Bionano Genomics Launches New Capabilities of the Saphyr System to Significantly Increase Its Cost Effectiveness, Speed and Ease of Use for Whole Human Genome Structural Variation Analysis and Digital Cytogenetics

The Saphyr platform is being used to drive the emergence of digital cytogenetics – a streamlined, comprehensive and cost-effective approach to modernize the clinical detection of structural variations which are at the root of human disease

SAN DIEGO, March 01, 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, announced at the 2019 Advances in Genome Biology and Technology (AGBT) meeting the launch of multiple new products and advancements for its Saphyr workflow that massively improve throughput, significantly speed up sample prep and allow for the detection of low-allele frequency structural variants.

Bionano has launched a new version of the Saphyr Chip that has 3 independent flowcells. The **3 x 1300 Saphyr Chip** running on Saphyr models that ship in 2019, which have a configuration that accommodates two chips at the same time, allow customers to map up to 42 whole human genomes per week, or to collect 1,300 Gbp (400x coverage) in less than 48 hours for samples in each of three flowcells. By dramatically increasing both throughput and the depth of coverage achievable in a flowcell, the new chip and dual-cartridge configuration of the Saphyr system now enable a cost & time effective pathway for comprehensive whole genome structural variation detection in the clinic.

The company is also now shipping a new kit for DNA isolation from blood and cells called Bionano Prep SP (solution phase). This kit dramatically reduces the time and effort to obtain extremely long, ultra-high molecular weight DNA by eliminating cumbersome, time-consuming steps like plug-lysis and drop dialysis. With **Bionano Prep SP**, users can manually process up to 6 patient samples in less than 3 hours or up to 12 patient samples per day, which reflects a savings of a full day from the workflow compared to the current plug-lysis approach. This new kit also costs less on a per sample basis, the protocol is automatable and the high purity of resulting DNA enables faster run times on the instrument and higher data quality.

Finally, Bionano is announcing the upcoming release of the latest version of **Bionano Solve,** its suite of data analysis tools, which for the first time will also be available in a cloud-based implementation called **Bionano Compute On-Demand.** This version of Bionano Solve contains a powerful new pipeline that analyzes single molecules for structural variation detection at low-allele fractions with the same ultra-high sensitivity and positive predictive value already associated with Bionano. The pipeline is particularly suited for analysis of complex, heterogeneous cancer samples and samples with germline mosaicism. All major types of structural variation can be detected with more than 80% sensitivity when present in just 5% allele fraction, while translocations and inversions can be detected with more than 90% sensitivity at this low frequency. With deeper coverage, even lower allele frequency calls can be achieved. A new copy number algorithm can detect fractional copy number changes, picking up large gains and losses present at as little as 10% allele fraction. Bionano and early-access users have successfully applied this workflow to various cancer samples, including leukemia, breast, ovarian, prostate, pancreatic, among others. This ability to deconvolute complex mixtures is a key component of our emerging digital cytogenetics workflow.

All these Saphyr updates are on showcase in Bionano's exhibit suite (#287) at the AGBT General Meeting taking place February 27 – March 2 in Marco Island, Florida.

Erik Holmlin, PhD, CEO of Bionano Genomics, commented, "The solutions we are putting into customers' hands are the fruits of years of work by our teams and show the remarkable ability of Bionano to continuously innovate to simplify our solution and expand the Saphyr system's utility. Taken together, everything we are releasing enables the easiest, most cost-effective path to high-depth genome maps. These improvements in turn enable detection of structural variants of all types associated with genetic diseases and complex disorders like

cancer, where heterogeneity of sample makes it particularly difficult to find the needle in the haystack that explains the pathology. These new Saphyr workflow advancements form the basis of a robust digital cytogenetics workflow."

About Bionano Genomics
Bionano is a life sciences instrumentation company in the genome analysis space. The Company 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, 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.

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