Georgia Esoteric and Molecular Laboratory at Augusta University Now Offers Diagnostic Service for Constitutional Genetic Disorders based on Optical Genome Mapping with Bionano's Saphyr System

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SAN DIEGO, May 03, 2021 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO), announced today that the Georgia Esoteric and Molecular (GEM) Laboratory at the Medical College of Georgia (MCG) at Augusta University is now offering diagnostic services for constitutional genetic disorders through a laboratory-developed test (LDT) based on optical genome mapping (OGM) with the Saphyr® System. The LDT developed by Dr. Ravindra Kolhe and his team is designed for pediatric patients suspected to have a neurodevelopmental genetic disorder. Dr. Kolhe is developing additional OGM-based LDTs for prenatal genetic disorders and other indications.

Current medical guidelines recommend that patients with a suspected genetic condition, such as a pediatric neurodevelopmental disorder like autism spectrum disorder, first undergo analysis for structural variation with whole-genome analysis by chromosomal microarray (CMA) and are tested for Fragile X. Depending on the results of these first-line tests, further whole-genome analysis by Karyotyping (KT) may be indicated. This workflow is widely considered to be cumbersome, time-consuming, expensive, and inefficient. The OGM-based LDT developed and validated by MCG's GEM laboratory provides all the information sought in the first-line CMA and Fragile X testing recommended by medical guidelines, as well as the information that would be sought in a reflex to KT, in a single assay. A single assay for the detection of all types of structural variants (SVs), like this LDT, offers the potential to achieve a higher rate of diagnosis using a workflow that is faster, easier and lower cost.

Ravindra Kolhe, MD, PhD, FCAP., commented: "Since our initial evaluation of Saphyr, we have been impressed by the ability of OGM to identify all structural variant types, which could be associated with a genetic disorder. During the development of our LDT, we found that OGM scored a perfect 100% on all relevant performance metrics (specificity, sensitivity, accuracy, and precision) on tested SVs when compared to standard of care methods. The validation of our LDT for constitutional cytogenetics is only the start, as we are continuing the development of similar LDTs for additional clinical applications, making OGM-based LDTs a key part of our menu of diagnostic tests."

Erik Holmlin, PhD, CEO of Bionano Genomics commented: "Dr. Kolhe and his team have made incredible progress in the last year, making breakthrough research discoveries with OGM in the genomes of patients with severe COVID-19 disease. Despite the enormous workload that the COVID-19 pandemic brought to their diagnostic lab, they have continued their fast-paced development of Saphyr-based LDTs. We want to congratulate Dr. Kolhe and the entire GEM lab on successfully validating this LDT, making them the first academic CLIA lab in the United States to offer diagnostic whole genome analysis with assays they developed on Saphyr. Several laboratories in the U.S. such as PerkinElmer Genomics and the University of Iowa Hospitals and Clinics have already launched Saphyr-based LDTs targeting a specific clinical indication. The MCG's GEM lab is only the second clinical lab to provide an LDT based on whole-genome analysis with OGM in the U.S., following Praxis Genomics. We expect more U.S. laboratories to develop LDTs for several clinical applications in the future, continuing to define Saphyr as a key tool for next-generation cytogenomics in cancer and genetic disease."

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 human genomes; the potential for Saphyr to become a central technique for studying DNA replication, DNA repair and genome instability; the potential for Saphyr-based DNA replication methods to enable the discovery of novel cancer treatments; our expectations regarding the broader adoption of Saphyr as a clinical tool to replace other diagnostic testing and genome analysis technologies; 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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