Preliminary Data Confirm Saphyr's Potential to Replace Traditional Cytogenetics Methods for Detection of Structural Variants in Certain Blood Cancers

Strong concordance with standard of care methods shows how Saphyr can transform cytogenetic workflows and provide an approach that may be faster and more cost-effective and may give better results

SAN DIEGO, Tuesday, August 13, 2019 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (NASDAQ: BNGO), a life sciences instrumentation company that develops and markets Saphyr®, a platform for ultra-sensitive and ultra-specific structural variation detection in genome analysis, today announced a summary of results from two key studies presented this week at the 2019 Cancer Genomics Consortium Annual Meeting in Nashville, Tennessee.

In a preliminary read-out of a multi-center clinical validation study using blinded samples, Professor Brynn Levy, Director of Cytogenetics at Columbia University, presented outcomes on the first 11 patient samples analyzed and unblinded. This study compares Saphyr to technologies used in traditional cytogenetics workflows for patient testing in oncology and is being run by a consortium of leading cytogenetics teams at institutions in the United States, including Columbia University, the MD Anderson Cancer Center of the University of Texas, the Mayo Clinic, the University of Washington, Penn State University, Augusta University and the PathGroup. In each of the 11 samples, Saphyr detected all known clinical variants identified by various combinations of karyotype, Fluorescent In-Situ Hybridization (FISH), and Chromosomal MicroArray (CMA), which define the current standard of care in cytogenetics. Some of the variants identified include: in Acute Myeloid Leukemia samples, a large inversion on chromosome 16, which creates a CBFB MYH11 fusion; in one B-Cell Acute Lymphoblastic Leukemia (B-ALL) sample, a BCR-ABL1 translocation, and deletions of tumor suppressor genes IKZF1 and CDK6; and in a separate B-ALL sample, a NF1 deletion, which is a well-known risk factor for childhood leukemia. This detailed characterization of variants allows for a precise treatment tailored to the specific patient's tumor.

During his presentation, Dr. Levy discussed the strong concordance of the size of the deletions and the breakpoints identified by Saphyr with those determined by microarray results. Based on the preliminary results, Dr. Levy concluded that Saphyr has the potential to be a powerful new tool in cytogenomics for assessing chromosome structure and copy number. Upon completion of the clinical validation phase, Dr. Levy's team plans to evaluate the benefits of using the Saphyr system for discovery of novel variants by analyzing samples previously deemed "normal" by karyotype, FISH, and CMA to identify the existence of any recurring abnormalities with prognostic and therapeutic value that may have been missed by traditional methods.

In a second study, Associate Professor Rashmi Kanagal-Shamanna, Microarray Director in the Molecular Diagnostics Lab of the University of Texas MD Anderson Cancer Center, presented results from the analysis of seven patient samples with Myelodysplastic Syndrome (MDS), a precursor to leukemia characterized by the presence of large structural variants. In addition to identifying all clinically relevant variants previously detected by karyotyping and CMA, Saphyr revealed additional structural variants of research interest that were missed by these methods, including deletions of the TP53 and TET2 genes, which have prognostic and therapeutic implications. Use of the Saphyr system further enabled elucidation of a complex rearrangement involving three chromosomes, with deletions and duplications at the breakpoints, all of which were not captured by other cytogenetic methods. Additionally, Saphyr facilitated precise mapping of variants within genomic co-ordinates, especially in cases involving complex rearrangements.

Dr. Kanagal-Shamanna stated that the high concordance between Bionano optical mapping and conventional techniques provides proof-of-concept for potential use of Saphyr as a single-platform for comprehensive assessment of all structural variants, including copy number variants and balanced rearrangements. In hematological malignancies, this eliminates need for cell culture and provides higher resolution than standard of care assays.

Erik Holmlin, PhD, CEO of Bionano, commented, "We are extremely pleased to hear the updates on these studies. We believe they are landmark studies that provide powerful evidence that Saphyr can lead a transformation of traditional cytogenetics as we know it by offering a streamlined workflow and superior results for better outcomes. We are grateful to Dr. Levy and to Dr. Kanaga-Shamanna for their efforts to bring Saphyr to the forefront of clinical applications in oncology and we believe that these results, coupled with Saphyr's improved workflow, can lead to rapid and wide adoption of the platform in the cytogenetics segment."

More information about Bionano Genomics is available at www.bionanogenomics.com

About Bionano Genomics

Bionano is a life sciences instrumentation company in the genome analysis space. Bionano develops and markets the Saphyr system, a 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 drive the adoption of digital cytogenetics, which is designed to be a more systematic, streamlined and industrialized form of traditional cytogenetics. The Saphyr system comprises an instrument, chip consumables, reagents and a suite of data analysis tools.

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 ability of Saphyr to improve treatment of cancer patients; conclusions as to Saphyr's potential as a powerful new tool in cytogenomics; planned studies evaluating the benefits of the Saphyr system in the cytogenetics space; Saphyr's potential contribution to improvements in traditional cytogenetics; and expectations regarding the rate and extent of adoption of the Saphyr system in the cytogenetics segment, and the impact of results from the studies conducted by Dr. Levy and Dr. Kanaga-Shamanna, as well as improvements in Saphyr workflow, in driving adoption. 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 that our sales, revenue, expense and other financial guidance may not be as expected, as well as risks and uncertainties associated with 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 key clinical studies to demonstrate the effectiveness of our products; 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, 2018 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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