insights into disease development and progression; failure of our OGM solutions to be adopted for analysis of BCP-ALL samples; the failure of OGM to be combined with WES for the analysis of BCP-ALL samples and to detect double hits; the failure of OGM to detect SVs consistent with the study results described in this press release; the failure of OGM to be used as a primary tool alongside NGS; the failure of the study results discussed in this press release to result in meaningful revisions to various risk classifications and disease stratifications; 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 our ability to continue as a "going concern"; 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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