Bionano Genomics Solidifies its Entry into Solid Tumor Analysis with Launch of New Kit and Protocol that Significantly Simplify Tissue and Solid Tumor Analysis

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Bionano's new Bionano Prep™ SP Tissue and Tumor Kit enables routine analysis of cancer biopsies and animal tissue expanding its addressable market to include solid tumors and model genomes commonly studied in pharmaceutical research and development

SAN DIEGO, July 09, 2020 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO), today announced that it has launched the new Bionano Prep™ SP Tissue and Tumor Kit, a DNA isolation kit developed expressly for analysis of tumors and tissue with Bionano's Saphyr system. The kit has been designed to simplify isolation of Ultra High Molecular Weight (UHMW) DNA from a variety of solid tumors and tissue types. The new kit and protocol for the Saphyr system make the analysis of genomic rearrangements in cancer and model genomes that are of interest in pharmaceutical development simpler and more feasible than currently available methods.

The new Bionano Prep SP Tissue and Tumor Kit allows for the consistent isolation of UHMW DNA in less than six hours from what is traditionally a difficult and highly complex sample type. Human and animal tissues and tumors vary widely and depending on the organ of origin, can contain high levels of fats or carbohydrates that can compromise the quality of the sequencing or optical mapping data. The new kit and related protocol enable consistent isolation of high quality UHMW DNA from as little as 5 mg of fresh or frozen tissue and tumor material, facilitating routine analyses from small amounts of starting material, such as those likely to be obtained from a needle aspirate. The new kit was successfully validated on a wide variety of tumors and tissues (bladder, lung, liver, kidney, colon, breast, prostate, brain, thyroid, ovary, testes and uterus).

DNA isolated with the kit is of unprecedented length, resulting in isolation of molecules up to megabase lengths. Genome imaging on the Saphyr system takes advantage of these extremely long molecules to detect all types of structural variants genome-wide in an unbiased fashion. In a single run, Saphyr can image enough molecules to span over 1,500x coverage of a human genome. This depth of coverage enables the detection of structural variants present in as little as 1% variant allele fraction. Altogether, the new kit for isolation of DNA from tissue and tumor, the high-throughput automated genome imaging on Saphyr, and the fully automated variant calling form a simplified, streamlined workflow for variant analysis from tissues and tumors.

Brandon LaBarge, MD, from the Penn State College of Medicine, who was part of the multisite early access to the new DNA isolation method, commented: "Earlier methods to purify long DNA involved agarose plugs and a tedious protocol with manual washing and digesting steps, taking up to three days to run four samples. These older methods provided inconsistent results, with several tumor samples failing altogether or generating limited throughput. With the new Bionano Prep SP Tissue and Tumor Kit, we were able to isolate ultra-high molecular weight DNA in less than six hours on six samples at a time, generating a consistent, high throughput on a variety of head and neck cancers."

Mark Oldakowski, Bionano's Chief Operating Officer commented: "With the launch of the Bionano Prep SP Tissue and Tumor Kit, we are bringing the speed, ease of use and DNA quality of our extremely popular SP kits to the most difficult and complex human sample types. By making the DNA isolation simpler, faster, and less expensive, we enable the routine analysis of solid tumors. Additionally, the new kit enables faster and streamlined processing of a variety of animal tissues, which we anticipate will greatly simplify the work of large consortia such as the Vertebrate Genome Project and work on model genome analysis for pharmaceutical research and development. Our next software release planned for later this summer is expected to make structural variant calling from non-human organisms more powerful and straightforward than before, and to maximize the benefit of our new DNA isolation kit."

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. 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. For more information, visit 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, among other things: the anticipated benefits of the new Bionano Prep SP Tissue and Tumor Kit; planned release of software and other improvements to the Saphyr system and the expected benefits of such improvements; and the general effectiveness and utility of the new kit and the Saphyr system. 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 the new Bionano Prep SP Tissue and Tumor Kit may not be was effective as expected, as well as 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 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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