Bionano Genomics Announces Back-to-Back Publications in the American Journal of Human Genetics that Compare Optical Genome Mapping to Traditional Methods for Structural Variant Analysis in Inherited Genetic Disease and Hematological Malignancies

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SAN DIEGO, July 07, 2021 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) announced today that two peer-reviewed studies from world renowned scientists and clinicians from prestigious institutions in Europe including Radboud University Medical Center, Cochin Hospital in Paris, Hospices Civils in Lyon and the University Hospital of Clermont-Ferrand were published back-to-back in the American Journal of Human Genetics. One study analyzed the genomes of patients with inherited genetic disease and one study those of hematological malignancies. These seminal papers outline the utility of optical genome mapping (OGM) as a superior alternative to traditional methods for structural variant (SV) analysis. The results showed OGM was 100% concordant with findings from fluorescent in-situ hybridization (FISH), karyotype, and CNV-microarray when these traditional methods identified one or more pathogenic variants in samples from study subjects. Additionally, the higher resolution of OGM for all types of variants relative to traditional cytogenomics techniques allowed for a more precise characterization of breakpoints and the identification of genes they affect, the detection of smaller cancer-associated events that usually escape detection by traditional means, and the discovery of additional complexity of rearrangements. These publications will appear in the August print issue and are available online today at http://www.cell.com/ajhg

			Number of Chromosomal Aberrations Identified			Concordant Aberrations Detected				
Study	**Clinical Research Application**	**Number of Patients**	**Traditional Methods (FISH,KT,Array)**	**OGM**	**OGM Sensitivity vs. Traditional Methods**	**Dels**	**Dups**	**Trans.**	**Inver.**	**Other***
Mantere *et al.*	Constitutional Disorders	85	99	99	99/99 (100%)	19	20	34	6	20
Kornelia *et al.*	Hematological Malignancies	52	160	176	160/160 (100%)	34	40	49	2	35

*Covering complex rearrangements, aneuploidy, isochromosomes, ring chromosomes, and insertions

Among the key conclusions presented in both studies, is that OGM has the potential to become a primary analysis for most molecular cytogenetics applications and provides a complement to existing sequencing-based methods for a more comprehensive view of genome variation. The authors describe OGM as a better alternative to traditional cytogenetics assays for both inherited genetic disease and hematological malignancy applications since it consolidates multiple antiquated methods requiring manual integration for interpretation into a single workflow with higher resolution for detection of all classes of SVs. Additionally, the authors highlight that the OGM workflow is ready to implement into routine clinical practice and that data can be easily analyzed by lab-oriented personnel, which is of crucial importance for clinical adoption and distinguishes OGM from sequencing-based methods which require complex analytical pipelines and specialized bioinformatic teams.

Dr. Laïla El Khattabi from Cochin Hospital in Paris, France, in collaboration with Dr. Alexander Hoischen and Dr. Caroline Schluth-Bolard, has led the consortium for this first publication where 85 constitutional samples with chromosomal aberrations in the context of developmental or reproductive disorders were analyzed by OGM and traditional cytogenetics techniques. She said, “OGM can really revolutionize the detection of chromosomal aberrations. I think it could be the most significant technological breakthrough in the history of cytogenetics since the CNV-microarray. This work is really just a beginning, and we are very enthusiastic about continuing it.”

The study of 52 hematological malignancy samples led by Dr. Alexander Hoischen from Radboud University Medical Center, Nijmegen, The Netherlands, analyzed a wide variety of myeloid and lymphoid samples (including CML, CLL, AML, ALL, MDS, MPN, and MM), representing the full range of hematological malignancy patients referred to the clinic. Dr. Hoischen, who co-coordinated the constitutional study as well, added, “I see many opportunities for advanced genome analysis methods to completely transform the way we analyze samples in our laboratories and clinics. Our goals are to provide workflows that find more variants, faster, so critically important information is available sooner and more reliably. OGM is one of the methods we believe is very promising. By streamlining the workflow and providing data and reports that can be readily interpreted and used by our teams without requiring specialized training, we believe OGM can become an alternative and maybe even a replacement for traditional cytogenetics in hematologic malignancies and genetic diseases. The fact that OGM and sequencing, including long-read sequencing, are highly complementary gives us an array of tools that can form the lab of the future. The progress Bionano has made with OGM has been substantial and we are excited about continuing to help guide them forward.”

Erik Holmlin, PhD, chief executive officer of Bionano Genomics, commented “Bionano is poised to substantially transform genetic analysis with OGM and these publications set the baseline for the transformation. In the past, we have seen methods that replace legacy workflows by being easier to implement and operate while providing a better result, which together drive wider adoption and utilization. Examples include the transformation of microbiology by rapid PCR methods, automation of immunohistochemistry and in-situ hybridization by integrated pathology instruments and the total transformation of DNA (Sanger) sequencing by next-generation sequencing. Each of these innovations has resulted in more efficient workflows with substantially better health outcomes than could have been possible with the legacy methods. We believe OGM with our Saphyr® system has the potential to similarly redefine structural variant analysis in genetics and cancer. The publications appearing today are an important step in that process. We are grateful to the study leaders and authors for their incredible work.”

The publication on constitutional samples is available at https://doi.org/10.1016/j.ajhg.2021.05.012, the publication on hematological malignancies is available at https://doi.org/10.1016/j.ajhg.2021.06.001

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: the potential for OGM with Saphyr to revolutionize cytogenetic analysis; our beliefs regarding the potential benefits of Bionano's Saphyr technology; the significance of large SVs in genetic research; 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, 2020 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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