Bionano Genomics Announces Publication of Comprehensive Validation of Optical Genome Mapping for Hematologic Neoplasms

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Key findings from evaluation of 59 Heme Samples and 10 Controls:

- *OGM detected 162/164 SVs detected by standard cytogenetics methods of karyotyping and FISH*
- *OGM detected chromosomal aberrations missed by karyotyping and FISH in 35 cases*
- *OGM Sensitivity: 98.7%*
- *OGM Specificity: 100%*
- *Positive Predictive Value: 100%*
- *Negative Predictive Value: 98%*
- *OGM Accuracy: 99.2%*
- *First-Pass Success Rate: 100%*
- *Limit of Detection (LOD) for* aneuploidies, translocations, interstitial deletions and duplications at 400X: 5% variant allele fraction

SAN DIEGO, March 18, 2022 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO), pioneer of optical genome mapping (OGM) solutions on the Saphyr® system and provider of N_XClinical™, the leading software solution for visualization, interpretation and reporting of genomic data, today announced the publication of comprehensive study results validating OGM for routine production use for genome-wide structural variant (SV) detection in hematological neoplasms.

This study, published by researchers from Emory University, Augusta University and Bionano, reported that OGM demonstrated robust performance across multiple technical and analytical metrics and recommended OGM as a potential first-tier cytogenetic test for the evaluation of hematological neoplasms. These results support the potential for OGM's use in settings where standardization is critical, such as clinical trials, and may help characterize genomic variants in hematological malignancies to stratify subjects or identify new therapeutic targets.

Researchers used 69 unique samples comprised of 59 hematological neoplasms (CLL, AML, MDS, MM, lymphoma, PCM, CML, ET and others*) and 10 phenotypically normal and cytogenetically negative samples for controls. The 59 hematological neoplasms consisted of 43 simple and 16 complex cases, which included all classes of SVs.

Within the 59 heme samples, OGM showed a 98.7% sensitivity and 100% specificity for detecting SVs previously reported with karyotyping and fluorescence in situ hybridization (FISH). Additionally, 35 of 43 simple cases had at least one clinically reported aberration, and OGM detected all of the reported variants, found additional aberrations in 23 cases, and corrected putative false-positive results in two of the cases. In complex cases, OGM revealed the identity of 12 marker chromosomes and one ring chromosome and found additional SVs, including 145 translocations and 67 putative novel gene fusions.

To evaluate technical and analytical reproducibility, inter-run, intra-run and inter-instrument comparisons were performed on six samples in triplicates. OGM demonstrated 100% reproducibility and a LoD of 5% for aneuploidies, translocations, interstitial deletions and duplications at 400x coverage.

"Increasingly, the body of evidence available on the performance of OGM in hematological malignancies demonstrates high performance and utility, but this study put OGM's performance to the test in a more routine, analytical environment," said Alka Chaubey, PhD, FACMG, chief medical officer at Bionano and one of the study authors. "OGM met or exceeded all tested laboratory quality measures."

Erik Holmlin, PhD, president and chief executive officer of Bionano commented, "This study shows the possibilities of OGM and why labs around the world are adopting it. The team at Augusta is one of the most experienced at practicing OGM and so we view this performance as setting a bar that others can aim to achieve. We are enthusiastic about working with the market and our own services lab and look forward to seeing these results performed consistently across our installed base."

This publication is available at: https://www.medrxiv.org/content/10.1101/2022.03.14.22272363v1

**Chronic Lymphocytic Leukemia (CLL), Acute Myeloid Leukemia (AML), Myelodysplastic Syndromes (MDS), Multiple Myeloma (MM), Plasma Cell Myeloma (PCM), Myeloproliferative Disorder (MPD), Chronic Myeloid Leukemia (CML), Essential Thrombocythemia (ET)*

About Bionano Genomics

Bionano Genomics 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 business, the Company also provides diagnostic testing for patients with clinical presentations consistent with autism spectrum disorder and other neurodevelopmental disabilities. Through its BioDiscovery business, 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. For more information, visit bionanogenomics.com, lineagen.com or biodiscovery.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 "may," "will," "expect," "plan," "anticipate," "estimate," "intend," "believe" 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 performance of OGM across metrics, its ability to meet regulatory standards and perform in settings where standardization is critical, expectations as to additional evidence supporting OGM, expectations about the installed base to consistently provide results similar to those in the study referenced in this press release, and the potential for OGM to become the standard of care within hematological neoplasm testing. 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 the COVID-19 pandemic on our business and the global economy; general market conditions; changes in the competitive landscape and the introduction of competitive technologies or improvements in existing technologies; the article that is referenced in this press release has not been peer reviewed, has not been finalized by the authors, may contain errors and reports information that has not been accepted by the scientific or medical community and is therefore subject to change; failure of future study results to support those demonstrated during the study 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; 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, 2021 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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