Bionano Genomics Announces Publication of the First Study to Combine OGM and NGS to Evaluate Myeloid Cancers

January 26, 2022

- *Whole genome analysis by OGM together with analysis using a 523-gene NGS panel can perform better and cost less than analysis with karyotyping, FISH, and a 54-gene NGS panel*
- *First study to publish results using N_XClinical software for simultaneous visualization and interpretation of sequence and copy number variants from NGS and OGM data*

SAN DIEGO, Jan. 26, 2022 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (BNGO), pioneer of optical genome mapping (OGM) solutions on the Saphyr® system and provider of N_XClinical™, the leading software solutions for visualization, interpretation and reporting of genomic data today announced the publication of a study that evaluated the performance and clinical utility of combining OGM and a 523-gene next-generation sequencing (NGS) panel for comprehensive evaluation of myeloid tumors and compared it to standard cytogenetic methods (karyotyping and fluorescence in situ hybridization (FISH) and a 54-gene NGS panel.

This study reported superior performance as compared to standard methods and marks two major developments in the ongoing evaluation of combined OGM and NGS workflows. This study is the first published example where the combination of workflows was applied in the context of myeloid cancers, and demonstrated higher sensitivity, resolution, accuracy and ability to reveal cryptic and clinically relevant novel variants in myeloid cancers as compared to standard methods. This is also the first study to publish results using the simultaneous visualization and interpretation of sequence and copy number variants (CNVs) in the BioDiscovery N_XClinical software v6.1 from OGM and NGS data.

“This research demonstrated that the combination of OGM and a 523-gene NGS panel is superior to standard methods and cost effective for comprehensive genomic profiling of myeloid cancers. When compared to whole-genome sequencing approaches that others have suggested, I believe it has better detection performance at a lower cost,” commented Dr. Ravindra Kolhe, Associate Dean for Translational Research at Medical College of Georgia and Director of the Georgia Esoteric and Molecular Laboratory at Augusta University. “With new tools to simultaneously visualize sequence variants and structural variants, we are well-positioned to move this approach into routine use, which we expect will deepen our understanding of hematological malignancies.”

The research, led by Dr. Kolhe’s team at the Medical College of Georgia/Augusta University, evaluated the use of OGM and a 523-gene NGS panel for genomic profiling of 15 myeloid tumors and compared results to karyotyping, FISH, and a 54-gene NGS panel. Results demonstrated 100% analytical concordance of OGM and the 523-gene NGS panel for variants found with traditional methods. In addition, OGM better characterized structural variants (SVs) previously reported by karyotyping in five cases and identified additional translocations and 11 CNVs.

“We believe this publication demonstrates the advantages of performing OGM side-by-side with NGS, for a combined workflow that can provide a more comprehensive, accurate detection of genetic variants at a cost and complexity that is practical for laboratories,” commented Erik Holmlin, PhD, President and Chief Executive Officer of Bionano. “With N_XClinical software that allows for combined visualization of sequence and structural variants, we believe we have provided a tool that can make a combined OGM and NGS approach simple, scalable and superior to traditional methods.”

The study is published online at medRxiv: https://www.medrxiv.org/content/10.1101/2022.01.15.22269355v1?ct=

Forward-Looking Statements of 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 www.bionanogenomics.com, www.lineagen.com or www.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” 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 of combined OGM and NGS workflows to provide a comprehensive evaluation of myeloid cancers, the potential benefits of combining OGM and NGS, including superior performance and cost-effectiveness as compared to SOC methods, and the potential for a combination of OGM and NGS to become the standard of care. 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, including the introduction of competitive technologies or improvements in existing technologies; failure of future study results to support those 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, 2020 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@bionanogenomics.com

Investor Relations:
Amy Conrad
Juniper Point
+1 (858) 366-3243
amy@juniper-point.com

Media Relations:
Michael Sullivan
Seismic
+1 (503) 799-7520
michael@teamseismic.com

Source: Bionano Genomics