# Bionano Customer Praxis Genomics Accredited by College of American Pathologists, Completing First LDT in US for Constitutional Genetic Disorders that Uses Whole Genome Analysis with Saphyr as Alternative to Chromosomal Microarray and Karyotyping

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SAN DIEGO, Dec. 28, 2020 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO), announced today that Praxis Genomics, LLC received accreditation from the College of American Pathologists (CAP), making it the first CAP-accredited, CLIA-certified diagnostic lab in the United States to offer a laboratory developed test (LDT) based on whole genome analysis with Saphyr. The LDT is designed for postnatal patients suspected of a constitutional genetic disorder. Praxis uses optical genome mapping (OGM) with Bionano's Saphyr System as an alternative to traditional methods of chromosomal microarray (CMA) and karyotyping (KT), as they seek to improve the rate of clinical diagnosis for patients with genetic disease. CMA and KT together typically diagnose 30-50% of patients tested. Recent studies have found that OGM with Saphyr is concordant with CMA and KT and also diagnoses a significant fraction (18-25%) of the patients who could not be diagnosed with traditional methods.

Medical guidelines recommend successive rounds of analysis with CMA, KT, repeat expansion testing, single gene or gene panel testing and whole exome sequencing until a pathogenic variant is identified or until the different techniques have been exhausted. At Praxis, this tiered approach is replaced by whole genome analysis using OGM with Saphyr for structural variants (SVs) and, when requested, whole genome analysis by next-generation sequencing (NGS) for single nucleotide variants (SNVs). This workflow eliminates costly and time-consuming steps like cell culture and tedious manual data analysis across multiple platforms and provides a streamlined approach for detection of all types of genomic aberrations designed to achieve a higher rate of diagnosis faster, easier, and at a lower economic cost to labs and payors.

Several diagnostic labs in the U.S. such as PerkinElmer Genomics and the University of Iowa Hospitals and Clinics have already launched Saphyr based LDTs targeting a specific clinical indication, a form of muscular dystrophy called FSHD1. While development of whole genome clinical tests with Saphyr have been in progress in Europe for various clinical applications including inherited genetic disorders and leukemias, the Praxis clinical service is the first to provide whole genome analysis in the U.S.

Erik Holmlin, PhD, CEO of Bionano Genomics commented: "We want to congratulate Praxis Genomics and its founder Dr. Peter L. Nagy on their CAP accreditation, making their Saphyr-based test the first whole genome analysis LDT in the U.S. in a CAP/CLIA setting. We believe this accreditation is a key step on the path to reimbursement of Saphyr-based LDTs by third party payors. While Praxis is first, we expect several other U.S. laboratories to offer whole genome LDTs for various clinical applications in the future, establishing Saphyr as a key tool for next generation cytogenomics. By adding whole genome sequencing, Praxis intends to demonstrate that Saphyr and NGS complement each other to provide answers to patients and families affected with genetic disorders. As more Saphyr-based tests enter the LDT stage worldwide, we believe it is possible to create a paradigm shift for cytogenomic applications in cancer and genetic disease that have the potential to improve patient outcomes."

Dr. Peter L. Nagy, Founder and CEO of Praxis Genomics will present case studies of diagnoses made with OGM at Bionano's Next-Generation Cytogenomics Symposium on January 11, 2021. Register for the event here: https://bit.ly/3fPULzs

**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 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, and 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: the capability of Praxis Genomics' LDT to replace the tiered approach for detection of pathogenic variants currently recommended by medical guidelines; our expectations regarding reimbursement for Saphyr-based LDTs by third party payors; Saphyr's potential as a powerful new tool in cytogenetics and its potential contribution to improvements in traditional cytogenetics; Praxis Genomics' intended use of the Saphyr system and our services, including to demonstrate Saphyr's capabilities in comparison to NGS; the ability to integrate data from the Saphyr system into other offerings by Praxis Genomics; expanded adoption and utilization of the Saphyr system for various clinical applications; improvements in patient outcomes driven by increased use of Saphyr-based tests in the LDT arena; and Saphyr's potential as an indispensable tool for personalized medicine and furthering understanding of cancer in the medical community. 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 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 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, 2019 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 Contact:**
Ashley R. Robinson
LifeSci Advisors, LLC
+1 (617) 430-7577
arr@lifesciadvisors.com

**Media Contact:**
Darren Opland, PhD
LifeSci Communications
+1 (617) 733-7668
darren@lifescicomms.com


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