Breakthrough Findings in Leukemias Presented at ASH 2019 Demonstrate Bionano Saphyr's Potential to Replace All Cytogenetic Methods and Show Additional Clinical Utility

December 5, 2019

Bionano's new DNA Isolation Kit for Bone Marrow Aspirates enables routine clinical analysis of Leukemia samples.

SAN DIEGO, Dec. 05, 2019 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (NASDAQ: BNGO), a life sciences instrumentation company that develops and markets the Saphyr® System, a genome imaging platform for ultra-sensitive and ultra-specific genome-wide structural variation detection, today announced four leukemia studies using its technology published in the special edition of the prestigious journal Blood prior to the start of the Annual Meeting of the American Society of Hematology (ASH) being held December 7-10th in Orlando, Florida. Bionano is today also announcing the launch of its DNA isolation kit for Bone Marrow Aspirates (BMA), the primary material collected in leukemia patients.

The new Bionano Prep™ SP Bone Marrow Aspirate Kit allows for the consistent isolation of Ultra High Molecular Weight (UHMW) DNA in just 4 hours from what is traditionally a more complex sample type, often containing cell clumps and other insoluble impurities. The Saphyr System analyzes these extremely long molecules to detect all types of structural variants, unbiased, genome-wide, down to 5% variant allele fraction.

Brandon Labarge, MD, from the Penn State Cancer Institute, who had early access to the new DNA isolation method, commented: "Our lab regularly receives BMAs from AML and ALL patients. Prior to the Bionano Prep SP BMA Kit, we did not have a reliable way to purify long molecules of DNA. This kit allows us to quickly and efficiently isolate UHMW DNA from BMA samples to further understand the molecular basis of diseases like AML and ALL using the Bionano Saphyr workflow. Molecular studies like these can ultimately affect how diagnostics tests, clinical trials, and therapies are designed for Leukemia patients."

The four different studies on various leukemias using Bionano technology were published in the November supplemental issue of Blood (Volume 134, Issue Supplement 1), the journal of the American Society of Hematology (ASH).

A team led by Professor Eva Kriegova from the Palacky University and University Hospital Olomouc in the Czech Republic used Bionano's Saphyr to analyze blood samples from patients with Chronic lymphocytic leukemia (CLL), the most common form of leukemia in adults in western countries. Saphyr identified 97% of all abnormalities that were detected by karyotype, FISH, microarray and NGS combined. Additionally, Bionano revealed numerous novel genomic rearrangements in the CLL genomes that were undetectable by standard methods. A study on a larger patient cohort and longer follow-up of patients is needed to determine of these genetic aberrations are associated with the clinical course and therapy response.

Dr. Guillermo Garcia-Manero from the University of Texas MD Anderson Cancer Center in Houston, Texas, led a study on 7 samples of patients with myelodysplastic syndrome (MDS), a precursor to leukemia characterized by the presence of large structural variants. All clinically relevant variants identified by karyotype and microarray were detected by Bionano. Bionano showed additional clinical utility over standard methods by identifying multiple structural variants missed by the standard of care, including the identification of a loss of TP53. This loss in an MDS patient with concurrent TP53 mutation has important prognostic and therapeutic implications.

Dr. Arndt Borkhardt from the Heinrich-Heine-University in Düsseldorf, Germany used Saphyr to identify the likely pathogenic duplication in a child with acute lymphoblastic leukemia (ALL). The team used Saphyr to compare the genomes of the child with both parents and identified a large duplication that contains the DUXAP8 gene, an oncogene that can explain both the blood cancer and the skeletal abnormalities seen in the patient.

Finally, a team led by Blanca Espinet, who leads the translational research group on hematological neoplasms at the Institut Hospital del Mar d'Investigacions Mèdiques (IMIM) in Barcelona, Spain, compared karyotyping and microarray to identify structural variants in CLL. The additional information that Saphyr provides in CLL patients helps elucidate the genomic complexity of these samples and might help predict clinical outcome.

The study by Dr. Espinet is presented at ASH as a poster in session 641on Monday, December 9, 2019, from 6 to 8 pm in Hall B, Level 2 of the Orange County Convention Center). The other studies are available in Blood (2019) 134 (Supplement_1): 5450.

Bionano Genomics will be an exhibitor at the 61st ASH Meeting, Exhibit #128.

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, including among other things, adoption of Saphyr as a routine tool in research and clinical settings and the effectiveness and utility of the Saphyr system in such settings. 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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Source: Bionano Genomics