Bionano and Diagens Sign Partnership to Commercialize the First Ever Clinical Cytogenetic Analysis that Combines OGM and Artificial Intelligence

April 17, 2024

- Bionano, a global leader in the transformation of the cytogenetic workflow with optical genome mapping (OGM), has entered into a strategic partnership with Hangzhou Diagens Biotechnology Co., Ltd. (Diagens), the pioneering leader in artificial intelligence (AI) chromosome karyotype analysis technology. Their joint endeavor aims to commercialize the first ever cytogenetic workflow that integrates OGM plus AI chromosome karyotype analysis
- Diagens will become an original equipment manufacturing (OEM) partner of Bionano in China
- Diagens has received Class I registration and approval for Bionano's OGM reagents from China's National Medical Products Administration (NMPA) and plans to register the Saphyr™ instrument with NMPA for clinical use in reproductive health
- The cytogenetics workflow that Diagens expects to develop will combine AI analysis and OGM as a transformative approach to detecting pathogenic structural variants (SVs) associated with recurrent pregnancy loss and other significant genome variants that could impact a pregnancy or lead to developmental issues for the newborn

SAN DIEGO, April 17, 2024 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (BNGO), a global leader in the transformation of the cytogenetic workflow with OGM, today announced that it has entered into an original equipment manufacturing (OEM) partnership agreement with Diagens, an assisted reproductive technology company based in China focused on the application of AI in cytogenetics. Through the partnership, the companies plan to commercialize the first ever cytogenetic workflow using OGM plus AI chromosome karyotype analysis to detect pathogenic SVs associated with recurrent pregnancy loss and other significant genome variants that may impact a pregnancy or lead to developmental issues in a newborn.

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"As a pioneer in AI chromosome karyotype analysis, we are very happy to establish a partnership with Bionano and to jointly explore the reproductive health market. Diagens offers cutting-edge AI technology to help our customers to achieve a better overall success rate of *in vitro* fertilization. Bionano's platform can help us achieve this goal as it can identify structural variations in a more precise way than karyotyping alone, and on a much broader scale. Additionally, we look forward to potentially expanding the cooperation into more fields, like blood cancer in the future," stated Ning Song, PhD, chief executive officer of Diagens.

Erik Holmlin, PhD, president and chief executive officer of Bionano, said, "We recognize the importance of AI in solving clinical bottlenecks and resolving other limitations, including the need for analysis and interpretation of data by highly trained individuals. We believe the transformative approach of combining OGM and AI in a cytogenetic workflow will advance SV detection in constitutional genetic disorder research that will have the potential to aid China's large population seeking support for reproductive health, including genetic analysis of individuals considering pregnancy, pre-implantation analysis of *in vitro* fertilized embryos, and other prenatal and postnatal genome analyses."

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, 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 provides OGM-based testing for certain laboratory developed tests. 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.purigenbio.com.

Except as specifically noted otherwise, Bionano's 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," "may," "expect," "plan," "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 combining AI analysis and OGM to detect pathogenic SVs associated with recurrent pregnancy loss and other genome variants that could impact a pregnancy or lead to developmental issues for the newborn; and the ability and utility of combining OGM and AI in a cytogenetic workflow to advance SV detection in constitutional genetic disorder research and aid China's 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; the ability of our OEM partner to obtain the registrations and approvals from the NMPA described in this press release; and other statements which 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,

supply chain disruptions, global pandemics, inflation and the ongoing conflicts between Ukraine and Russian and Israel and Hamas, on our business and the global economy; general market conditions; the failure of the combined AI analysis and OGM to detect pathogenic SVs associated with recurrent pregnancy loss and other genome variants that could impact a pregnancy or lead to developmental issues for the newborn; the failure of and the ability and utility of combining OGM and AI in a cytogenetic workflow to advance SV detection in constitutional genetic disorder research and aid China's 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; the failure of our OEM partner to obtain the registrations and approvals from the NMPA to commercialize the solutions described in this press release; the failure of our OEM partner to achieve market success in the commercialization of the solutions described in this press release; changes in the competitive landscape and the introduction of competitive technologies or improvements to existing technologies; changes in our strategic and commercial plans or the strategic or commercial plans of our OEM partner; our need and ability to obtain sufficient financing to fund our strategic plans and commercialization efforts, our ability to effectively manage our uses of cash, and our ability to continue as a "going concern"; the ability of institutions to obtain funding to support adoption or continued use of our technologies and the solutions offered by our OEM partner; 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.

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