Saphyr Study Is First to Analyze Cancer Regulation at Level of Single DNA Molecules, Opens Promising New Avenue of Cancer Research

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Publication on novel Saphyr based method to analyze DNA methylation in cancer genomes enables new field of cancer research and drug target discovery

SAN DIEGO, Feb. 02, 2021 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO), announced today the publication of a study that measured DNA methylation, the chemical modification of the DNA that controls gene regulation, of the various regions regulating cancer genes on single DNA molecules. The study led by Dr. Yuval Ebenstein at the Tel Aviv University found that optical genome mapping (OGM) with Bionano's Saphyr® system combined with a custom labeling method developed by the scientists was capable of analyzing regulatory regions that work together to turn cancer genes on and off over distances of hundreds of thousands of basepairs. The ability to measure these relationships on single DNA molecules is something that was previously impossible. Only Saphyr can detect these long-distance connections in methylation profiles because it's the only technology that can generate such long-range, single molecule data at high throughput and coverage.

While most of the important information in our genome is encoded in the sequence and the structural organization of the sequence, the regulation of genes is partially registered through chemical labels attached to the DNA. These chemical labels, called DNA methylation, can turn genes on and off at specific time points and in certain tissues. A normal cell can only become cancerous and grow excessively by making multiple changes to the genome and the way it is regulated. These changes include single nucleotide variations, structural variations and changes to DNA methylation patterns that can happen to the actual cancer gene, to the promoter region that switches the gene on and off, or to enhancer regions that can be hundreds of thousands of basepairs removed from the cancer gene. Studying these methylation patterns has been difficult or impossible because current methods only allow you to measure values averaged over dozens or hundreds of cells. To fully understand how cancer genes are turned on and off, it is important to measure the methylation status of a gene, its promoter, and its enhancers on individual, single molecules, which is impossible with short-read or long-read sequencing because their read lengths are insufficient.

The study by Dr. Ebenstein is the first to systematically analyze more than one hundred thousand promoter-enhancer pairs up to 200,000 basepairs apart, on millions of single molecules. This large dataset enabled them to correctly distinguish between normal and tumor cells with an error rate smaller than 1%.

Yuval Ebenstein, PhD, commented: "Long methylation reads at such high coverage just never existed before, mostly because Saphyr produces the highest fraction of the longest reads compared to any other platform. This dataset allows us to analyze long range information on the single-molecule level, which opens up a whole new avenue for complex disease specific epigenetic biomarkers. This study can be dramatic for early cancer diagnostics where the normal and cancer cells have a very similar genetic background but the extreme changes in enhancer methylation distinguish the cancer cells. This data may for the first time allow us to discover new biomarkers and point to novel drug targets in places of the genome where no one has looked before."

Erik Holmlin, PhD, CEO of Bionano Genomics commented: "While Bionano Genomics is laser focused on bringing comprehensive, whole genome structural variation detection to the clinic, scientists around the world are pushing the boundaries of what our single molecule analysis system Saphyr can do. Dr. Ebenstein's team has developed a novel application of our technology that contributes to solving unique scientific questions. The epigenetic regulation of cancer genes through DNA methylation of its promoters and enhancers has been difficult or impossible to study with current methods that are limited by short read lengths. We are excited about the possibilities for discoveries of novel diagnostics and treatments for cancer that this application enables."

The publication is available at https://www.biorxiv.org/content/10.1101/2021.01.28.428654v1

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, including in the comprehensive analysis of cancer genomes; 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

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