Bionano Announces Publication of a Study that Applied OGM to Discovery of Structural Variants Driving Drug Resistance and Sensitivity in Cancer

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SAN DIEGO, Jan. 25, 2024 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced a peer-reviewed publication in *Cancers* from a team of cancer researchers primarily at the NCI-Designated Cancer Center, Sanford Burnham Prebys Medical Discovery Institute and Scripps MD Anderson in La Jolla, California. The publication describes what could be the first study to use optical genome mapping (OGM) for the discovery of structural variants (SVs) that drive drug resistance and sensitivity in cancer.

Study Design

Patient Samples. The study analyzed 26 leukemia samples from 23 subjects, including 3 samples from subjects after relapse.

Genome Variation Signatures. The study compared genome variation signatures obtained from the leukemia samples by OGM and by classical cytogenetic methods including karyotyping (KT) and fluorescence *in situ* hybridization (FISH).

Drug Library. The study used a broad collection of 120 cancer drugs based on the Oncology Drug Library (ODL, ODL2 and ODL3) and the FDA-approved oncology collection drugs from the NCI's Developmental Therapeutics Program, including some experimental agents and those in phase II/III trials.

Drug Resistance & Sensitivity Assay. The study used a cell viability and drug screening assay based on growing leukemia-enriched cell collections in the presence of different concentrations of drug agents to measure cell viability. Cells that grew well in the presence of drugs were determined to be resistant and those that didn't were determined to be sensitive.

Key Findings

Overall, the study shows that OGM for SV detection combined with drug sensitivity data for the same samples is a useful approach to identifying potentially pathogenic SVs that may be drivers of drug sensitivity or resistance.

Key findings are as follows:

- OGM detected all SVs that had been observed using classical cytogenetic methods as well as multiple additional variants that were not previously reported
- *BCR-ABL1* translocated leukemia samples are sensitive to the tyrosine kinase inhibitor Nilotinib, as expected, but exhibit resistance to proteasome inhibitors
- Drug sensitivities associated with previously unreported genomic rearrangements were revealed
- Leukemia samples with *KMT2A* translocations are associated with drug sensitivities to the microtubule disruptors Paclitaxel and Cabazitaxel and resistance to Bcl-2 family inhibitors
- Chemosensitivity associations with SVs detected by OGM are able to reveal several potential new treatment strategies for leukemia

"This paper represents incredibly well-done research that demonstrates the potential biological and clinical significance of structural variants and the ability of OGM to detect SVs in a reliable and efficient sample to answer workflow. SVs are historically underrepresented in genomics studies due to limitations associated with classical cytogenetic methods and sequencing. We are pleased to see this type of biomarker discovery research and hope it will lead others to conduct more studies, which we believe will help pharmaceutical companies develop better drugs and clinicians provide the right drugs to the right patients," commented Erik Holmlin, PhD, president and chief executive officer of Bionano.

The paper is available at: https://www.mdpi.com/2072-6694/16/2/418.

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 isotachophoresis (ITP) technology. For more information, visit www.bionano.com, www.bionanolaboratories.com or www.purigenbio.com.

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,” “could,” “potential,” “will” 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: the ability and utility of OGM to detect SVs in leukemia samples; the ability and utility of OGM to detect SVs that drive drug resistance and sensitivity in cancer; the ability and utility of OGM to detect SVs compared to classical cytogenetic methods, including FISH and KT; the ability and utility of OGM to detect SVs in a reliable and efficient sample to answer workflow; the ability and utility of OGM to detect novel causative or pathogenic SVs associated with drug efficacy and resistance; and execution of our stated strategies and plans. 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 potential future 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; the failure of OGM to detect SVs in leukemia samples; the failure of OGM to detect SVs that drive drug resistance and sensitivity in cancer; the failure of OGM to detect SVs compared to classical cytogenetic methods, including FISH and KT; the failure of OGM to detect SVs in a reliable and efficient sample to answer workflow; the failure of OGM to detect novel causative or pathogenic SVs associated with drug efficacy and resistance; study results that differ or contradict the results reported in the study referenced in this press release; changes in the competitive landscape and the introduction of competitive technologies or improvements to existing technologies; changes in our strategic and commercial plans; our need and 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, 2022 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.

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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