



Bionano Announces Publication Showing that OGM Detects Over 1250 Structural Variants, including 56 Gene Fusions, in Pediatric Leukemia that were Missed by Whole Genome Sequencing

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SAN DIEGO, April 11, 2024 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced the publication of a study from Penn State College of Medicine that used optical genome mapping (OGM) to search for clinically and biologically relevant genomic variations in pediatric B-cell acute lymphoblastic leukemia (B-ALL). The study also used whole genome sequencing (WGS) for variant detection and evaluated the two approaches side-by-side and the potential benefit of integrating WGS and OGM to obtain a comprehensive analysis of genetic variation. The study concluded that OGM together with WGS can potentially identify new therapeutic targets and improve personalized medicine in pediatric leukemia and other cancers by providing a more complete view of genome variation, including structural variation.

The study findings showed that, of the 3,075 total SVs detected in the B-ALL samples, 1,255 were uniquely detected by OGM. The study also found that WGS detected 66 gene fusions, and that OGM was able to detect an additional 56 fusions that were missed by WGS. Several of the gene fusions detected by OGM were also not previously found by other methods of analysis, and their expression was confirmed by RNA sequencing, indicating their potential to be used as prognostic biomarkers or possible therapeutic targets. These study findings highlight the potential benefit of using OGM for SV detection in B-ALL, as many SVs went undetected with WGS alone.

Erik Holmlin, PhD, president and chief executive officer of Bionano, commented, "We believe OGM's ability to interrogate genome-wide SVs in an important size range makes OGM a viable alternative to traditional cytogenetic methods, and potentially a strong complement to sequencing. These study results highlight the potential benefit of adding OGM to a WGS workflow for a more comprehensive analysis of genetic variation in blood cancers, which may improve clinical diagnostics in future research, as better resolution of SVs can help illuminate the genetic drivers in cancer."

The publication is available at: <https://www.mdpi.com/2075-4426/14/3/291>

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.

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 "believe," "can," "may," "potential" 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 SVs and gene fusions in pediatric B-ALL samples; the utility of OGM to identify new therapeutic targets and improve personalized medicine in pediatric leukemia and other cancers; the utility of combining OGM with WGS to identify new therapeutic targets and improve personalized medicine in pediatric leukemia and other cancers; the utility of adding OGM to a WGS workflow for a more comprehensive analysis of genetic variation in blood cancers and improve clinical diagnostics in future research; 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 potential future bank failures, supply chain disruptions, global pandemics, inflation and the ongoing conflicts between Ukraine and Russian and Israel and Hamas, on our business and the global economy; general market conditions; the failure of OGM to detect SVs and gene fusions in pediatric B-ALL samples; the failure of OGM to identify new therapeutic targets and improve personalized medicine in pediatric leukemia and other cancers; the failure of combining OGM with WGS to identify new therapeutic targets and improve personalized medicine in pediatric leukemia and other cancers; the failure of adding OGM to a WGS workflow for a more comprehensive analysis of genetic variation in blood cancers and improve clinical diagnostics in future research; study results that differ or contradict the results reported in the study referenced in this press release; changes in the competitive landscape and the introduction of competitive technologies or improvements to existing technologies; changes in our strategic and commercial plans; our need and ability to obtain sufficient financing to fund our strategic plans and commercialization efforts, our ability to effectively manage our uses of cash, and our ability to continue as a "going concern"; 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, 2023 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.

CONTACTS

Company Contact:

Erik Holmlin, CEO
Bionano Genomics, Inc.
+1 (858) 888-7610
eholmlin@bionano.com

Investor Relations:

David Holmes
Gilmartin Group
+1 (858) 888-7625
IR@bionano.com

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