Dr. Gordana Raca from Children's Hospital Los Angeles Presents Findings That Show Saphyr Detects Druggable Gene Fusions in Pediatric Acute Leukemias that NGS and Cytogenetics Missed

January 29, 2021

SAN DIEGO, Jan. 29, 2021 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) announced a presentation by the Director of the Clinical Cytogenomics Laboratory of Children's Hospital Los Angeles, Dr. Gordana Raca, in which she reported on the performance of optical genome mapping (OGM) for the clinical analysis of pediatric acute leukemias. She demonstrated how OGM with Saphyr detected clinically important structural variants (SVs) that can alter patient care and treatment decisions. These SVs were not detected when the samples were evaluated with a combination of next-generation sequencing (NGS) and three cytogenetic methods that are the standard of care in leukemia testing today. She concluded that OGM would be advantageous in clinical testing because it detects all types of SVs but with better precision, higher resolution and better sensitivity than traditional methods, including next generation sequencing (NGS).

Leukemia accounts for more than a quarter of cancer cases in children and remains the second leading cause of cancer death. Karyotyping and fluorescent in situ hybridization (FISH) do not efficiently detect genetic subtypes, so Children's Hospital Los Angeles (CHLA) currently combines four different methods to characterize their patients' leukemia genomes: karyotyping, extensive FISH panels, chromosomal microarray (CMA), and a custom-designed NGS gene panel for pediatric cancers called OncoKids. Still, 15% of pediatric Acute Lymphoblastic Leukemia (ALL) cases showed no main genetic driver after those four tests.

The study analyzed one Acute Myeloid Leukemia (AML) case and eight ALL cases which had normal karyotypes and tested negative for commonly known genetic drivers by the standard of care in leukemia testing. Among Dr. Raca's findings was that Saphyr detected gene fusions that aided in patient stratification and prognosis, including one gene fusion that can be treated with drugs such as Gleevec. The gene fusions were missed by the traditional techniques because they either had not been reported in pediatric cancer before and were therefore not part of the OncoKids NGS panel, or because they were simply undetectable by standard methods. In seven out of eight cases, OGM detected SVs that CHLA's four separate analysis methods missed. OGM was also able to identify the exact copy number, location and orientation of a repeat in the *PAX5* gene that defines a novel ALL subtype, which other methods were unable to do.

Erik Holmlin, PhD, CEO of Bionano Genomics, commented: "CHLA is one of the top 5 pediatric cancer hospitals in the nation and a pioneer in the use of novel diagnostic and therapeutic tools. Dr. Raca's results with Saphyr demonstrate the importance of comprehensive genome-wide detection of structural variation in pediatric cancers, something no gene panels or current cytogenetic methods can currently provide, which can leave many children without an accurate diagnosis and without optimal clinical care. We believe that as pediatric centers around the world adopt Saphyr for research and develop assays for clinical use, Saphyr will continue to transform cytogenomic testing with a single assay that can provide more actionable results, faster."

A recording of the presentation by Dr. Raca can be viewed on bionanogenomics.com at http://bit.ly/2YlBuxU

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. Bionano provides 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; 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.

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