



Bionano Laboratories Expands its Clinical Testing Menu with Launch of its First OGM-Based Laboratory Developed Test (LDT) for Hematological Malignancies

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SAN DIEGO, Jan. 24, 2023 (GLOBE NEWSWIRE) -- Bionano Laboratories today announced the launch of OGM-Dx™ HemeOne™, a laboratory developed test (LDT) based on optical genome mapping (OGM) analysis of blood or bone marrow samples to detect structural variants (SVs) of diagnostic and prognostic utility in individuals with a new or an existing diagnosis of a hematological malignancy. Compared to traditional cytogenetic methods, this OGM-based assay offers a streamlined and improved workflow to assess pathogenic SVs relevant to hematological malignancies including Acute Lymphoblastic Leukemia (ALL), Acute Myeloid Leukemia (AML), B-Cell Lymphoma, Chronic Lymphocytic Leukemia (CLL), Chronic Myelogenous Leukemia (CML) and Myelodysplastic Syndrome (MDS).

OGM-Dx HemeOne is the second OGM-based LDT launched by Bionano Laboratories, following the laboratory's LDT for facioscapulohumeral muscular dystrophy (FSHD), which was released in September 2022. The OGM-Dx HemeOne reports from this LDT will include a targeted analysis of guidelines-based, disease specific SVs as well as a whole genome analysis for the detection or recurrent and novel biomarkers associated with various hematological malignancy indications.

"We are pleased to see the launch of Bionano Laboratories' LDT for heme malignancies, which can assist patients in their diagnostic and prognostic journey. Our laboratory's robust LDT validation is designed to provide a comprehensive evaluation of genome wide SVs that will allow oncologists to assess the best potential therapies for their malignancy patients. We believe the continued development of OGM-based LDTs will allow Bionano Laboratories to help create a roadmap for how OGM might be leveraged in a clinical setting," stated Justin Leighton, vice president of laboratory business at Bionano Laboratories.

About Bionano Laboratories:

Bionano Laboratories provides access to genetic answers and support utilizing cutting-edge technologies to advance the way you see the genome. Our clinical services offer a genetic testing experience that combines a comprehensive testing portfolio with thoughtful and accessible support options for the diagnostic journey. Bionano Laboratories also offers direct access to optical genome mapping for applications across basic, translational and clinical research. For more information, visit www.bionanolaboratories.com

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," "potential," "will" 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-Dx HemeOne to detect SVs of diagnostic and prognostic utility in individuals with a new or an existing diagnosis of a hematological malignancy including ALL, AML, B-Cell Lymphoma, CLL, CML and MDS; and the ability of OGM-based LDTs to remove barriers for OGM adoption in clinical and research settings. 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 geopolitical and macroeconomic developments, such as the ongoing Ukraine-Russian conflict, and related sanctions, and the COVID-19 pandemic, on our business and the global economy; the failure of OGM-Dx HemeOne to detect SVs of diagnostic and prognostic utility in individuals with a new or an existing diagnosis of a hematological malignancy including ALL, AML, B-Cell Lymphoma, CLL, CML and MDS; the failure of OGM-based LDTs to remove barriers for OGM adoption in clinical and research settings; 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; 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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