Bionano Laboratories Announces New Category I CPT Code for OGM Use in Hematological Malignancy Analysis

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SAN DIEGO, June 17, 2024 (GLOBE NEWSWIRE) – Bionano Laboratories, a clinical laboratory services business of Bionano Genomics, Inc. (Nasdaq: BNGO), today announced the editorial panel of the American Medical Association (AMA) established a new Category I Current Procedural Terminology (CPT®) code for the use of optical genome mapping (OGM) in cytogenomic genome-wide analysis to detect structural and copy number variations related to hematological malignancies. The CPT code is a key component in obtaining reimbursement for the OGM-Dx™ HemeOne laboratory developed test (LDT) from third party payers. The Category I CPT code is expected to be included in the next CPT codebook and to be effective January 1, 2025.

The establishment of a new Category I CPT code for OGM implies that it has met the standards of acceptance by the medical community, in contrast to a Category III code, which is generally applied to emerging technologies. As part of the application review process, the panel collects input from stakeholders across the health care community to ensure CPT content reflects the coding and data-driven demands of modern health care.

“We believe this approval of a Category I CPT code for OGM is a game changer for clinical OGM testing. The criteria that the AMA uses for Category I CPT code approval is rigorous, and this approval is significant,” said Donna Polizio, global head of market access at Bionano Laboratories. “OGM-Dx HemeOne is used to detect all classes of structural variants that are traditionally tested by multiple methods such as karyotyping, chromosomal microarray, and fluorescence *in situ* hybridization (FISH) analysis. We believe the CPT code is an important step forward for Bionano Laboratories and its efforts to obtain reimbursement for this assay and that establishing a Category I CPT code will raise the awareness and utility of OGM.”

About Bionano Laboratories:

Bionano Laboratories provides access to genetic answers and support utilizing cutting-edge technologies to advance the way the world sees the genome. Its clinical diagnostics services offer optical genome mapping (OGM) testing that combines a comprehensive testing portfolio with thoughtful and accessible support options. Bionano Laboratories also offers direct access to OGMfor applications across basic, translational and clinical research. For more information, visit www.bionanolaboratories.com

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 optical genome mapping (OGM) solutions, diagnostic services and software. The Company offers OGM solutions for applications across basic, translational and clinical research. The Company also offers an industry-leading, platform-agnostic genome analysis software solution, and nucleic acid extraction and purification solutions using proprietary isotachophoresis (ITP) technology. Through its Lineagen, Inc. d/b/a Bionano Laboratories business, the Company also offers OGM-based diagnostic testing services.

For more information, visit www.bionano.com, www.bionanolaboratories.com or www.purigenbio.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,” “expect,” 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 the Category I CPT code to drive use and adoption of the OGM-Dx HemeOne test and other OGM-based tests; the ability of the OGM-Dx HemeOne test to obtain coverage and reimbursement; whether the Category I CPT code will ultimately be important for clinical OGM testing; and any other statements that are not of historical fact. 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 recent and potential future bank failures, the ongoing conflicts between Ukraine and Russian and Israel and Hamans, and related sanctions, and any global pandemics, on our business and the global economy; the failure of the Category I CPT code to drive use and adoption of the OGM-Dx HemeOne test and other OGM-based tests; the failure of the OGM-Dx HemeOne test to obtain coverage and reimbursement; the failure of the Category I CPT code to ultimately be important for clinical OGM testing 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; 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, 2023 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.

CONTACTS

Company Contact:
Erik Holmlin, CEO
Bionano Genomics, Inc.

+1 (858) 888-7610
eholmlin@bionano.com

Investor Relations:
David Holmes
Gilmartin Group
+1 (858) 888-7625
IR@bionano.com