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Bionano Genomics Releases Major Update to Its Suite of Software Tools That Simplifies Clinical Analysis, Reduces Time to Actionable Results and Makes Adoption by Clinical Labs Easier

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Reduced compute time, faster variant analysis, more comprehensive clinical annotation and streamlined workflow for non-human model genomes used in drug development improve Saphyr's best in class structural variation analysis even further

SAN DIEGO, Oct. 21, 2020 (GLOBE NEWSWIRE) -- Bionano Genomics (NASDAQ: BNGO) announces the most significant update to its suite of software tools for data analysis since the launch of Saphyr in 2017. This version of Bionano Access contains over 100 new features and revisions designed to simplify and accelerate every step in the data analysis workflow and make Bionano data easier to interpret. The update is available now as a free download and will be included with Saphyr systems going forward. With these enhancements, it is expected that clinical labs that adopt Saphyr can more readily develop assays for a wide range of genetic diseases, including tests for pediatric neuro-developmental disorders, liquid biopsies for blood cancers like leukemias, lymphomas and multiple myeloma and tests for solid tumors as well.

Current clinical standards of care for diagnostic testing in genetic disease and cancer are based on a series of medical guidelines that recommend structural variation (SV) analysis as first-tier testing. For genetic disease, chromosomal microarray (CMA) analysis is first tier and karyotyping (KT) and fluorescence in-situ hybridization (FISH) are used as reflex tests. Medical guidelines for testing in heme malignancies recommend using KT as first tier testing, alongside some rapid FISH assays and FISH panels, and recommend using CMA as reflex tests. In multiple publications and presentations, Saphyr has been shown to provide a single test that is 100% concordant with the testing methods currently recommended by these guidelines, which requires the use of three different technologies. To-date, this capability has not been shown by any other genome analysis platform. Saphyr has been shown to be significantly more sensitive and specific for SVs than next-generation sequencing (NGS) and to outperform long-read sequencing platforms from PacBio and Oxford Nanopore Technologies. This software updates further enhance Saphyr's unique advantages for customers.

Building on the success of Bionano EnFocus[™] FSHD Analysis tools that automate the analysis of variants in a form of muscular dystrophy, this update is expected to be a key step forward in finalizing other EnFocus panels that automate analysis of variants in patients with genetic diseases, including autism spectrum disorder, developmental delay and repeat expansion disorders, patients with various heme malignancies, such as AML and CLL leukemias, and patients with solid tumors. This new version of the software makes it possible for Bionano EnFocus FSHD to run on the PC that ships with the Saphyr instrument without the need for cloud-based analysis or costly compute clusters. However, for analysis run on Bionano's cloud-based Compute On Demand, the updated software is more efficient, expands capacity and reduces the analysis time, in some cases by threefold. For discovery research, like in cancer research where exceptional sensitivity is essential, cloud-based analysis now finishes in hours rather than in days.

Mark Oldakowski, Chief Operating Officer of Bionano Genomics, who led the development of the software commented: "With the improvements to our analysis and visualization software announced today, Saphyr continues to increase its lead as the most powerful genome analysis platform for the detection of structural variants and copy number variations in human genomes and complex cancer samples. Saphyr's unique ability to detect structural variants down to 1% allele fraction, genome-wide and unbiased, without enrichment or amplification and with the highest sensitivities and lowest false positives is unmatched by current short or long-read sequencing technologies. The new capabilities and improvements to our software further simplify and speed up the analysis and interpretation of clinical samples and we believe that these updates may help accelerate Saphyr's adoption for Next-Generation Cytogenomics in the estimated 2,500 cytogenetics labs around the world."

Bionano Solve v3.6 and Bionano Access v1.6 are available for download at https://bionanogenomics.com/support/software-downloads/

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. Forwardlooking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the improved performance of our technology as a result of the recent software update; increased adoption of Saphyr resulting from this update and other recent updates; the ability of our technology to support future development of assays by clinical laboratories; Saphyr's capabilities in comparison to other genome analysis technologies and potential to replace traditional cytogenetic technologies; the accelerated adoption of Saphyr for Next-Generation Cytogenomics in cytogenetics labs; and the advancement of our strategic objectives. 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 ability of medical and research institutions to obtain funding to support adoption or continued use of our technologies; 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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