



Bionano Announces Second OEM Partner has Received China NMPA Approval for DNA Extraction and Labeling Products for IVD Use of OGM in Reproductive Health

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- Bionano original equipment manufacturing (OEM) partner A-smart MedTech (A-smart) obtained reagent class I registration and approval for DNA isolation and labeling kits for optical genome mapping (OGM) from China's National Medical Products Administration (NMPA)
- Reagents can be utilized for *in vitro* diagnostics (IVD) use in reproductive health in China
- With this NMPA registration, A-smart can sell OGM reagents to independent clinical laboratories and Chinese hospitals

SAN DIEGO, Aug. 28, 2023 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced that its Chinese original equipment manufacturing (OEM) partner, A-smart MedTech (A-smart), an assisted reproductive technology company, has obtained reagent class I registrations from China's National Medical Products Administration (NMPA) for Bionano's DNA extraction kit and labeling products. A-smart is Bionano's second Chinese OEM partner to obtain approval from NMPA for the Company's optical genome mapping (OGM) solutions.

NMPA issued two approvals to A-smart: one for Bionano's G2 direct label and stain (DLS) DNA labeling kit and one for Bionano's G2 SP bone marrow aspirate (BMA) DNA isolation kit. A-smart received IVD Class I labels, enabling these reagents to be used for *in vitro* diagnostics in China.

"As a company focused on reproductive medicine, A-smart has been exploring cutting-edge technology to help our customers to achieve a better overall success rate of *in vitro* fertilization. We believe Bionano's platform can help us achieve this goal as it helps identify structural variations in a more precise way and on a much broader scale. We are happy to be off to a good start with the NMPA certificate and are looking forward to the next milestones," commented Zhuo Li, PhD, chief technology officer at A-smart.

Erik Holmlin, PhD, president and chief executive officer of Bionano, commented, "We want to congratulate A-smart, our second OEM partner to receive NMPA approval for our reagents. We believe the expansion of NMPA approvals can help make OGM available to China's large population seeking support for reproductive health, including genetic analysis of people considering pregnancy, pre-implantation analysis of *in vitro* fertilized embryos, and other prenatal and postnatal genome analyses, which we believe will help Bionano grow sales of the Company's OGM systems in China."

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 isotachopheresis (ITP) technology. For more information, visit www.bionano.com, www.bionanolaboratories.com or www.purigenbio.com.

Unless specifically identified, Bionano's OGM products are for research use only and not for use in diagnostic procedures.

Forward-Looking Statements of Bionano

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "can," "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 impact and utility of OGM in the analysis of samples for *in vitro* fertilization or other reproductive health purposes; the impact of NMPA approvals or the adoption of our OGM solutions for reproductive health or other purposes; the anticipated benefits of Bionano's platform for our OEM partners in China and the ultimate success of our OEM partners; and the expected growth of sales of the Company's OGM systems in China. 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 Ukraine-Russian conflict, and related sanctions, and any global pandemics, on our business and the global economy; execution of our stated strategies and plans, including those related to our OEM partners in China; 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; failure of our OGM solutions to be adopted for the analysis of samples for reproductive health applications; failure of our OGM solutions to provide the anticipated benefits in the identification of structural variants relevant to reproductive health; failure of our OEM partners to execute on their commercial plans; failure of NMPA approvals to drive adoption or use of our OGM solutions for reproductive health applications; 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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