Bionano Genomics Expands Its Diagnostic Testing Menu with Launch of Lineagen's EpiPanelDx PLUS Gene Panel Test that Identifies Genetic Conditions Related to Epilepsy

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EpiPanel^{Dx} PLUS adds to Lineagen's expanding menu of diagnostic tests for children with developmental disorders and provides an offering designed specifically for patients that have experienced seizures or other epilepsy-related symptoms

SAN DIEGO, Sept. 14, 2020 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) today announced the release of EpiPanel^{Dx} PLUS™ by its diagnostics services business, Lineagen. The new laboratory developed test (LDT) and associated clinical support bolsters Lineagen's diagnostic services for physicians providing care for pediatric patients with neurodevelopmental disorders (NDDs). EpiPanel^{Dx} PLUS is based on a proprietary panel of 223 genes associated with epilepsy-related conditions, more genes than typically found on epilepsy panels available from other service providers and customized for Lineagen's core market of neurodevelopmental disorders.

Epilepsy refers to an array of neurological disorders characterized by involuntary seizures and affects approximately 1.2% of the population, or 3.4 million people, in the United States. It is frequently comorbid with other NDDs of childhood development, including intellectual disability and autism spectrum disorder and also can co-occur with neuro-behavioral disorders such as attention deficit hyperactivity disorder (ADHD). Collectively, NDDs represent the most common form of developmental disorder with an estimated prevalence of 1 out of 6 children affected in industrialized countries. Lineagen's current menu of FirstStep ^{Dx} PLUS® chromosomal microarray and NextStep^{Dx} PLUS ™whole exome sequencing offers leading molecular diagnostic tests designed to help pediatricians and pediatric neurodevelopmental specialists manage their patients with NDDs. Offering such physicians a test for epilepsy allows Lineagen to more comprehensively serve their needs.

"Identifying the underlying genetic variants that may explain the underlying cause of seizures is extremely important because it informs multiple aspects of clinical care," said Alka Chaubey, PhD, Chief Medical Officer of Bionano Genomics. "This test allows for personalized treatment of the patient, can predict the recurrence risk for other members of the family, and ends the diagnostic odyssey, which for many families can mean years of doctor visits, invasive tests, and failed or even harmful treatments."

EpiPanel^{Dx} PLUS is designed for patients who have experienced seizures, infantile spasms, encephalopathy, or febrile seizures, and has an expected 30% diagnostic yield. Lineagen also offers testing to the parents of the patients. By including the analysis of the genomes of one or both biological parents of the patient from the start, it is possible to increase the detection rate of disease-causing variants and inform on recurrence risk for the family. EpiPanel^{Dx} PLUS has been curated based on thorough literature review and includes genes with pathogenic variants identified in more than 2,000 epileptic patients tested by Lineagen.

The use of a targeted gene panel such as EpiPanel^{Dx} PLUS fits the testing strategy that is recommended by the American Academy of Neurology and complements existing genetic tests offered by Lineagen such as FirstStep^{Dx} PLUS chromosomal microarray and NextStep^{Dx} PLUS whole exome sequencing, which are recommended for patients who show a wider array of neurological symptoms. To help tailor medical management, Lineagen also offers pharmacogenomic testing which includes certain genes that are responsible for the metabolism of important anti-epileptic or anticonvulsant drugs prescribed for epilepsy.

"We already have a depth of knowledge on epilepsy genetics," added Dr Chaubey. "We recently tested a 3-year-old girl with muscle spasms and seizures, as well as her parents, and identified a mutation in the *SLC2A1* gene. Based on these results, the doctor was able to treat the child with a simple ketogenic diet and over-the-counter supplementation. If she had instead been treated with barbiturates, at one time a standard treatment for epilepsy patients and now contraindicated in patients with this specific genetic condition, her seizures likely would have gotten worse. This case is one of many where results of a genetic test enabled the family and treating physician to significantly improve the quality of life of the child and family."

"Adding the EpiPanel^{Dx} PLUS test to Lineagen's menu is a critical step forward in our plan for Lineagen to grow and continue supporting the physicians who rely on them," said Erik Holmlin, PhD, Chief Executive Officer of Bionano Genomics. "This test also forms the basis of how we envision incorporating the Saphyr system for comprehensive structural variation analysis into an improved diagnostic testing approach for epilepsy. In its current form, the EpiPanel^{Dx} test uses next generation sequencing (NGS) to identify single nucleotide variants and for evidence of gene deletion or duplication in 223 genes. Deletions and duplications are examples of structural variations (SVs) that NGS can detect with reasonable sensitivity, but otherwise, NGS is essentially blind to certain SVs that Saphyr detects with ease. We believe using Saphyr in conjunction with NGS can enable later generations of EpiPanel^{Dx} PLUS to have potentially higher diagnostic yields by identifying more genetic variations, which may in turn diagnose more patients, and be a unique combination in the industry."

The EpiPanel^{Dx} PLUS diagnostic test is available now with full clinical support including genetic counselling. More details on the diagnostic test are available at https://lineagen.com/epipanel/

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, intended use of Lineagen's tests, including NextStep ^{DX}, anticipated benefits of expanded test offerings from Lineagen, anticipated improvements in patient treatment and diagnosis attributable to Lineagen's tests, potential combinations or other uses of the Saphyr system in conjunction with Lineagen's tests and any improvements in diagnostic testing generated from such uses. 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; failure of our products to achieve the stated objectives or anticipated benefits; 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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