Bionano Announces Publication Showing that OGM Identifies Variant that Indicates Use of Proven Therapy in Acute Promyelocytic Leukemia

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- *A case study published by researchers at Johns Hopkins University showed that optical genome mapping (OGM) detected a structural variant that was missed by karyotyping and non-informative by FISH, which they classified as a PML::RARA fusion known to occur in acute promyelocytic leukemia (APL)*
- *The researchers reported that APL, an aggressive subtype of acute myelogenous leukemia (AML), responds well to treatment with all-trans retinoic acid (ATRA) and arsenic trioxide (ATO) classes of targeted therapies but that in about 13% of cases of APL, conventional cytogenetics fails to identify the variant(s) that indicate(s) these treatment*
- *Identification of this PML::RARA fusion variant by OGM is consistent with previously reported findings which show that OGM can detect variants found by standard cytogenetics and can also find additional variants that are missed by these techniques*

SAN DIEGO, Jan. 07, 2025 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced a publication from the Johns Hopkins University School of Medicine in *Genes* showing that optical genome mapping (OGM) identifies a variant in an aggressive form of acute myelogenous leukemia (AML) known as acute promyelocytic leukemia, or APL. This variant is often missed by conventional cytogenetic techniques.

In the case study, researchers reported that OGM detected a structural variant that was missed by karyotyping and non-informative by FISH, which they classified as a *PML::RARA* fusion known to occur in APL. According to the publication, APL is a subtype of AML that responds well to treatment with all-trans retinoic acid (ATRA) and arsenic trioxide (ATO) classes of targeted therapies but that in about 13% of cases of APL, conventional cytogenetics either fails or is unable to clearly identify the variant(s) that indicate(s) these treatment(s). Notably, identification of this *PML::RARA* fusion variant by OGM is consistent with previously reported findings which show OGM can detect variants found by standard cytogenetics but can also find likely pathogenic variants that are missed or deemed uninterpretable by these techniques.

Erik Holmlin, president and chief executive officer of Bionano, commented, “This case study supports the view that the standard of care techniques used for devastating diseases like blood cancer are insufficient to reliably guide therapy selection and patient management, due to their tendency to miss actionable variants for a significant fraction of cases. It also shows that OGM, with its higher resolution, streamlined workflow and ability to find more variants, can be a suitable alternative to these techniques, and could result in better therapy selection and patient management decisions.”

The full research publication is available at: Optical Genome Mapping Reveals Complex and Cryptic Rearrangement Involving PML::RARA Fusion in Acute Promyelocytic Leukemia.

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 “ability,” “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 ability to detect variants undetected by traditional cytogenetic techniques; OGM’s ability to detect the PML::RARA fusion in acute promyelocytic leukemia (APL); the potential utility that variants detected by OGM may have in therapy selection or patient management decisions; the utility of OGM for uses described in the publication referenced in this press release; the utility and ability of OGM to detect variants missed by 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: 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 detect variants undetected by traditional cytogenetic techniques; the failure of OGM to detect the PML::RARA fusion in acute promyelocytic leukemia (APL); the failure of OGM to prove useful in therapy selection or patient management decisions; the failure of OGM to be useful for the applications described in the publication referenced in this press release; the failure of OGM to detect variants missed by traditional cytogenetic techniques; 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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