

Bionano Customer Praxis Genomics Receives DEX Z-Codes from Palmetto for their Whole Genome Analysis LDT on Saphyr

March 3, 2021

SAN DIEGO, March 03, 2021 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) announced today that Praxis Genomics, LLC received DEX Z-codes from Palmetto MoIDX for its entire testing menu of laboratory developed tests (LDTs) based on Saphyr. The DEX Z-Code modifier is a unique 5-character alpha-numeric code associated with certain molecular diagnostics tests and is typically used by certain payers as an adjunct to non-specific CPT codes when no specific CPT code applies. The code, submitted on a claim along with a particular CPT code provides greater clarity to help payers and physicians understand which test is being ordered, performed and billed. The process removes the need for the provider to submit large amounts of additional information with every claim and can expedite claim payment. The assignment of DEX Z-codes to Praxis's menu of Saphyr-based LDTs is potentially a major step forward in the coding and eventual coverage of Saphyr-based tests.

Praxis is the first CAP-accredited, CLIA-certified diagnostic lab in the United States to develop and offer commercially an LDT based on whole genome analysis with Saphyr. Praxis uses optical genome mapping (OGM) 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. The Z-codes allow for a path for Medicare coverage and private insurance reimbursement for OGM with Saphyr of patients with suspected genetic disease.

The Saphyr system is capable of handling Praxis' sample workload after the latest updates to the system enabled it to map 96 human samples per week, or about 5,000 per year. Bionano continues to focus on improving the throughput of OGM for even higher volume laboratories and aims to increase the throughput of a single system to as much as 17,000 samples per year by the first half of 2023, while reducing the consumables cost to a target price of \$100 per sample.

"We are impressed with the progress of Praxis Genomics and its founder Dr. Peter L. Nagy towards making OGM a first line test for genetic disease genome analysis," commented Erik Holmlin, PhD, CEO of Bionano Genomics. "Following Praxis' CAP accreditation, we believe that the assignment of MoIDX Z-codes for Saphyr testing is an important next step to enable more widespread reimbursement of OGM by private and public payers. Praxis once again is the first U.S. laboratory to pass this milestone, and we believe other U.S. labs will follow in Praxis' footsteps over time and build the path towards reimbursement. Bionano continues to invest in making OGM faster and even more cost effective to make it the cytogenomics solution suiting the full range of testing volumes, from small, local cytogenetics labs to high-volume commercial or academic testing sites."

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: our expectations regarding potential reimbursement of Praxis' menu of Saphyr-based LDTs; the capability of Praxis' menu of Saphyr-based LDTs to replace the tiered approach recommended by medical guidelines and to become a first line test for genetic disease genome analysis; our expectations regarding future reimbursement potential 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; our expectations regarding further widespread 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 our strategic plans. 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.

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Source: Bionano Genomics