Bionano Announces Publication from Johns Hopkins School of Medicine Showing that OGM Outperformed Multiple Cytogenetic Assays in a Study of Bone and Soft Tissue Tumor Analysis

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- *In the largest study to date of bone and soft tissue tumors, OGM detected 100% of the variants found by multiple standard techniques, including karyotyping, fluorescent in-situ hybridization (FISH) & gene fusion assays*
- *OGM was also more sensitive, including detection of diagnostic or pathogenic variants missed by karyotype in 74% (14/19) of cases that failed or were negative by karyotyping*
- *When OGM results and next-generation sequencing (NGS) results were combined, diagnostic and pathogenic structural variants (SVs), copy number variants (CNVs), and/or single nucleotide variants (SNVs) were found in ~98% of cases, a substantially greater rate than when karyotyping, FISH and NGS are used*

SAN DIEGO, Dec. 23, 2024 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced a publication in *Modern Pathology* by a group of researchers at the Johns Hopkins University School of Medicine, showing that optical genome mapping (OGM) can outperform traditional techniques in analysis of bone and soft tissue tumors. Several prior publications have shown the utility of OGM compared to traditional cytogenetics in studies of hematologic malignancies, however, data on the application of OGM in solid tumors has been relatively sparse. This study provides compelling support for extending the utility of OGM in cancer beyond hematologic malignancies to solid tumors.

Key findings:

1. **OGM detected all variants revealed by conventional cytogenetics:** OGM showed 100% concordance, identifying all pathogenic variants detected by standard of care cytogenetic methods. The specificity of OGM was assessed to be 100%, i.e. OGM correctly identified the same pathogenic SVs and CNVs detected by standard of care/routine cytogenetics (karyotyping and FISH).
2. **OGM detected pathogenic variants missed by karyotyping: In 74% of cases with normal or failed karyotype,** OGM detected diagnostic or pathogenic SVs that were missed by karyotyping. Further, in 6 cases that failed to yield any karyotyping results due to culture failure, OGM detected pathogenic SVs in all of them. Variants found by OGM but missed by standard of care included the *EWSR1::ETV1* fusion, which is a key molecular hallmark of clear cell sarcoma and helps to differentiate it from other soft tissue sarcomas and melanomas.
3. **OGM resolved complex cancer genomes:** Study authors found that OGM data could re-characterized and better defined complex structural rearrangements including chromoanagenesis in 27% of cases and complex 3-6-way translocations in 15% of cases when compared to traditional cytogenetic methods.
4. **OGM combined with NGS found pathogenic variants in 98% of cases***, a substantially greater rate than when karyotyping, FISH and NGS are used*: The integrated approach of the combination of OGM and NGS resulted in the detection of pathogenic SVs and sequence variants in ~98% of cases. OGM was 100% concordant with NGS for aneuploidy detection.
5. **OGM findings have the potential to qualify subjects for targeted therapies that otherwise would not have been possible:** The authors state that several of the OGM findings could result in the potential for these cases to qualify for either targeted treatments or clinical trials. For example, cases with potential to be treated by CDK4/6 inhibitors (palbociclib, ribociclib, abemaciclib), TRK inhibitors (larotrectinib, entrectinib), pan-FGFR inhibitors (erdafitinib or futibatinib) were highlighted.

Erik Holmlin, president and chief executive officer of Bionano commented, “Approximately 50% of bone and soft tissue tumor samples fail to reveal actionable information for proper classification of disease, prognosis and therapeutic management because they either fail to culture or because traditional techniques in cytogenetics lack adequate sensitivity and specificity to reliably detect relevant variants. We have seen increasing evidence for OGM as a valuable alternative to cytogenetic methods in blood cancers, and we are thrilled to see researchers at Johns Hopkins publishing this compelling case for extending OGM’s utility to bone and soft tissue tumors.”

The full research publication is available at: https://doi.org/10.1016/j.modpat.2024.100684

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 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. Words such as "can," "could," "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, OGM's utility for applications in bone and soft tissue cancers; OGM's ability to detect SVs and CNVs concordant with traditional cytogenetic methods, including karyotyping and FISH; OGM's ability to detect SVs and CNVs not detected with transitional cytogenetic methods; the utility and ability of OGM to detect diagnostically relevant or pathogenic SVs and CNVs; the ability of OGM and NGS in combination to detect more SVs than when combining karyotyping, FISH and NGS; the potential for OGM to be useful in qualifying subjects for targeted therapies or clinical trials; the utility of OGM for uses described in the publication referenced in this press release; the ability of OGM to re-characterized and better defined complex structural rearrangements when compared to traditional cytogenetic methods; OGM's ability and utility for adoption across a wider spectrum of cancers including blood, bone and soft tissue cancers and the increase in adoption and utilization as an alternative to traditional cytogenetic methods; the utility of OGM for applications in areas reported in this press release; 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: global and macroeconomic events, such as recent and potential 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; changes in the competitive landscape and the introduction of competitive technologies or improvements to existing technologies; the failure of OGM to prove useful for applications in bone and soft tissue cancers; the failure of OGM to detect SVs concordant with traditional cytogenetic methods, including karyotyping and FISH; the failure of OGM to detect SVs and CNVs not detected with transitional cytogenetic methods; the failure of OGM to detect diagnostically relevant or pathogenic SVs and CNVs; the failure of OGM to prove useful for applications described in the publication referenced in this press release; the failure of OGM to be more widely adopted across a wider spectrum of cancers including blood, bone and soft tissue cancers and the increase in adoption and utilization as an alternative to traditional cytogenetic methods; the failure of OGM and NGS in combination to detect more SVs than when combining karyotyping, FISH and NGS; the failure of OGM to be useful in qualifying subjects for targeted therapies or clinical trials; the failure of OGM to prove useful for applications in areas reported in this press release; the failure of OGM to re-characterized and better defined complex structural rearrangements when compared to traditional cytogenetic methods future publications that contradict the findings of the publication referenced in this press release; changes in our strategic and commercial plans; our 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.

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