

# Genomic Vision technology to be tested by NIST (US Gaithersburg) for establishing standards methods for Genome Editing based product registration by FDA

**Bagneux (France), Genomic Vision (FR0011799907 – GV),** a biotechnology company developing molecular assays and Artificial Intelligence tools to control quality and safety of genetically modified genomes, today announced that its Molecular Combing technology will be used by the US National Institute of Standards and Technology (NIST) to characterize and quantify intended and unintended genome editing events in NIST's control material.

The Molecular Combing technology is currently used for monitoring DNA replication in cancerous cell, for early cancer detection and the diagnosis of genetic diseases. Genomic Vision has been part of the NIST Genome Editing Consortium since March 2019. The consortium's goal is to address pre-competitive measurement needs which may eventually help to speed the process of bringing genome editing products to the market. The Consortium has 33 formal members and three working groups. Genomic Vision participates in the first working group, known as "Specificity" which aims to qualify the genomic assays used for evaluating genome editing outputs, and to design the control materials needed to increase confidence in genome editing.

On October 18<sup>th</sup>, 2019, working group projects were defined and it was decided that Genomic Vision will use their Quality Control Assay (QCA) to confirm mid-size to large variants engineered into cells as controls. Indeed, Genomic Vision FiberVision® platform provides a powerful quality control tool for the safety and the optimization of gene editing projects thanks to its high sensitivity and digital quantification capacity. This platform allows an unbiased assessment of genetic events through the direct visualization on single DNA molecules. Combing technology requires no DNA amplification and completes NGS/PCR based assays.

**Samantha Maragh, Leader of the Genome Editing Program at the NIST, stated:** "One of NIST's missions consists of playing a pivotal role in helping to define the measurements and standards for cellular and gene therapies and other regenerative medicine. I am glad to have innovative industry partners participating in the Consortium who can apply their technology to solving some of the measurement challenges of genome editing."

The National Institute of Standards and Technology (NIST) was founded in 1901 and is now part of the U.S. Department of Commerce. NIST is one of the nation's oldest physical science laboratories, and addresses measurement research needs in multiple fields including chemistry, IT, engineering and biology. The NIST Genome Editing Consortium addresses the measurements and standards needed to increase confidence and lower the risk of utilizing genome editing technologies in research and commercial products (www.nist.gov).

**Stéphane Altaba, Chief Operating Officer of Genomic Vision, commented:** *"Implementing our technology in the scope of the NIST consortium into specific work packages will confirm the value of the molecular combing in detecting and quantifying unwanted events. The work we have performed in collaboration with Editas Medicine (Cecilia Cotta-Ramusino et al., CSHL Meeting: Genome Engineering: The CRISPR-Cas9 Revolution, July 21-23, 2017) and for other gene editing companies already demonstrated the relevance of our technology in this field but we wanted to take the time to go along the* 

regulatory pathway and join the NIST Consortium. We appreciate the way that this initiative will enable us to interact on a regular basis with all the major players in gene editing and will give us the opportunity to use our technology to set up standard tools. It is exciting to contribute to the fabulous story of gene editing."

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#### ABOUT GENOMIC VISION

GENOMIC VISION is a biotechnology company developing molecular assays and Artificial Intelligence tools to control quality and safety of genetically modified genomes, in particular in genome editing technologies and biomanufacturing processes. These tools are currently used for monitoring DNA replication in cancerous cells, for early cancer detection, and the diagnosis of genetic diseases. Based near Paris, in Bagneux, the Company has approximately 30 employees. GENOMIC VISION is a publicly listed company in compartment C of Euronext's regulated market in Paris (Euronext: GV - ISIN: FR0011799907).

For further information, please visit www.genomicvision.com

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## FORWARD LOOKING STATEMENT

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