Bionano Announces Three New Peer-Reviewed Studies Demonstrate Clinical Value of Bionano's Optical Genome Mapping Across Myelodysplastic Syndromes and Acute Myeloid Leukemia

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Independent research teams at MD Anderson Cancer Center, the University of Oulu, and the Josep Carreras Leukaemia Research Institute report that optical genome mapping (OGM) uncovers clinically significant genomic alterations missed by conventional cytogenetics, with direct implications for risk stratification across MDS, AML, and therapy-related myeloid neoplasms

SAN DIEGO, Sept. 14, 2026 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today highlighted three new independently authored, peer-reviewed publications demonstrating the clinical utility of OGM in high-risk hematologic malignancies — myelodysplastic syndromes (MDS), acute myeloid leukemia (AML), and therapy-related myeloid neoplasms (t-MN). The studies, published in Modern Pathology, the International Journal of Cancer, and npj Precision Oncology, reinforce a growing body of evidence that OGM can detect prognostically important structural genomic alterations that elude standard karyotyping, FISH, and targeted sequencing panels.

MD Anderson Cancer Center: Chromoanagenesis by OGM defines an ultra-high-risk MDS subset.

Researchers at The University of Texas MD Anderson Cancer Center, led by Guilin Tang, PhD, used OGM to study 332 samples from subjects with MDS, identifying chromoanagenesis (CAG), a catastrophic single-event genomic restructuring process, in 15.9% of cases overall and 17.6% of newly diagnosed subjects. The study, published in Modern Pathology (Wei et al., 2026), found that:

- CAG-positive by OGM subjects had a median overall survival of just 9.9 months, significantly shorter than non-CAG subjects where median survival was not reached.
- CAG by OGM showed the potential to confer prognostic information beyond existing risk-stratification systems, potentially enabling the identification of patients for early allogeneic transplantation or TP53-targeted clinical trials.

University of Oulu: Cryptic structural variants uncovered in "normal karyotype" AML.

A separate study from the University of Oulu and collaborators, led by Tuomo Mantere, PhD, used OGM to analyze 48 samples of cytogenetically normal AML (CN-AML) — a subgroup that appears unremarkable on standard karyotyping but is clinically heterogeneous. Published in the International Journal of Cancer (Turtinen et al., 2026), the study found that:

- OGM detected clinically relevant structural variants or copy-neutral loss-of-heterozygosity in 46% of cases classified as "normal" by conventional karyotyping.
- Recurrent alterations included KMT2A partial tandem duplications (10% of cases), RUNX1 disruptions, NF1 deletions, and a novel putative FOXP1:EYA2 fusion not previously reported in the literature.
- Subjects with OGM-detected abnormalities had significantly worse overall survival than those without ($p = 0.005$).

Josep Carreras Leukaemia Research Institute: OGM refines risk in therapy-related neoplasms and younger MDS.

A multicenter Spanish study led by Mar Mallo, PhD, and Francesc Solé, PhD, at the Josep Carreras Leukaemia Research Institute in collaboration with a Spanish hospital network applied OGM to two clinically distinct: 48 subjects with therapy-related myeloid neoplasms (t-MN) and 65 subjects with younger-onset MDS (yMDS, age ≤60). Published in npj Precision Oncology (Mestre et al., 2026), the study found that:

- OGM was interpretable in 100% of samples, including all 8 cases where conventional banding analysis (CBA) failed due to lack of dividing cells, and identified 134 additional genomic alterations.
- OGM refined cytogenetic classification in 52.0% of karyotypically abnormal cases and detected clinically relevant structural alterations in 9.8% of cases with a normal karyotype, including reclassification of subjects into the therapeutically relevant MDS with isolated 5q- category.
- OGM-defined genomic complexity was independently associated with overall survival; chromoanagenesis emerged as the strongest independent predictor of inferior survival in multivariable analysis (HR 9.26), exceeding even TP53 mutation status.
- Integrating OGM findings into IPSS-R and IPSS-M scoring shifted 16.7% of t-MN and up to 12.8% of yMDS subjects into higher-risk prognostic categories, which could have implications for treatment planning, including identification of biallelic TP53 inactivation.

Key highlights across all three studies:

- Three independent academic centers, spanning the U.S., Finland, and Spain, each show the potential for OGM to identify clinically actionable genomic complexity that conventional cytogenetic workups miss.
- All three studies link OGM findings directly to overall and/or disease-specific survival.

- Findings support a potential role for OGM in refining prognostication beyond IPSS-R/IPSS-M and ELN2022 classification systems, including in patients who otherwise appear lower-risk by standard testing, and in cases where conventional karyotyping fails outright due to lack of dividing cells.
- Across all three cohorts, chromoanagenesis and TP53 disruption consistently emerge as markers of a biologically distinct, ultra-high-risk disease subset best captured by genome-wide structural variant detection.

"These three independent studies, spanning MDS, AML, and therapy-related myeloid neoplasms, all point to the same conclusion: a meaningful fraction of high-risk genomic complexity in myeloid malignancies is simply invisible to conventional karyotyping," said Al Luderer, PhD, chairman and interim chief executive officer of Bionano. "As OGM adoption continues to expand, we expect to see more of this kind of evidence connecting structural variant detection directly to potential patient outcomes and treatment decisions."

Turtinen et al.: https://doi.org/10.1002/ijc.70548
Wei et al.: https://doi.org/10.1016/j.modpat.2026.101031
Mestre et al.: https://doi.org/10.1038/s41698-026-01671-z

About Bionano Genomics
Bionano is a provider of genome analysis solutions that 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. Bionano offers OGM solutions for applications across basic, translational, and clinical research, as well as an industry-leading, platform-agnostic genome analysis software solution and nucleic acid extraction and purification solutions using proprietary isotachophoresis (ITP) technology. Through its 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 safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this press release, including statements regarding our future results of operations or financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. Words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” 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 forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our expectations regarding market adoption of our products; our commercial prospects and future financial and operating results; and the utility of OGM for the applications referenced in this press release. Each of these forward-looking statements involves risks and uncertainties. Accordingly, investors and prospective investors are cautioned not to place undue reliance on these forward-looking statements as they involve inherent risk and uncertainty (both general and specific) and should note that they are provided as a general guide only and should not be relied on as an indication or guarantee of future performance. There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to: our ability to improve our margins, extend our cash runway and reach a potential pathway to profitability; our ability to continue as a going concern as disclosed in our filings with the SEC, which requires us to manage costs and obtain significant additional financing to fund our strategic plans and commercialization efforts; our ability to execute on our strategy and achieve our objectives; the impact and utility of our cost savings initiative and our recent financing; our ability to continue to drive OGM (as defined above) adoption by potential customers for routine use in genomic analysis; the impact, or lack thereof, of Category I CPT codes to accelerate or increase the adoption of OGM; continued research, presentations and publications involving OGM and its utility compared to traditional cytogenetics and our technologies; the impact of our Stratys™ system and VIA™ software to increase throughput and simplify analysis of OGM data; our ability to drive adoption of OGM and our technology solutions; our ability to further deploy new products and applications for our technology platforms; our expectations and beliefs regarding future growth of the business and the markets in which we operate; our ability to consummate any strategic alternatives including the risk that if we fail to obtain additional financing we may seek relief under applicable insolvency laws; the size and growth potential of the markets for our products, and our ability to serve those markets; the rate and degree of market acceptance of our products; our ability to manage the growth of our business and integrate acquired businesses; the fact that we are limited to “research use only” with respect to many of the materials and components used in our consumable products including our assays; our ability to expand our commercial organization to address effectively existing and new markets that we intend to target; the impact from future regulatory, judicial, and legislative changes or developments in the U.S. and foreign countries; our ability to compete effectively in a competitive industry; the introduction of competitive technologies or improvements in existing technologies and the success of any such technologies; the performance of our third-party contract sales organizations, suppliers and manufacturers; our ability to attract and retain key scientific or management personnel; the accuracy of our estimates regarding expenses, future revenues, reimbursement rates, capital requirements and needs for additional financing; the impact of adverse geopolitical and macroeconomic developments, such as recent and future bank failures, ongoing international conflicts, and related sanctions, regional or global pandemics, inflation, tariffs, increased cost of goods, supply chain issues, and global financial market conditions; on our business and operations, as well as the business or operations of our suppliers, customers, manufacturers, research partners and other third parties with whom we conduct business and our expectations with respect to the duration of such impacts and the resulting effects on our business; our ability to realize the anticipated benefits and synergies of our prior and any future acquisitions or other strategic transactions; our ability to attract collaborators and strategic partnerships; 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 (“SEC”), including, without limitation, our Annual Report on Form 10-K for the year ended December 31, 2025, any subsequently filed Quarterly Reports on Form 10-Q and in other filings subsequently made by us with the SEC. 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, except as may be required by law.

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