



Bionano Announces Publication of First Multi-Site Study to Analyze the Utility of OGM in Multiple Myeloma

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SAN DIEGO, July 23, 2024 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO), today announced the publication of the first multi-site study in multiple myeloma (MM) comparing optical genome mapping (OGM) to traditional cytogenetic methods for the detection of structural variants (SVs).

Multiple myeloma is a type of blood cancer originating in the plasma cell, known as a plasma cell neoplasm (PCN), and though sensitive and accurate identification of genetic abnormalities in MM samples is critical for patient risk stratification, predication of response to therapy options, and understanding of pathogenesis, many genome analysis methodologies, including fluorescence *in situ* hybridization (FISH) and chromosomal microarray (CMA), are limited in their ability to detect complex gene rearrangements in PCN samples. Additionally, karyotype (KT) fails for PCNs at a higher rate than for leukemias because plasma cells are fragile and grow poorly in culture, leaving additional unmet need. Because OGM doesn't require culture, it may be well suited to fill this gap.

In this study, conducted by researchers at University of Texas MD Anderson Cancer Center and The Johns Hopkins Hospital, researchers concurrently analyzed 45 PCN samples using KT, FISH, OGM, and next-generation sequencing (NGS). OGM uniquely identified complex genomic rearrangements that are associated with cancer proliferation and progression, resulting in a change in prognostication beyond that indicated by traditional cytogenetic analysis in 18% of cases. In at least five cases (11%), OGM's unique findings provided precise information to predict response to target therapies like BCMA monoclonal antibody, CAR-T, or GPRC5D targeted therapies, which may have therapeutic implications. The study results highlight OGM's ability to provide researchers with a highly sensitive, accurate genome-wide analysis that can lead to a more comprehensive understanding of genetic subtypes in PCN when compared with FISH and KT.

Key findings:

- Compared to FISH, OGM achieved 100% sensitivity, specificity, and accuracy in cases after CD138 selection and 96.6% sensitivity, 100% specificity, and 98.3% accuracy in unselected cases
- OGM detected gains of chromosome 1q in several samples, a known high-risk factor in MM
- OGM revealed 18 hyperdiploidy, 4 hypodiploidy, and 9 *IGH* or *MYC* rearrangements undetected by FISH
- In 18% of cases (8 out of 45), OGM identified chromoanagenesis that was undetected by FISH
- In 18% of cases (8 out of 45), OGM changed the prognostication beyond that indicated by standard cytogenetics/FISH analysis
- OGM detected 366 novel structural variants and copy number variants that are potentially relevant to the formation and development of MM

"Though many research studies demonstrate OGM's utility in leukemias and other blood cancers, we were pleased to see robust findings from the first multi-site study of OGM in multiple myeloma, which is a blood cancer that is more difficult for researchers to assess. OGM has the potential to identify pathogenically relevant variants missed by other methods that further our understanding of MM, which we believe may lead to greater adoption of the workflow in labs focused on cancer research," 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 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 isotachopheresis (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.

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 "ability," "believe," "can," "may," "potential," 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 and utility of OGM to detect SVs missed by other cytogenetic methods, including KT, FISH, and CMA; the ability and utility of OGM to provide highly sensitive, accurate genome-wide analysis, that can lead to a more comprehensive understanding of genetic subtypes in PCN when compared with FISH and KT; the ability and utility of OGM to detect SVs relevant to multiple myeloma; the ability of OGM to provide results that are concordant traditional methods, including FISH and KT; the ability of OGM to detect SVs that are relevant to prognostication; 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 SVs missed by other cytogenetic methods, including KT, FISH, and CMA; the failure of OGM to provide highly sensitive, accurate genome-wide analysis, that can lead to a more comprehensive understanding of genetic subtypes in PCN when compared with FISH and KT; the failure of OGM to detect SVs relevant to multiple myeloma; the failure of OGM to provide results that are concordant traditional methods, including FISH and KT; the failure of OGM to detect SVs that are relevant to prognostication; 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; our ability to effectively manage our uses of cash, and our ability to continue as a "going concern"; the ability of institutions to obtain funding to support adoption or continued use of our technologies; 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.

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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