Bionano Announces Publication Demonstrating Utility of OGM as an Alternative to KT and CMA for Evaluating CRISPR-Edited Cells as Part of Stem Cell Therapy Development

August 30, 2023

SAN DIEGO, Aug. 30, 2023 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced a publication in *Nature Communications* demonstrating the utility of optical genome mapping (OGM) as an alternative to karyotyping (KT) and chromosomal microarray (CMA) for the evaluation of CRISPR-Cas9 edited human induced pluripotent stem cell (iPSC) lines in order to uncover possible pathogenic structural alterations that may limit their usefulness for stem cell therapy.

The study authors found that approximately 15% of CRISPR-Cas9 edited genomes (2 of 13) had potentially pathogenic large chromosomal deletions at unexpected off-target sites. In addition to those two off-target deletions, the authors reported a large, unexpected deletion at the target site.

“This study is an example of how OGM can be used as part of developing cell and gene therapies, including stem cell therapies. The expansion of iPSC-mediated cell therapy faces risks due to off-target structural variations that may be introduced during CRISPR-Cas9 genome editing. Since genome aberrations caused by CRISPR-Cas9 editing could lead to unforeseen adverse effects, we believe careful and comprehensive analysis of edited genomes is important in developing these therapies and their manufacture," commented Erik Holmlin, PhD, president and chief executive officer of Bionano.

The paper is available at: https://www.nature.com/articles/s41467-023-40901-x.

About Bionano
Bionano 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. 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. The Company additionally offers nucleic acid extraction and purification solutions using proprietary isotachophoresis technology. For more information, visit www.bionano.com, www.bionanolaboratories.com or www.purigenbio.com.

Unless specifically noted otherwise, Bionano’s OGM products are for research use only and not for use in diagnostic procedures.

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,” “could,” 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 utility of OGM in uncovering possible pathogenic structural alterations in CRISPR-Cas9 edited genomes; the utility and ability of OGM to be used as part of developing cell and gene therapies, including stem cell therapies; the importance of comprehensive analysis of edited genomes in order to develop cell and gene therapies, including stem cell therapies, and their manufacture; and our ability to drive adoption of OGM and our technology solutions to be used as part of developing cell and gene therapies including stem cell therapies. 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 timing and amount of revenue we are able to recognize in a given fiscal period; the impact of adverse geopolitical and macroeconomic events, such as recent and potential future bank failures, global pandemics and the ongoing conflict between Ukraine and Russia, 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; changes in our strategic and commercial plans; our ability to obtain sufficient financing to fund our strategic plans and commercialization efforts and our ability to continue as a “going concern”; the ability of medical and research institutions to obtain funding to support adoption or continued use of our technologies; study results that differ or contradict the results mentioned in this press release; failure of OGM to prove useful in uncovering possible pathogenic structural alterations in CRISPR-Cas9 edited genomes; failure of OGM to be used as part of developing cell and gene therapies including stem cell therapies; failure of 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, 2022 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