Bionano Genomics Announces Adoption of Its Saphyr® System by Clinical Cytogenetics Groups in Academia and Industry to Replace Traditional Methods for Clinical Testing

Successful validation of Saphyr to replace "gold standard" method of southern blotting for molecular diagnosis of FSHD supports broad utility of Saphyr

SAN DIEGO, Wednesday, Oct 16, 2019 -- Bionano Genomics, Inc. (NASDAQ: BNGO), a life sciences instrumentation company that develops and markets the Saphyr® system, a genome imaging platform for ultra-sensitive and ultra-specific genome-wide structural variation detection, today announced that leading organizations, including PerkinElmer Genomics and the University of Iowa, have adopted Saphyr for use in their clinical genomics laboratories. PerkinElmer Genomics and the University of Iowa have developed assays based on the Bionano optical mapping technology to expand their comprehensive suite of genetic tests assessing disease-associated chromosomal abnormalities. Their lead indication is Facioscapulohumeral Muscular Dystrophy (FSHD).

FSHD is one of the most prevalent forms of muscular dystrophy and affects approximately 1 in 10,000 individuals. It is caused by changes in the number of repeats in a section of chromosome 4. To correctly diagnose FSHD, an exact count of the repeat number is necessary. To date, molecular diagnoses for FSHD are generated using outdated Southern Blot techniques, which are imprecise, labor intensive and involve radioactive labeling methods which are being phased out of laboratory use for safety reasons. In contrast, the assays developed by PerkinElmer Genomics and the University of Iowa with the Bionano EnFocus™ FSHD Analysis tool are reproducible, safe, fast, and automated with minimal hands-on time. These assays provide an exact repeat number for the pathogenic and non-pathogenic variants, give a high-resolution view of the repeat regions and have a high sensitivity to mosaicism.

Jamshid Arjomand, Ph.D., CSO of the FSHD Society, the leading research-focused patient organization for FSHD, said, "The FSHD community has been waiting years for an accessible and robust assay like this. The lack of timely and affordable genetic testing has been a major hurdle for the FSHD community. Thousands of patients have never received a molecular diagnosis, which limits successful recruitment into the increasing number of clinical research and clinical trial studies for this devastating disease. We are delighted that Bionano's Saphyr system enables a more precise and higher throughput method for FSHD genetic testing and are grateful to diagnostic groups and companies that are making genetic testing more accessible to our families."

"We are pleased to be the first US laboratory to develop and validate an assay based on the Bionano Saphyr system in a clinical setting under CLIA/CAP guidelines" stated Madhuri Hegde, Ph.D., FACMG, Vice President and CSO of PerkinElmer Genomics. "We are committed to helping patients and families that need genetic testing and are excited about the strong clinical utility of this assay for the molecular assessment of FSHD patients."

Erik Holmlin, Ph.D., CEO of Bionano, commented, “We have always believed that Bionano’s unique ability to image long, intact DNA molecules could enable the Saphyr system users to develop assays in a clinical setting to modernize and streamline the practice of cytogenetics. Our teams have worked tirelessly to improve the speed, quality, throughput, and robustness of the optical mapping application of genome imaging while simultaneously reducing cost, assay complexity and data analysis. We believe Saphyr is ready to be adopted for assay development in a routine clinical workflow, and we are thrilled that PerkinElmer Genomics and the University of Iowa are taking the lead in making the Saphyr system a tool for next-generation cytogenomics, with many other academic, CRO and reference laboratories expected to follow. We believe that FSHD is just the start of a wide array of clinical genetics assays that labs will develop with our technology.”

Results of the PerkinElmer Genomics FSHD evaluation study using the Saphyr system will be presented by Alka Chaubey, Ph.D., FACMG, Head of Cytogenomics and Laboratory Director at PerkinElmer Genomics at the Bionano Genomics ASHG exhibitor workshop on Thursday, Oct. 17, 2019 from 12:45 pm – 2:00 pm at the Houston Marriott Marquis. More information about the workshop can be found online, and a recording will be made available on Bionano’s website.

Bionano will showcase the Bionano EnFocus FSHD Analysis tool for fast, streamlined bioinformatics assessment of the FSHD locus from genome-wide optical mapping data at booth #527 during the annual American Society of Human Genetics Annual Meeting, Oct. 15-19, 2019.

About Bionano Genomics

Bionano is a life sciences instrumentation company in the genome analysis space. Bionano develops and markets the Saphyr system, 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 establish digital cytogenetics, which is designed to be a more systematic, streamlined and industrialized form of traditional cytogenetics. The Saphyr system comprises an instrument, chip consumables, reagents and a suite of data analysis tools. More information about Bionano Genomics is available at www.bionanogenomics.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, including, among other things: conclusions as to Saphyr’s potential as a powerful new tool in cytogenetics; Saphyr’s potential contribution to improvements in traditional cytogenetics; the University of Iowa’s or PerkinElmer Genomics’ plans to develop additional assays using our technology; our beliefs regarding the Saphyr system’s readiness for clinical adoption and our expectations regarding adoption by other academic, CRO and reference laboratories labs using our technology; PerkinElmer Genomics’ commercial plans; plans of other Saphyr system users to implement their own assays for FSHD and other genetic disorders; and certain planned presentations by PerkinElmer Genomics and us. 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 that our sales, revenue, expense and other financial guidance may not be as expected, as well as risks and uncertainties

associated with 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 key clinical studies to demonstrate the effectiveness of our products; 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, 2018 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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