



Bionano Announces Publication Showing that OGM Identifies Genetic Aberrations in Sarcoma Samples that May Lead to Improved Diagnosis but were Missed by Classical Cytogenetics

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SAN DIEGO, April 03, 2024 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO), today announced the publication of a peer-reviewed study that compared optical genome mapping (OGM) to classical cytogenetic techniques used for analysis of solid tumor cancer samples consisting of soft tissue and bone sarcomas, including fluorescence *in situ* hybridization (FISH) and karyotyping (KT). OGM demonstrated high levels of concordance with FISH and KT but was also shown to exclusively detect alterations in known oncogenes and tumor suppressor genes and to identify additional pathogenic aberrations, including chromothripsis and chromoplexy, that were not detected by multiple other cytogenetic methods.

Sarcomas represent over 100 histological subtypes and are highly heterogenous in their genetic landscape and prognosis. Accurate diagnosis of these tumors is dependent on the identification of underlying genetic aberrations, which can include large, and often complex, structural variants (SVs) or copy number variants (CNVs) involving oncogenes or tumor suppressor genes. The detection of SVs and CNVs remains challenging and typically requires multiple traditional cytogenetic techniques. In this study, researchers demonstrated OGM's ability to detect aberrations as small as 500 bp, which is approximately 10,000-fold higher resolution than that of KT. As shown in this study, OGM can provide better characterization of the genomic complexity of sarcoma samples when compared to traditional cytogenetic techniques, due to the workflow's high resolution and comprehensive, genome-wide analysis.

Key findings:

- OGM was concordant with traditional methods for the detection of pathogenic variants in 32 out of 35 cases (91%)
- OGM detected loss of *CDKN2A/B* in 9 out of 38 cases (24%), all missed by classical methods, which is associated with poor prognosis in soft tissue sarcomas
- OGM uniquely detected chromothripsis in 9 out of 35 cases (26%)
- In 5 out of 25 cases (20%) with diagnostic fusions, OGM showed that chains of rearrangements generated the fusions, three of which involved chromoplexy

"Characterization of sarcoma is enormously challenging and requires several different techniques, which often yield equivocal results that don't explain the underlying disorder. We are pleased to see results from this study on the use of OGM to investigate sarcomas, which provided the study authors with insights into the genomic complexity underlying various aberrations, highlighting the high sensitivity and robustness of our workflow and enhancing our understanding of tumor biology. We believe this study is an important advancement for OGM and for the cancer research community as it now illustrates the utility of OGM not only in cancer, but in an important solid tumor," commented Erik Holmlin, PhD, president and chief executive officer of Bionano.

The publication can be viewed [here](#).

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 "believe," "can," "may" 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 to detect aberrations as small as 500 bp; the potential of OGM to deliver concordant results with traditional cytogenetic methods; the ability of OGM to uniquely identify SVs when compared to traditional cytogenetic methods; the ability of OGM to detect pathogenically relevant SVs in sarcomas; the future potential for OGM to provide improved diagnoses of sarcomas when compared to traditional cytogenetic techniques; 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 conflicts between Ukraine and Russia and Israel and Hamas, and related sanctions, and any global pandemics, inflation, or supply disruptions, 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; the failure of OGM to detect aberrations as small as 500 bp; the failure of OGM to deliver concordant results with traditional cytogenetic methods; the failure of OGM to uniquely identify SVs when compared to traditional cytogenetic methods; the failure of OGM to detect pathogenically relevant SVs in sarcomas; the failure of OGM to provide improved diagnoses of sarcomas when compared to traditional cytogenetic techniques; future study results that contradict or 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, 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 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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