

Bionano Genomics Announces Pre-Clinical Evaluation of Optical Genome Mapping by the Foundation for Embryonic Competence

April 14, 2021

SAN DIEGO, April 14, 2021 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) announced the launch of an IRB-approved preclinical evaluation study using optical genome mapping (OGM) by the Foundation for Embryonic Competence (FEC) based in Basking Ridge, NJ. FEC is a nonprofit organization providing preimplantation embryo diagnostic tests for patients who are undergoing in vitro fertilization (IVF).

In the study, FEC will use OGM with the Saphyr system as a research tool to analyze the genomes of couples who have experienced recurrent pregnancy loss or recurrent embryo implantation failure. The study's objective is to determine whether the improved resolution of OGM, compared to traditional methods, can identify structural rearrangements that could form the basis of downstream targeted testing the embryos before implantation, and thereby potentially lead to improved outcomes of the IVF procedure.

Richard T. Scott, Jr, MD, HCLD FACOG, Founding Partner of IVIRMA Global and the Clinical Director, Andrology and Endocrinology Laboratory Director, of RMANJ said, "This study is anticipated to demonstrate the improvements in the structural variation detection in couples when there is difficulty to conceive, or where there is recurrent pregnancy loss or unexplained failure during embryo preimplantation. In such cases, the genome of the parents is usually analyzed to identify structural variants in the genome that can predispose to failed pregnancies after which embryos created through IVF can be screened for unbalanced derivatives".

Better preimplantation testing can reduce the risk of having a child with a genetic condition and may improve significantly the pregnancy and delivery rate per embryo transfer. Currently, karyotyping is the standard of care method to identify structural variants in the parents, but this methodology has a low resolution and is imprecise. "The utility of OGM is being evaluated to comprehensively characterize the structural variations in the genome, including balanced translocations and inversions. The added advantage is the ability to identify cryptic structural variations typically missed by standard of care methods," said Chaim Jalas, CTO of FEC labs.

"The preclinical IRB approved validation study of OGM by FEC for IVF applications is an example of what we are seeing as continued, ongoing growth of the numerous applications for OGM", commented Erik Holmlin, PhD, CEO of Bionano Genomics. "FEC's plan to evaluate the utility of OGM for IVF procedures adds yet another application for OGM, one that may help the thousands of couples in the US that undergo IVF procedures every year to have a successful pregnancy and a healthy child, despite a family history of genetic disease, infertility or pregnancy loss."

About Bionano Genomics

Bionano is a genome analysis company providing tools and services based on its Saphyr system to scientists and clinicians conducting genetic research and patient testing, and providing diagnostic testing for those with autism spectrum disorder (ASD) and other neurodevelopmental disabilities through its Lineagen business. Bionano's Saphyr system is a research use only platform for ultra-sensitive and ultra-specific structural variation detection that enables researchers and clinicians to accelerate the search for new diagnostics and therapeutic targets and to streamline the study of changes in chromosomes, which is known as cytogenetics. The Saphyr system is comprised of an instrument, chip consumables, reagents and a suite of data analysis tools. Bionano provides genome analysis services to provide access to data generated by the Saphyr system for researchers who prefer not to adopt the Saphyr system in their labs. Lineagen has been providing genetic testing services to families and their healthcare providers for over nine years and has performed over 65,000 tests for those with neurodevelopmental concerns. For more information, visit www.bionanogenomics.com or www.lineagen.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" 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: improvements in IVF procedures attributable to research conducted with OGM; the results of the FEC's study; potential improvements in preimplantation testing and overall results of such improvements; and the execution of Bionano's strategy. 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 actual study results may not demonstrate the anticipated benefits; the impact of the COVID-19 pandemic on our business and the global economy; general market conditions; changes in the competitive landscape and the introduction of competitive products; 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; the loss of key members of management and our commercial team; 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, 2020 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@bionanogenomics.com

**Investor Relations and
Media Contact:**

Amy Conrad

Juniper Point

+1 (858) 366-3243

amy@juniper-point.com



Source: Bionano Genomics