



Bionano Genomics Announces Publication of Study Demonstrating Utility of OGM as Part of a Comprehensive Workflow for Quality Evaluation of Human Induced Pluripotent Stem Cells (iPSCs)

September 8, 2022

SAN DIEGO, Sept. 08, 2022 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO), today announced the publication of a study demonstrating the utility of optical genome mapping (OGM) as part of a workflow to evaluate the quality of hypoinmunogenic induced pluripotent stem cells (iPSCs) which could be used in regenerative medicine. This research provides scientific and practical support for OGM's ability to detect cryptic and balanced structural variants (SVs) in CRISPR-edited cells, some of which were not detected by karyotyping, and which may impact the genomic integrity of iPSCs.

The expansion of iPSC-mediated cell therapy faces risks due to immune rejection caused by mismatches of human leukocyte antigens (HLAs) between donor and recipient. Researchers in this study developed a new strategy for the reduction of immune rejection using CRISPR-Cas9 genome editing to selectively knock out the HLA-A and HLA-B genes while retaining HLA-C and other non-classical HLAs.

In order to optimize the selection of CRISPR-Cas9 edited iPSC subclones, researchers in the study performed a stringent genomic integrity assessment using whole-genome sequencing (WGS), karyotyping (KT) and OGM. In the study, OGM matched the karyotype and genome sequencing findings of deletions and translocations and identified complicated genomic rearrangements missed by other methods. OGM was also able to detect distinctive mutations in iPSCs that researchers could then avoid using.

"Bionano is gratified to see research that demonstrates OGM's utility to the field of regenerative medicine. This paper outlines a rigorous assessment of genomic integrity that could be applied to iPSCs that might eventually be used to restore functionally impaired tissues or organs. We are pleased that the authors included OGM as part of the development of new methods to analyze the quality of genome-edited cells. We believe this strategy could be advantageous not only for the simplification of the production process but also for the reduction of unintended genomic mutations at off-target sites or unexpected large deletions at on-target sites that may be caused by effects of guide RNA (gRNAs)," commented Erik Holmlin, PhD, president and chief executive officer of Bionano Genomics.

The paper is available at: [https://www.cell.com/molecular-therapy-family/methods/fulltext/S2329-0501\(22\)00075-4](https://www.cell.com/molecular-therapy-family/methods/fulltext/S2329-0501(22)00075-4)

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 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.lineagen.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 "may," "could," "believe" 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 and utility of OGM to detect cryptic and balanced SVs in CRISPR-edited cells, the utility of OGM in quality and genomic integrity assessment of iPSCs, and the potential for OGM to become part of a cell therapy workflow. 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; failure of OGM to detect cryptic and balanced SVs in CRISPR-edited cells; failure of OGM to become part of genomic integrity assessment of iPSCs; failure of future study results to support those demonstrated during the presentations referenced in this press release; 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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