



University Hospitals Leuven in Belgium Outlines their Menu Expansion Plans for Optical Genome Mapping as One of their Primary Analyses in Leukemias & Lymphomas and Genetic Disease

December 23, 2021

SAN DIEGO, Dec. 23, 2021 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (BNGO), pioneer of optical genome mapping (OGM) solutions on the Saphyr® system and provider of the leading software solutions for visualization, interpretation and reporting of genomic data, today announced that University Hospitals Leuven in Belgium, after previously receiving its accreditation from the Belgian Accreditation Body (BELAC) for using OGM in analysis of acute lymphoblastic leukemia (ALL), is expanding its BELAC-accredited menu to include acute myeloid leukemia (AML), chronic lymphocytic leukemia (CLL) and facioscapulohumeral muscular dystrophy (FSHD).

"With the flexibility we now have as an accredited laboratory by BELAC, our teams can develop OGM-based assays addressing hematological malignancies without the need for a new audit," said Barbara Dewaele, PhD, supervisor of the Laboratory for Genetics of Malignant Disorders at University Hospitals Leuven. "We are excited to move forward using this valuable tool to analyze the genomes of patients with cancer and rare diseases."

At the European Cytogenomics Conference in July 2021, Dr. Dewaele shared the results of implementing an OGM-based assay for ALL patients that her team developed with Bionano's Saphyr® system. As presented by Dr. Dewaele and her team, compared to their existing workflow, the new workflow including OGM as a primary analysis method reduced the number of fluorescence in-situ hybridization probes used by 90% and eliminated the need for multiplexed ligation polymorphism assays. In their new workflow including OGM, it is complemented with karyotyping to detect ploidy changes and the presence of small subclones. This transformation resulted in a turnaround time that was 14 days faster, a cost savings of approximately 50% and higher overall success rates in finding pathogenic variants in samples.

In parallel, as part of their menu expansion efforts, and under the direction of Dr. Valérie Race, Center for Human Genetics at University Hospitals Leuven, a validation of Bionano's EnFocus™ FSHD tool will be conducted on a prospective cohort of FSHD samples to confirm OGM's capability to accurately measure the length of D4Z4 repeat arrays and assess reproducibility and repeatability of the workflow. Preliminary results were presented at the European Society of Human Genetics conference in August 2021, and reported that OGM can be a powerful and robust technique for FSHD testing in genetic diagnostic laboratories by providing results that are concordant with the current gold standard, Southern blot analysis in a substantially simpler workflow that does not use radioactivity.

Dr. Dewaele reported that she and her colleagues have doubled their weekly sample volume relative to when they first started using their Saphyr system and believe they are on track to reach their goal of 500 samples per year with this instrument. The teams at University Hospitals Leuven believe that the time and cost savings from using OGM-based assays could be a competitive advantage relative to traditional techniques. OGM is also complementary to many of the tools used in typical molecular pathology and cytogenomics labs and, as a result, it can be helpful to interpretation of results from assays such as karyotyping, which can be used to confirm OGM findings.

Erik Holmlin, PhD, President and CEO of Bionano Genomics, commented, "We are impressed at the drive and persistence of Dr. Dewaele and all of the teams at Leuven, which has enabled the hospital to expand its lab testing portfolio. We are thrilled that University Hospitals Leuven has determined its plans for menu expansion, which are facilitated by the accreditation and formal confirmation letter received from BELAC. We believe that the path followed by Dr. Dewaele is indicative of what other labs can follow along the way to making OGM an essential and widely used method in clinical genomics research," said Dr. Holmlin. "OGM can allow new workflows that are faster and provide answers to questions quickly, which may allow for treatment decisions to be taken sooner. Since OGM has been shown to find clinically relevant variants that other techniques may miss, it may also provide answers to questions researchers may not know they had about these specific cancers and genetic diseases."

Dr. Barbara Dewaele will be presenting at Bionano's Symposium on January 11, 2022. At the Symposium, more than 25 esteemed speakers from around the world will present their latest scientific findings using Bionano's Saphyr system for OGM in constitutional cytogenomics, hematologic malignancies, solid tumors, and in combination with next-generation sequencing. A link to register for the Bionano Genomics 2022 Symposium is available at <https://www.labroots.com/ms/virtual-event/bngo2022>

About Bionano Genomics

Bionano is a provider of genome analysis solutions that can enable researchers and clinicians to reveal answers to challenging questions in biology and medicine. The Company's mission is to transform the way the world sees the genome through OGM solutions, diagnostic services and software. The Company offers OGM solutions for applications across basic, translational and clinical research. Through its Lineagen business, the Company also provides diagnostic testing for patients with clinical presentations consistent with autism spectrum disorder and other neurodevelopmental disabilities. Through its BioDiscovery business, the Company also offers an industry-leading, platform-agnostic software solution, which integrates next-generation sequencing and microarray data designed to provide analysis, visualization, interpretation and reporting of copy number variants, single-nucleotide variants and absence of heterozygosity across the genome in one consolidated view. For more information, visit www.bionanogenomics.com, www.lineagen.com or www.biodiscovery.com.

Forward-Looking Statements of Bionano Genomics

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 inability or delays in the University Hospitals Leuven to expand its menu; the inability for other labs to utilize the steps taken by University Hospitals Leuven to make OGM a widely used method; the ability for University Hospitals Leuven to continue processing the increased volume of samples; OGM's ability to provide new, faster workflows; OGM's ability to find clinically relevant variants that other techniques miss and to provide answers to questions not yet asked; Dr. Dewaele's ability to present at Bionano's Symposium; and the impact of the expansion of our commercial leadership team, including our expectations regarding the growth of Saphyr® and our ability to bolster customer support and experience globally. 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, technologies or improvements in existing technologies; failure of OGM to accurately and consistently perform as observed by University Hospitals Leuven or others; subsequent results could negate the results observed by University Hospitals Leuven or others; 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; 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:

Amy Conrad

Juniper Point

+1 (858) 366-3243

amy@juniper-point.com

Media Relations:

Michael Sullivan

Seismic

+1 (503) 799-7520

michael@teamseismic.com



Source: Bionano Genomics