OGM Evaluated as a Method for Investigating Abnormal NIPT Results due to its Ability to Detect Chromosomal Structural Variations Found in Recurrent Pregnancy Loss

October 14, 2022

SAN DIEGO, Oct. 14, 2022 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced the publication of a peer-reviewed study evaluating optical genome mapping (OGM) as a method for investigating abnormal noninvasive prenatal testing (NIPT) results because of its ability to accurately identify complex structural aberrations relevant to recurrent pregnancy loss and infertility.

In a case study from Hangzhou Maternity and Child Care Hospital, researchers analyzed samples from a pregnant subject who had an abnormal NIPT result in her second pregnancy, after experiencing a spontaneous abortion the prior year. The study sought to determine OGM's utility for detection of chromosome breakages and fusions found in complex chromosomal rearrangements (CCR), which can significantly increase an abnormal pregnancy outcome for carrier couples. The study reports that about 70% of CCR carriers are phenotypically normal, but they have a high risk of recurrent miscarriage, subfertility or infertility, and pregnancy abnormalities due to conceiving offspring with unbalanced CCRs.

The researchers used OGM as part of a confirmatory workflow after amniocentesis, karyotyping (KT), and chromosomal microarray analysis (CMA) identified suspected structural rearrangements with unknown origins, believed to indicate a CCR event. The study reported that OGM revealed complex structural aberrations that KT and CMA did not identify, confirming the subject as a carrier of a CCR involving three chromosomes and four breakpoints, and thereby aiding researchers in subsequent prenatal diagnosis and genetic counseling.

Erik Holmlin, PhD, president and chief executive officer of Bionano commented, "We are pleased to see the study provide validation of OGM's potential utility for prenatal analysis and show how OGM may help researchers understand the underlying genetic etiology of recurrent miscarriage or pregnancy abnormalities. We believe OGM could be used as a comprehensive follow-up genome analysis in cases with a positive NIPT screen or for some high-risk pregnancies."

This publication can be found here: https://molecularcytogenetics.biomedcentral.com/articles/10.1186/s13039-022-00619-9

About Bionano Genomics

Bionano Genomics is a provider of genome analysis solutions that can enable researchers and clinicians to reveal answers to challenging questions in biology and medicine. The Company's mission is to transform the way the world sees the genome through OGM solutions, diagnostic services and software. The Company offers OGM solutions for applications across basic, translational and clinical research. Through its Lineagen, Inc. d/b/a Bionano Laboratories business, the Company also provides diagnostic testing for patients with clinical presentations consistent with autism spectrum disorder and other neurodevelopmental disabilities. Through its BioDiscovery business, the Company also offers an industry-leading, platform-agnostic software solution, which integrates next-generation sequencing and microarray data designed to provide analysis, visualization, interpretation and reporting of copy number variants, single-nucleotide variants and absence of heterozygosity across the genome in one consolidated view. For more information, visit www.bionanogenomics.com, www.bionanolaboratories.com or www.biodiscovery.com

Forward-Looking Statements of Bionano Genomics

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "can," "may," "potential" 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 ability of OGM to detect chromosome breakages and fusions found in CCRs, the utility of OGM for prenatal analysis. 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 technologies or improvements to existing technologies; failure of future study results to support those demonstrated in the paper referenced in this press release; failure OGM to detect CCRs; failure of OGM to detect genomic structural variations in a prenatal analysis; 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; 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, 2021 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