



International Consortium for Optical Genome Mapping Publishes Expert Recommendations for Integration of OGM as a Standard-of-Care Cytogenetic Assay for Diagnostic Workflows in Blood Cancers

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SAN DIEGO, May 02, 2025 (GLOBE NEWSWIRE) -- Bionano Laboratories, a wholly-owned subsidiary of Bionano Genomics, Inc. (Nasdaq: BNGO) that offers CLIA-certified laboratory developed tests (LDTs) based on optical genome mapping (OGM), today announced the publication in the *American Journal of Hematology* of expert recommendations from the International Consortium for Optical Genome Mapping (ICOGM) for the integration of OGM as a standard-of-care (SOC) cytogenetic assay for diagnostic workflows in various clinical settings.

Nineteen (19) experts from the ICOGM, representing relevant multidisciplinary fields, conducted an in-depth review of the classification of hematolymphoid malignancies using the World Health Organization (WHO, 5th ed.) and ICC (International Consensus Classification) criteria and published studies of OGM performance to assess whether OGM could provide a comprehensive analysis of the genome sufficient for better diagnosis, prognosis and treatment compared to existing SOC workflows across several indications. Based on the assessment, the ICOGM developed a set of expert recommendations for OGM (A) as a first-line test in place of karyotyping, fluorescent *in situ* hybridization (FISH) and chromosomal microarray analysis (CMA) in some clinical settings; or (B) as an alternative to the traditional methods in other clinical settings when these traditional methods are insufficient.

Summary of Key Recommendations for Clinical Use of OGM:

A. OGM is recommended as a first-line test for AML, MDS, MPN, B-ALL, T-ALL, pediatric leukemias and unexplained eosinophilia and myeloid/lymphoid neoplasms with eosinophilia:

OGM is recommended as a first-line cytogenetic tool in place of conventional karyotyping and FISH (except for rapid *PML::RARA* detection in APL) when high-resolution genome-wide structural variation (SV) detection is required.

1. OGM allows for the identification of cryptic fusions of genes for which targeted therapy may be available (e.g. *KMT2A*, *MECOM*, *NUP98*)
2. OGM avoids the need for large FISH panels or multiple orthogonal assays
3. OGM's unbiased detection improves risk stratification and guides targeted therapy

B. OGM is recommended as an alternative to karyotyping/FISH/CMA for CLL, Plasma cell neoplasms/Multiple Myeloma, aplastic anemia, bone marrow failure syndromes and germline predisposition syndrome:

1. Conventional karyotyping fails or yields no metaphases
2. FISH/CMA do not detect known abnormalities despite clinical suspicion
3. Complex or ambiguous chromosomal abnormalities need resolution
4. Low-frequency or rare hematologic malignancies require cost-effective broad analysis
5. Additional structural variant data may impact diagnostic clarity or therapy decisions
6. For CLL/SLL; OGM as a viable alternative to FISH and CMA, except for low-level *TP53* deletions.
7. For plasma cell disorders, OGM is recommended to be effective when used with CD138 enrichment

"We believe this publication is a landmark for the global clinical cytogenomics community. The consensus from a global panel of experts confirms that OGM-based assays, like the LDTs we offer at Bionano Laboratories, can replace or be used to augment tests based on traditional methods. The drivers behind these recommendations are the ability of our OGM LDTs to yield higher diagnostic clarity within a simplified laboratory workflow that is more cost effective with a faster turnaround time. These expert recommendations establish that OGM-based LDTs are aligned with the latest diagnostic (WHO5, ICC) and prognostic (comprehensive cytogenetic scoring system (CCS), revised international prognostic scoring system (IPSS-R) and molecular international prognostic scoring system (IPSS-M)) classification systems for hematologic malignancies. It's a win for our laboratory, for clinicians and, more importantly, for patients," commented Dr Alka Chaubey, PhD, FACMG, chief medical officer of Bionano.

For more information or to read the full publication, visit: <https://doi.org/10.1002/ajh.27688>

About Bionano Laboratories:

Lineagen, Inc. d/b/a Bionano Laboratories provides access to genetic answers and support utilizing cutting-edge technologies to advance the way the world sees the genome. Its clinical diagnostics services offer optical genome mapping (OGM) testing that combines a comprehensive testing portfolio with thoughtful and accessible support options. Bionano Laboratories also offers direct access to OGM for applications across basic, translational and clinical research. For more information, visit www.bionanolaboratories.com

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, www.bionanolaboratories.com or www.purigenbio.com.

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,” “believe,” “can,” “could,” “may,” 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 be an alternative to traditional cytogenomic methods as described in the publication referenced in this press release; the ability and utility of OGM to become a SOC cytogenetic assay for diagnostic workflows in various clinical settings as described in the publication referenced in this publication; and the ability of OGM to be implemented in clinical settings. 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 impact of adverse geopolitical and macroeconomic events, such as bank failures, the ongoing conflicts between Ukraine and Russia and in the Middle East and related sanctions, regional or global pandemics, uncertain market conditions, including tariffs and inflation, and supply chain disruptions on our business and the global economy; the failure of OGM to be an alternative to traditional cytogenomic methods as described in the publication referenced in this press release; the failure of OGM to become a SOC cytogenetic assay for diagnostic workflows in various clinical settings as described in the publication referenced in this publication; the failure of OGM to be implemented in clinical settings; the ability of the OGM workflow to offer the anticipated benefits for and contributions to the areas reported in the publication referenced in this press release; future recommendations contradicting the recommendations reported in the publication referenced in this press release; general market conditions; . 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