Bionano Genomics Announces the First Publication Using OGM to Analyze Impact of Chromothripsis and TP53 Abnormalities on Chronic Lymphocytic Leukemia (CLL) Patients with High Genomic Complexity

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SAN DIEGO, Aug. 25, 2022 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced the publication of the first study to use optical genome mapping (OGM) to analyze the impact of chromothripsis (cth) and *TP53* abnormalities on chronic lymphocytic leukemia (CLL) patients with high genomic complexity. Researchers aimed to determine whether poor prognostic outcomes observed in cases with cth might be related not only to the chromothriptic event itself but also to the presence of complex karyotypes or *TP53* abnormalities.

The paper, published in *Cancers* journal, was conducted by a multi-center group of researchers from hospitals and academic labs across a number of European countries. The study compared the cytogenomic aberrations observed by genomic microarrays and chromosome banding analysis (CBA) to those observed using OGM. Researchers analyzed a cohort of 162 CLL patients with complex karyotypes, including a subset of 33 CLL patients with cth, to determine whether the presence of cth indicated poor survival outcomes.

In this study, researchers were able to show, for the first time, OGM's ability to detect cth, and also showed that the OGM results were highly concordant with chromosomal microarray results. The study noted that detecting cth using some traditional cytogenetic approaches can be challenging and reported that OGM was able to reveal rearrangements associated with cth events, including intra-chromosomal and inter-chromosomal translocations. In addition, OGM was able to detect a case with a higher complexity profile, comprising chained translocations involving several chromosomes, which may be characteristic of another event known as chromoplexy.

Though cases with cth showed shorter time to first treatment (TTFT) than non-cth samples, when researchers stratified patients based on *TP53* status, cth was no longer associated with TTFT. Only *TP53* maintained its significance in the multivariate analysis for TTFT, including cth and genome complexity defined by genomic microarrays, leading the researchers to suggest that *TP53* abnormalities, rather than cth itself, underlie the poor prognosis observed in this subset.

"We are excited to see the adoption of OGM in the hematologic community in Spain. This team of researchers have done outstanding work diving into some complex questions in cancer. The results of this study show that while chromothripsis plays a factor in the proliferation of structural variation, *TP53* emerges as a critical biomarker with high prognostic value. We believe the study also shows that OGM was unique in its potential to reveal these critical events. The report shows that a few of the variants detected by CMA were not detected by OGM, which we believe reflects the performance of earlier versions of our analysis software and will help guide development of future versions. It is noteworthy that this publication documents OGM's ability to analyze *TP53* variants, because we are aware of new international classification subtypes that emphasize the importance of *TP53* structural variants in conjunction with single nucleotide variants," commented Erik Holmlin, PhD, president and chief executive officer of Bionano Genomics.

This publication can be found here: https://www.mdpi.com/2072-6694/14/15/3715

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 "believe," "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 and utility of OGM to analyze chromothripsis (cth) and *TP53* abnormalities on chronic lymphocytic leukemia (CLL) patients with high genomic complexity. 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 OGM to achieve utility in the analysis of chromothripsis (cth) and *TP53* abnormalities on chronic lymphocytic leukemia (CLL) patients with high genomic complexity; failure of future study results to support those demonstrated in the paper 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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