Day Two of Bionano's Next-Generation Cytogenomics Symposium: Saphyr Outperforms Standard Cytogenetics in Heme Malignancies, is Less Expensive, Provides Actionable Information Faster, in Single Assay

January 13, 2021

1. *Global customer consensus on Saphyr's capability to identify actionable variants in hematological malignancies detected by several cytogenomic methods combined*

2. *Saphyr identifies additional variants missed by traditional methods that have prognostic and therapeutic value, with a faster turn-around time and lower cost*

3. *KU Leuven Hospitals, Belgium, is implementing a Saphyr-based assay they developed for routine diagnostic use in Acute Lymphoblastic Leukemias in their clinic, replacing or reducing significantly the number of traditional cytogenomic tests*

SAN DIEGO, Jan. 13, 2021 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) announced that day two of its five-day Next-Generation Cytogenomics Symposium featured eight Saphyr users presenting their results and experiences using the Saphyr® system for optical genome mapping (OGM) to analyze the genomes of patients with heme malignancies. The presentations by scientists and clinicians from leading hospitals and medical research institutions in Europe, the US and China discussed results on a variety of blood cancers, including Myelodysplastic Syndromes and a number of acute and chronic leukemias, and all 8 studies showed that Saphyr-based analyses of hematological malignancies can identify actionable variants detected by several cytogenomic methods combined, find additional important variants missed by traditional methods with prognostic and therapeutic value, and can do so with a shorter turn-around time and at a lower cost.

Dr. Tuomo Mantere, University of Oulu, Finland and Radboud University Medical Center, the Netherlands presented an update on published work evaluating OGM for the analysis of 52 patient samples with a variety of forms of leukemia. Saphyr showed 100% concordance with previous findings from the 3 standard cytogenetic methods of karyotyping, fluorescent in-situ hybridization (FISH) and chromosomal microarray (CMA) combined for simple cases. In complex cases it finds more complexity than standard methods could, and more closely represents the actual structure of the cancer genome than current methods.

Dr. Blanca Espinet and Dr. Anna Puiggros, Hospital del Mar in Barcelona, Spain presented their study on Chronic Lymphocytic Leukemia (CLL), comparing Saphyr results on 10 non-complex and 12 complex CLL samples against Cytoscan HD and karyotype. Early conclusions for the study show that Saphyr detected most of the previously known abnormalities but provided additional structural information and detected many additional genomic abnormalities, making it a valuable tool to assess genomic complexity.

Dr. Gordana Raca, Director of the Clinical Cytogenomics Laboratory, Children's Hospital Los Angeles presented on a pilot study on pediatric Acute Lymphocytic Leukemia (B-ALL) comparing the performance of OGM against standard testing. She presented the actionable finding of a druggable gene fusion that was missed by standard methods and not identified by their custom gene panel, since it was not expected in B-ALL, illustrating the importance of genome-wide, unbiased structural variation (SV) detection as provided by Saphyr. In half of the studied samples Saphyr identified complex rearrangements entirely missed by standard cytogenetics because karyotyping requires cells to be cultured. Karyotyping therefore can show a skewed picture of the genome since cancer cells often don't grow well in culture and only the cells that do are analyzed. Saphyr doesn't require culturing, and thus shows the true state of the cancer genome. Dr. Raca concluded that Saphyr showed important results for research applications and for the clinic, that it was able to detect a large number of variants that were missed by karyotyping and that it can identify the mechanisms that generate cancer driving mutations.

Dr. Rashmi Kanagal-Shamanna, Director of the Molecular Diagnostic Laboratory, MD Anderson Cancer Center presented on her work comparing OGM performance on Myelodysplastic Syndromes (MDS) against standard of care methods. She has successfully completed her previously presented pilot study on 12 samples but has since expanded the study to 50 more. She summarized that OGM with Saphyr is a single assay that detects all types of SVs, voiding the need for multiple confirmatory tests, is faster and less expensive, and has immense potential to serve as a high throughput platform for structural variant analysis.

Dr. Valentin Lestringant, CHU Amiens in France compared the performance of OGM against four existing methods in 10 ALL samples. He presented how Saphyr identified three well-described ALL rearrangements creating fusion genes that were missed by all four standard methods.

Dr. Hongxing Liu and Dr. Bo Chen, Lu Daopei Institute of Hematology, Beijing, China presented their analysis with Saphyr of 14 acute leukemias and compared with results from karyotyping, multiplex PCR and RNA-seq. Saphyr identified a total of 10 fusion genes including one never before identified fusion. Of the 10 identified by OGM, 4 were missed by PCR and 5 missed by karyotyping. They concluded that OGM is a powerful tool for SV detection because it has high throughput, high resolution and high accuracy, and unlike PCR-based assays for fusion detection it is unbiased and genome wide.

Barbara Dewaele, PhD, Supervisor of the Laboratory for Genetics of Hematological Malignancies at KU Leuven in Belgium presented on 10 B-ALL and 10 T-ALL samples analyzed with OGM. Their current clinical workflow requires them to run up to 12 tests successively, which is costly, laborious and takes up to 4 weeks. She concluded that Saphyr provided informative results in each case, had no false positives, and identified all known translocations with a turn-around time of just one week. Additionally, Saphyr identified several important variants that were missed by all other

methods.

Based on the results of this study, the KU Leuven hospital is implementing the Saphyr-based assay they developed for the routine diagnosis of B-ALL and T-ALL in their clinic immediately, replacing their multiplex ligation-dependent probe amplification (MLPA) assay entirely, reducing the number of most FISH tests ran on each sample to zero or one, and similarly reducing PCR based tests. They plan to expand its use to AML and CLL leukemias in the near future.

Brynn Levy, PhD, FACMG, Director of the Clinical Cytogenetics Laboratory at Columbia University, presented on the national multicenter evaluation of Saphyr in Acute Myeloid Leukemia, representing a consortium that includes the most important cancer research and treatment centers in the US. The previously reported and published study compared OGM results on 100 AML samples against karyotype, FISH and CMA. Dr. Levy concluded that OGM is concordant with all three traditional cytogenomics tools combined, and provides additional clinically useful information, missed by traditional methods, in 11% of the cases, and better characterizes the identified events in 40% of patients. Saphyr improves on genome analysis for AML patients by combining 3 assays in one, represents a significant time and cost saving, and provides a more objective, automated analysis that would remove subjective testing decisions at individual sites and could potentially remove disparity in healthcare.

The symposium continues throughout the week. The full schedule of speakers and registration access is available at http://bit.ly/3pLPT28

About Bionano Genomics
Bionano is a genome analysis company providing tools and services based on its Saphyr system to scientists and clinicians conducting genetic research and patient testing and providing diagnostic testing for those with autism spectrum disorder (ASD) and other neurodevelopmental disabilities through its Lineagen business. Bionano's Saphyr system is a research use only platform for ultra-sensitive and ultra-specific structural variation detection that enables researchers and clinicians to accelerate the search for new diagnostics and therapeutic targets and to streamline the study of changes in chromosomes, which is known as cytogenetics. The Saphyr system is comprised of an instrument, chip consumables, reagents and a suite of data analysis tools, and genome analysis services to provide access to data generated by the Saphyr system for researchers who prefer not to adopt the Saphyr system in their labs. Lineagen has been providing genetic testing services to families and their healthcare providers for over nine years and has performed over 65,000 tests for those with neurodevelopmental concerns. For more information, visit www.bionanogenomics.com or www.lineagen.com.

Forward-Looking Statements
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 timing and content of the presentations identified in this press release; the effectiveness and utility of Bionano's technology in basic genetic research and clinical settings, and in the contexts and applications contemplated by the presentations identified in this press release; adoption of Saphyr as a standard platform in research and pathology settings; and the execution of Bionano's strategy. 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 products; 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; the loss of key members of management and our commercial team; 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, 2019 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 Contact:
Ashley R. Robinson
LifeSci Advisors, LLC
+1 (617) 430-7577
arr@lifesciadvisors.com

Media Contact:
Darren Opland, PhD
LifeSci Communications
+1 (617) 733-7668
darren@lifescicomms.com

Source: Bionano Genomics