



BioNano Genomics and Berry Genomics to Co-Develop Next-Generation Mapping System for CFDA-Approved Clinical Use in China

BioNano's Irys® chosen by Berry for the development, manufacture and marketing of a chromosomal structural variation detection system for multiple clinical applications in China

SAN DIEGO & BEIJING – August 17, 2016 – Berry Genomics Co., Ltd. announced today that it has chosen BioNano Genomics' Irys® system for next-generation mapping (NGM) as the platform on which Berry will seek Chinese Food and Drug Administration (CFDA) regulatory approval for a number of clinical indications in China.

Under the agreement, the companies will co-develop an NGM system to provide cost-effective, easy-to-use assays for detection of chromosomal structural variations. The new assays and instrument system are to be validated in clinical settings in China and submitted for review under the CFDA's medical device registration process.

The system will integrate proprietary assays designed by BioNano and Berry with a next-generation mapping instrument based on BioNano's Irys® platform. Berry will exclusively manufacture and market the system and assays in China for clinical use in selected indications. BioNano will continue to market its Irys® system in China to the rest of the research community, including genomics centers, governmental and academic institutions, translational research facilities and pharmaceutical companies.

"Chromosomal structural variation-based testing is a very rapidly expanding market in China and the existing detection modalities, such as karyotyping, FISH and microarrays, are slow, labor-intensive and oftentimes deficient in detecting the full spectrum of genetic variation. We sought to address all of these deficiencies with our upcoming product offering, and NGM was found to be the right approach," said Daixing Zhou, Ph.D., CEO of Berry Genomics. "As the clear leader in NGM, BioNano is our ideal partner. BioNano is the only company that provides a commercially viable method for the systematic and comprehensive detection of large structural variations. These variations are the roots of many human diseases and the existing technologies, including next-generation sequencing, cannot readily and comprehensively find them."

"Berry has become the leader in non-invasive prenatal testing in China through innovative offerings, and we seek to help Berry achieve that same level of leadership in a broad array of genetic diseases and cancer with our

NGM platform,” said Erik Holmlin, Ph.D., CEO of BioNano Genomics. “This partnership is an example of our goal of working with the leading clinical companies around the world that seek to take human disease diagnosis to the next level via our Irys® technology.”

About BioNano Genomics

BioNano Genomics, Inc., the leader in next-generation mapping (NGM), provides customers with genome analysis tools that advance human, plant and animal genomics and accelerate the development of clinical diagnostics. The Company’s Irys® System uses NanoChannel® arrays integrated within the IrysChip® to image genomes at the single-molecule level with average single-molecule lengths of about 350,000 base pairs, which leads the genomics industry. The long-range genomic information obtained with the Irys System helps decipher complex DNA involving repeats, which are the primary cause of inaccurate and incomplete genome assembly.

On its own, next-generation mapping with the Irys System enables detection of structural variants, many of which have been shown to be associated with human disease as well as complex traits in plants and animals. As a companion to next-generation sequencing (NGS), next-generation mapping with the Irys System integrates with sequence assemblies to create contiguous hybrid scaffolds that reveal the highly informative native structure of the chromosome.

Only BioNano Genomics provides long-range genomic information with the cost-efficiency and throughput to keep up with advances in next-generation sequencing.

The Irys System has been adopted by a growing number of leading institutions around the world, including: National Cancer Institute (NCI), National Institutes of Health (NIH), Wellcome Trust Sanger Institute, BGI, Garvan Institute, Salk Institute, Mount Sinai and Washington University. Investors in the Company include Domain Associates, Legend Capital, Novartis Venture Fund and Monashee Investment Management.

For more information, please visit www.BioNanoGenomics.com.

About Berry Genomics

Berry Genomics is a leading biotech company in China that develops and commercializes genomics-based integrated solutions for clinical applications, primarily in genetic testing and oncology testing. Berry pioneered non-invasive prenatal testing (NIPT) in China and today is the leading NIPT IVD product provider, as well as the leading provider of the test, in China. Like NIPT, the products and technologies under development at Berry Genomics will address unmet needs of other genetic diseases and cancer.

For more information, please visit www.BerryGenomics.com.

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