



Bionano Announces China NMPA Approval for DNA Extraction and Labeling Products for IVD Use in Hematologic Malignancies

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- Bionano original equipment manufacturing (OEM) partner Beijing Genome Precision Technology (BGPT) obtained reagent class I registration and approval for DNA isolation and labeling kits from China's National Medical Products Administration (NMPA)
- Reagents can be utilized for *in vitro* diagnostics use in hematologic malignancies in China
- With this NMPA registration, BGPT can sell optical genome mapping (OGM) reagents to independent clinical laboratories (ICLs) while it seeks approval for Bionano's Saphyr[®] system

SAN DIEGO, Feb. 22, 2023 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (BNGO) today announced that its Chinese original equipment manufacturing (OEM) partner, Beijing Genome Precision Technology (BGPT), a comprehensive molecular diagnostics company, has obtained reagent class I registrations from China's National Medical Products Administration (NMPA) for Bionano's DNA extraction kit and labeling products.

NMPA issued three approvals to BGPT: two for Bionano's direct label and stain (DLS) DNA labeling kits and one for Bionano's bone marrow aspirate (BMA) DNA isolation kit. The NMPA registrations for Bionano's products enable these reagents to be used for *in vitro* diagnostics in China. Eventually, they are expected to help sales and placements of both Bionano's instruments and reagents in China.

"As a molecular diagnostic product company focused on blood tumors, we are very happy to establish a cooperative relationship with Bionano and to jointly explore the blood tumor market. Obtaining the NMPA Class I certificate is only a starting point," stated Ye Feng, PhD, president and chief executive officer of BGPT.

Erik Holmlin, PhD, president and chief executive officer of Bionano, commented, "We are really excited to see our OEM partner BGPT receive NMPA approval for our reagents, which can help make optical genome mapping (OGM) available in China. We look forward to seeing continued progress in the Chinese market."

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.bionano.com, www.bionanolaboratories.com or www.biodiscovery.com

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "can," "believe," "anticipate," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances and the negatives thereof) 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 optical genome mapping (OGM) in the analysis of hematological malignancies in China; the impact of NMPA approvals on the adoption of our OGM solutions; the anticipated benefits and ultimate success of our collaborations; and other statements that are not historical facts.

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-Russia conflict, related sanctions and the COVID-19 pandemic, on our business and the global economy; challenges inherent in developing, manufacturing and commercializing products; our ability to further deploy new products and applications and expand the markets for our technology platforms; failure of our OGM solutions to be adopted for the analysis of hematological malignancies in China; our expectations and beliefs regarding future growth of the business and the markets in which we operate; changes in our strategic and commercial plans; our ability to obtain sufficient financing to fund our strategic plans and commercialization efforts; and 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 are under no duty to update any of these forward-looking statements after the date they are made to conform these statements to actual results or revised expectations, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date the statements are made. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements contained in this press release.

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