

Takeaways from AMP 2019 in Baltimore: Users of Bionano's Saphyr System Presented Results from Multiple Studies Demonstrating the System's Utility for a Variety of Disease Indications

Saphyr provides a platform that streamlines traditional workflows and provides a path to solving previously intractable scientific questions connected to the mechanisms of disease

SAN DIEGO, Tuesday, November 12, 2019 (GLOBE NEWSWIRE) -- [Bionano Genomics, Inc.](#) (NASDAQ: BNGO), a life sciences instrumentation company that develops and markets Saphyr®, a platform for ultra-sensitive and ultra-specific structural variation detection in genome analysis, today announced key takeaways from presentations by Saphyr users given between November 6-9 in Baltimore at the annual meeting of the Association for Molecular Pathology (AMP) and the associated corporate workshop.

Focusing on molecular diagnostics, quality health care through excellence in clinical molecular testing is at the core of AMP. The association organizes an annual meeting to further its vision of providing global expertise in molecular testing that drives patient care. Saphyr users chose AMP as a venue to present updates to their findings using the Saphyr System for a variety of disease indications:

Moffitt Cancer Center. A team of clinicians and scientists from the Moffitt Cancer Center and Bionano Genomics, led by Dr. Anthony Magliocco, M.D, of Protean BioDiagnostics, presented a study on HPV-positive ovarian tumors and two pairs of primary ovarian tumors with matched ascites. Ascites is the abnormal build-up of fluid in the abdomen, which can be caused by an inflammatory reaction to metastatic cancer cells. Bionano whole genome imaging demonstrated in pairs of primary ovarian tumors with matched ascites that primary tumors contained many more rearrangements and had an unstable copy number profile compared to the ascites, with very few shared aberrations. This observed difference could have important implications for treatment of ovarian cancer, since ascetic fluid is considered the primary route of metastasis and origin of recurrent disease, and it is possible that the less complex genome of ascetic fluid requires a different therapeutic approach than the complex primary tumor genome.

MD Anderson Cancer Center. Professor Rashmi Kanagal-Shamanna, M.D., from the University of Texas MD Anderson Cancer Center in Houston, presented a validation study on the use of Saphyr for the clinical assessment of patients with Myelodysplastic Syndromes, or MDS. MDS is a precursor for Acute Myeloid Leukemia (AML), and the number and type of structural variation in the cancer genome has extreme predictive value on the median survival time, which varies from five years for genomes with a single reported variant to just over five months for those with more than three abnormalities.

In a pilot study on 10 patient samples, Saphyr identified 100% of all aberrations detected by karyotype and microarray analysis. Dr. Kanagal-Shamanna stated that this exact concordance between Bionano genome imaging and clinical diagnostic assays, and the high throughput of the Saphyr instrument, make it a candidate single-platform assay for clinical diagnostics. Dr. Kanagal-Shamanna discussed the planned expansion of the study to 100 MDS cases with the goal of identifying new genomic aberrations that only Saphyr can detect and that alter the risk or affect management of the disease.

Radboud University Medical Center, Netherlands. A team led by Professor Alexander Hoischen, Ph.D, from Radboud University Medical Center, presented an update on their ongoing validation of Saphyr as a tool to replace FISH, karyotyping and CNV-microarrays for the clinical analysis of leukemias and genetic disease. Of the samples analyzed so far, Saphyr identified all clinically relevant, previously reported

aberrations observed using the three other technologies. They concluded that Bionano genome imaging is capable of replacing most traditional cytogenetic tests.

“We are pleased to see our users succeed in addressing their needs using Saphyr and with the progress clinicians are making towards establishing Saphyr as the leading platform for streamlining cytogenetic testing.” commented Erik Holmlin, Ph.D., CEO of Bionano. He added “Data generated by the Saphyr system are answering difficult questions in complex genetic diseases that have been historically very challenging according to each of the presenters who described their experiences with Saphyr. We are grateful to all our customers and collaborators for their inspiration and for their work in showing what Saphyr can do.”

More information about Bionano Genomics is available at www.bionanogenomics.com.

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 drive the adoption of 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.

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, the implications of clinical observations using data generated by Saphyr, impact of research incorporating the Saphyr system on the treatment of ovarian cancer, planned studies involving the use of Saphyr, Saphyr’s candidacy as a single-platform assay for clinical diagnostics, potential of Saphyr to replace most classical traditional tests and development of Saphyr as the leading platform for streamlining cytogenetic testing. 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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