Bionano Announces Publication Showing OGM Can Overcome Key Limitations of Targeted RNA-Seq for Cytogenetic Investigation in Acute Leukemia

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SAN DIEGO, Nov. 06, 2025 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced the publication of a study in *Cancers* from The University of Texas MD Anderson Cancer Center showing how optical genome mapping (OGM) can address key limitations of targeted RNA-sequencing (RNA-seq) panels in detecting therapeutically-relevant gene rearrangements in acute leukemias. This peer-reviewed publication, entitled “Comparative Analysis of Targeted RNA-Seq and Optical Genome Mapping for Detecting Gene Rearrangements in Acute Leukemia,” is the first to describe the comparison of OGM and RNA-seq in cancer.

While RNA-seq panels are useful for detecting expressed variants, including chimeric transcripts, they have limitations. For example, when rearrangements lead to overexpression of a gene under a hijacked enhancer or when fusion transcripts are absent or poorly expressed, RNA-seq analysis may yield false-negative results. OGM complements RNA-seq with its ability to detect structural variants (SVs) at the DNA level that RNA-seq may fail to detect, including cryptic rearrangements, fusion genes, enhancer-hijackings, and large-scale events more commonly identified with legacy cytogenetic techniques.

Summary of Key Findings

- A total of 234 gene rearrangements or fusions were detected by OGM and/or RNA-seq across 206 subjects (43.6%) in a cohort of 467 acute leukemia research subjects. This rate varied across different leukemia types, from 36.1% in acute myelogenous leukemia (AML) to 75% in T-cell acute lymphoblastic leukemia (T-ALL)
- 175 of the 234 gene rearrangements or fusions (74.7%) were detected by both OGM and the targeted RNA-seq panel
- OGM uniquely identified 37 events (15.8%) of varying complexity, whereas the RNA-seq panel uniquely identified 22 events (9.4%), mostly small gene insertions and intrachromosomal deletions
- Tier 1 aberrations, which are classified as those having well-established prognostic, diagnostic, or therapeutic relevance according to guidelines set by medical societies such as WHO, NCCN and ICC, were found by OGM and/or RNA-seq in 147 of the 467 subjects (31.5%)
- RNA-seq detected just 20.6% of the enhancer-hijacking events detected by OGM. Gene rearrangements or fusions in this class, such as *MECOM, BCL11B* and *IGH* rearrangements, can be important to reliably detect since they are known to be drivers of leukemogenesis

Overall, this study from The University of Texas MD Anderson Cancer Center showed that OGM can identify a higher proportion of clinically significant SVs compared to a 108-gene targeted RNA-seq panel. Using OGM and RNA-seq together on the same cohort would yield the most comprehensive result in acute leukemia cases.

“This study is a great representation of how the utility of OGM is continuing to expand,” said Erik Holmlin, PhD, president and CEO of Bionano. “With this comparison against RNA-seq, we believe OGM is growing its footprint in digital pathology where it is imperative to use tools that reveal the complete architecture of the cancer genome and capture cryptic events that other technologies miss. The combination of OGM and RNA-seq can deliver the most comprehensive analysis of genome to potentially impact disease classification, risk stratification, and therapeutic selection.”

The full research publication, *Comparative Analysis of Targeted RNA-Seq and Optical Genome Mapping for Detecting Gene Rearrangements in Acute Leukemia*, is available at: https://www.mdpi.com/2072-6694/17/21/3458.

About Bionano Genomics

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 optical genome mapping (OGM) solutions, diagnostic services and software. The Company offers OGM solutions for applications across basic, translational and clinical research. The Company also offers an industry-leading, platform-agnostic genome analysis software solution, and nucleic acid extraction and purification solutions using proprietary isotachophoresis (ITP) technology. Through its Lineagen, Inc. d/b/a Bionano Laboratories business, the Company also offers OGM-based diagnostic testing services.

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

Bionano’s 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. All statements other than statements of historical facts contained in this press release, including statements regarding our future results of operations or financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. Words such as “ability,” “believe,” “can,” “may,” “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, current expectations, or future expectations concerning, among other things; the ability and utility of OGM to address key limitations of RNA-seq panels in detecting therapeutically-relevant gene rearrangements in acute leukemias; the ability and utility of OGM to detect SVs at the DNA level that RNA-seq may fail to detect; the ability and utility of OGM to identify a higher proportion of clinically significant SVs compared to what a 108-gene targeted RNA-seq panel can identify; the ability and utility of using OGM

and RNA-seq together on the same cohort to yield the most comprehensive result in acute leukemia cases; whether OGM is growing its footprint in digital pathology; the ability and utility of combining OGM with RNA-seq to deliver the most comprehensive analysis of genome to potentially impact disease classification, risk stratification and therapeutic selection;and any other statements that are not of historical fact. Each of these forward-looking statements involves risks and uncertainties. Accordingly, investors and prospective investors are cautioned not to place undue reliance on these forward-looking statements as they involve inherent risk and uncertainty (both general and specific) and should note that they are provided as a general guide only and should not be relied on as an indication or guarantee of future performance. 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 failure of OGM to address key limitations of RNA-seq panels in detecting therapeutically-relevant gene rearrangements in acute leukemias; the failure of OGM to detect SVs at the DNA level that RNA-seq may fail to detect; the failure of OGM to identify a higher proportion of clinically significant SVs compared to what a 108-gene targeted RNA-seq panel can identify; the failure of OGM and RNA-seq used together on the same cohort to yield the most comprehensive result in acute leukemia cases; the failure of OGM to growing its footprint in digital pathology; the failure of a combined OGM with RNA-seq to deliver the most comprehensive analysis of genome to potentially impact disease classification, risk stratification and therapeutic selection; the failure of OGM be useful in the applications described in the publications referenced in this press release; future publications that differ or contradict the findings of the publication referenced in this press release; our ability to obtain sufficient financing to fund our business plans and commercialization efforts and our ability to continue as a “going concern,” which requires us to manage costs and obtain significant additional financing to fund our business plans and commercialization efforts; the risk that if we fail to obtain additional financing we may seek relief under applicable insolvency laws; the impact of adverse geopolitical and macroeconomic events, such as the ongoing conflicts between Ukraine and Russia and in the Middle East and uncertain market conditions, including inflation, tariffs, and supply chain disruptions, 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; changes in our strategic and commercial plans; 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 including those described in our filings with the Securities and Exchange Commission (“SEC”), including, without limitation, our Annual Report on Form 10-K for the year ended December 31, 2024, our Quarterly Reports on Form 10-Q and in other filings subsequently made by us with the SEC. 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, except as may be required by law.

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