



GENOMICS | DIAGNOSTIC TESTS | GENETICS | R&D

The clinical trial undertaken by Genomic Vision and Reims University Hospital to validate a new test for the early detection and treatment of cervical cancer was chosen for an oral presentation at the Eurogin Congress in Salzburg

Bagneux (France) - Genomic Vision (FR0011799907 – GV), DNA molecular combing specialist that develops tests for the diagnostics market and tools for the life sciences research market, today announces that the IDAHO clinical trial launched at the end of 2015 in France, which aims to validate the integration of the oncogenic, i.e. high-risk, human papillomavirus (HPV-HR) as an indicator of the severity of cervical lesions and the risk of developing cervical cancer, was presented by Professor Christine Clavel, project coordinator, via an oral presentation at the Eurogin (EUropean Research Organisation on Genital Infection and Neoplasia) Congress held in Salzburg, Austria, from June 15 to 18, 2016.

The integration of HPV-HR DNA in a host's genome is considered to be a key stage in the progression of precancerous lesions into cancerous lesions in the cervix. The aim of this study is to determine whether the integration of HPV-HR DNA in patients' genomes is a sufficient diagnostic (severity of lesions) and prognostic (risk of progression of lesions) indicator. Genomic Vision's molecular combing technique is currently the only one that allows the frequency of the integration of high-risk HPV-HR to be detected, in a direct and high resolution manner.

The IDAHO clinical trial comprises two phases:

- The first phase began in December 2015, and aims to show that the integration of HPV is a biomarker for diagnosing high-risk precancerous lesions that require appropriate treatment to be defined. The number of patients to be included in this study has been able to be reduced from 3,500 to 1,550 thanks to the new technical developments of the HPV test by molecular combing, which now detects 14 high-risk HPV instead of the initial 5.
- During the second phase, women who test positive for HPV infection with no declared lesions or with low-grade lesions will be monitored for 3 years. This will make it possible to validate the integration of HPV DNA as a prognostic biomarker.

Professor Christine Clavel, molecular biologist in the Biopathology laboratory at Reims University Hospital, who presented the study at the conference, says: *“This innovative approach should enable us to better understand the integration of high-risk HPV in the host's genome, notably in terms of the frequency of the integration. Indeed, HPV infections being frequent but often temporary, current HPV tests are sensitive but not specific enough to detect high-grade lesions. Searching for new biomarkers, identifying among HPV-positive women those who will actually develop a precancerous lesion, remains crucial. If the results of this study are conclusive, we will then be able to consider viral integration to be an efficient diagnostic and prognostic tool enabling cervical cancer screening to be optimized and the best course of treatment for the patient to be determined.”*

Upcoming financial publication

2016 half-year results, Tuesday, July 26, 2016* (before trading)

** indicative date, which may be subject to change*

ABOUT GENOMIC VISION

Founded in 2004, Genomic Vision is a DNA molecular combing specialist that develops tests for the diagnostics market and tools for the life sciences research market. Using its innovative technology that allows the direct visualization of individual DNA molecules, Genomic Vision detects quantitative and qualitative variations in the genome that are at the origin of numerous serious pathologies. The Company is developing a solid portfolio of tests that initially target breast and colon cancers. Since 2013, the Company has marketed the CombHelix FSHD test for identifying facioscapulohumeral dystrophy (FSHD), a myopathy that is difficult to detect. It is marketed in the United States through a strategic alliance with Quest Diagnostics, the American leader in diagnostic laboratory tests, and in France directly by the Company. Genomic Vision has been listed on Compartment C of Euronext Paris since April 2014.

ABOUT MOLECULAR COMBING

DNA molecular combing technology significantly improves the structural and functional analysis of DNA molecules. DNA fibers are stretched over glass slides, as if "combed", and uniformly aligned over the entire surface. It is then possible to identify genetic anomalies by locating specific genes or sequences in the patient's genome using genetic markers, a technique developed by Genomic Vision and patented under the name Genomic Morse Code. This exploration of the entire genome at high resolution via a simple analysis enables the direct visualization of genetic anomalies that are undetectable by other technologies.

For further information, please go to: www.genomicvision.com

ABOUT THE REIMS UNIVERSITY HOSPITAL

In keeping with public service values, the Reims University Hospital ("Centre Hospitalier Universitaire de Reims", or "CHU de Reims") strives to meet one goal: to provide, through its 15 medical departments, excellent care and high-quality treatment to all patients in the Champagne-Ardenne region of France. The Reims University Hospital also works hard to maintain its positioning as a university hospital and to promote the involvement of its medical staff in innovative research projects. Professor Christine Clavel and Doctor Véronique Dalstein, molecular biologists in the Reims University Hospital's Biopathology laboratory, headed by Professor Philippe Birembaut, have for many years been involved in research into HPV infections and use of the HPV test in clinical practice, notably in cervical cancer screening. This area of research is part of the Eastern France Cancer Research Cluster's virus and cancer focus. Their research work in this field has received domestic and international acclaim.

For further information, please go to: www.chu-reims.fr

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