MD Anderson Cancer Center Publication Shows How Bionano's Saphyr System Can Significantly Reduce Time to Actionable Results for Myelodysplastic Syndrome Patients

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1. *In a head-to-head comparison against traditional cytogenomics methods, Saphyr identified all actionable variants, plus important variants missed, improving clinical stratification for patient treatment*

2. *In a single assay with comprehensive detection of relevant variants, Saphyr eliminates need for sequential and confirmatory tests and can transform a multi-week process to actionable results in just 4 days, which may translate to patients being treated sooner*

SAN DIEGO, Jan. 19, 2021 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) announced the publication of a study in medRxiv by a team led by Dr. Rashmi Kanagal-Shamanna, Director of the Molecular Diagnostic Laboratory, the MD Anderson Cancer Center comparing the performance optical genome mapping (OGM) with Saphyr against standard of care methods for the analysis of cancer genomes in patients with Myelodysplastic Syndromes (MDS). MDS is a precursor to Acute Myeloid Leukemia and structural variation analysis is important for clinical management of patients with MDS. The study found that OGM detected all clinically important variants identified by the standard of care methods in a single assay plus several clinically relevant aberrations that were missed by such standard of care methods, that OGM eliminated the need for multiple confirmatory tests, and significantly reduced the turn-around time for results, potentially allowing for treatment decisions to happen sooner so patients can be treated more quickly.

For the clinical work-up of MDS, most well-characterized copy number variations (CNVs) and structural variations (SVs) are identified using a combination of the traditional cytogenetic techniques, including karyotyping for balanced events such as translocations and inversions, chromosomal microarray (CMA) for the detection of CNVs, and multiple fluorescent in-situ hybridization (FISH) tests for the detection of important gene or locus specific aberrations. Several tests are run sequentially after initial data analysis to confirm gene-specific variants, leading to a diagnostic process that can span several weeks.

In this study, Dr. Kanagal-Shamanna evaluated the performance of OGM in a series of 12 previously well-characterized MDS cases using clinical bone marrow samples. OGM successfully facilitated detection and detailed characterization of all 26 clonal chromosomal variants identified with karyotyping and CMA when present above the level of detection sensitivity. Further, OGM uncovered additional clinically relevant aberrations in one third of patients that were undetectable by standard of care technologies, all of which were subsequently confirmed by alternate platforms. OGM permitted precise gene-level mapping of clinically informative genes such as *TP53*, *TET2* and *KMT2A*, which was not previously possible using conventional cytogenetic techniques, voiding the need for multiple confirmatory assays. Overall, OGM served as a single platform assay to identify different types of structural chromosomal alterations of clinical significance.

Rashmi Kanagal-Shamanna, MD, commented: "Currently, the first step of clinical management of MDS patients is prognostic risk-stratification using the R-IPSS scoring system, which is dependent on the number and type of structural variants, degree of cytopenia(s) and bone marrow blast percentage. In our study, OGM was able to comprehensively identify all SVs in a single assay, as well as detect additional SVs of potential clinical significance that were cryptic by standard of care technologies. Moving forward, I envision OGM to be a 'one-stop shop' for high-throughput chromosomal analysis and SV profiling for routine clinical evaluation of MDS and other hematological malignancies."

Erik Holmlin, PhD, CEO of Bionano Genomics, commented: "The MD Anderson Cancer Center is one of the world's most important cancer research and treatment centers. We are proud that several of our Saphyr systems are in use there, and grateful for Dr. Rashmi Kanagal-Shamanna's pioneering work in bringing OGM to patients with hematological malignancies. During our Next-Generation Cytogenomics Symposium, more than 30 speakers from around the world demonstrated Saphyr's ability to identify more actionable variants than standard of care methods in solid tumors and heme malignancies, and pathogenic variants in a variety of genetic disorders. Dr. Kanagal-Shamanna's work is an important demonstration of Saphyr's potential to revolutionize cytogenomic testing with a single assay that provides actionable results faster, with less hands-on time and for a lower cost than required by the current combination of several complex, traditional methods."

The study is available on medRxiv at https://www.medrxiv.org/content/10.1101/2021.01.13.21249611v1

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: Saphyr's capabilities in comparison to and in conjunction with other genome analysis technologies, including in the comprehensive analysis of cancer genomes for patients with MDS; the potential for Saphyr to reduce or eliminate sequential and confirmatory assays and expedite patient treatment; our expectations regarding the adoption of Saphyr as a clinical tool to replace traditional standard of care cytogenomic testing methods; 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.

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