



## German Accreditation of Laboratory Developed Tests on Bionano's Saphyr System Accelerates Utilization in Clinical Diagnostics

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### First official European accreditation of Saphyr-based laboratory developed test helps pave the way for broader adoption of Saphyr for clinical diagnostics applications

SAN DIEGO, Sept. 24, 2020 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (Nasdaq: BNGO) announced today that MVZ Martinsried, a leading clinical diagnostics service provider in Germany, received accreditation for use of Bionano's digital cytogenetics platform, Saphyr, for laboratory developed tests (LDTs) as an important component of their testing services moving forward. Approval was awarded by Deutsche Akkreditierungsstelle GmbH (DAkKS), the national accreditation body for the Federal Republic of Germany, following the one of the most stringent review process in Europe.

The approval accredits LDTs developed by MVZ Martinsried for the detection of the following types of structural variants (SVs): translocations, inversions and duplications. Translocations, for example, cause different forms of leukemia and myeloma, including chronic myelogenous leukemia and multiple myeloma, and different forms of solid tumor cancers, including non-small cell lung cancer. Inversions and duplications are also often implicated in cancers and all three types are known to occur in constitutional genetic disorders. These so-called balanced genome rearrangements are challenging to detect by sequencing and microarrays, yet the standard of care for detecting them is karyotyping (KT) and fluorescence in situ hybridization (FISH). Genome analysis with Saphyr consolidates into a single assay the SV detection capabilities, including balanced rearrangements, of three separate structural variant analysis techniques (KT, FISH and chromosomal microarrays).

"MVZ Martinsried's receipt of this first European accreditation for use of Saphyr-based LDTs is an important milestone towards broader accreditation and adoption across Europe and other regions. Achieving this accreditation in Germany, the largest market in Europe, is also significant because the German accreditation process follows a very high standard," said Erik Holmlin, chief executive officer of Bionano Genomics. "KT and FISH are fairly antiquated and cumbersome workflows that labs have been seeking to replace with a single assay for some time. Saphyr can offer them that opportunity, having been repeatedly shown to give results that are concordant with these technologies, while providing the potential for the detection of variants at higher resolution and also the detection of incrementally more variants from each sample. We believe Saphyr can help support improved diagnosis of patients, leading to a higher overall diagnostic yield, compared to the standard of care."

The DAkKS accreditation of the workflow to detect balanced structural variations, positions Saphyr within MVZ Martinsried's routine diagnostic workflow, with the potential to replace most of its tests previously run on KT and FISH.

#### 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](http://www.bionanogenomics.com) or [www.lineagen.com](http://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. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: MVZ Martinsried's anticipated use of Saphyr in its testing services; potential broader accreditation or use of Saphyr for clinical use in Europe and other regions; Saphyr's effectiveness and utility in clinical settings; Saphyr's capabilities in comparison to other genome analysis technologies; and the future development of assays using our technology. 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 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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