Press release

GENOMICS | DIAGNOSTIC TESTS | GENETICS | R&D

Genomic Vision and Reims University Hospital Launch Clinical Study to Establish New Screening Tool for Early Detection and Prevention of Cervical Cancer

The Largest Study ever Undertaken Using the Molecular Combing Technique on 3,500 Patients at 11 French Hospitals

Bagneux France (December 14, 2015) – Genomic Vision (GV: EN Paris), a molecular diagnostics company specializing in the development of diagnostic tests for genetic diseases and cancers based on molecular combing technology, today announces that it has signed a partnership agreement with the **Reims University Hospital (*CHU de Reims*)** for a clinical study aiming to validate the integration of the high-risk human papillomavirus (HPV-HR) as an appropriate indicator of the progression of cervical lesions towards cervical cancer. This prospective multicenter study, called IDAHO (*Intégration de l'ADN des HPV Oncogènes*, or integration of oncogenic HPV DNA), will involve 3,500 patients to be treated at 11 leading French gynecology hospitals.

HPV-HR DNA is the only independent risk factor for cervical cancer, which is the second most common form of cancer in women, behind breast cancer. Every year, almost 500,000 new cases and between 250,000 and 300,000 deaths are recorded worldwide. Due to its slow progression, cervical cancer can be prevented through screening and the treatment of precancerous lesions.

This study aims to validate the integration of HPV-HR DNA in patients' genomes as an indicator of the severity of cervical lesions. This indicator will also help identify lesions presenting a high risk of developing cervical cancer. Genomic Vision's molecular combing technique is currently the only one that allows direct and high-resolution visualization of the integration of high-risk HPV genomes, as shown by the data presented by the Company at the 29th International Papillomavirus Conference & Clinical Workshop in Seattle (see the press release of August 25, 2014).

Thus far, screening has been essentially based on cervical smears and tests to detect viral RNA or DNA (HPV tests). Cervical smears are not sensitive enough while HPV tests, which are highly sensitive, are not sufficiently specific. These tests result in unnecessary, invasive and expensive clinical examinations, as well as excessive treatments that can have detrimental effects on the future pregnancies of these women, who are often young.

"*The goal of the IDAHO study is to overcome this diagnostic insufficiency by identifying a biomarker that can specifically differentiate between women with a high risk of developing cervical cancer, and who therefore require treatment, and women with a low risk who require*

appropriate monitoring," **explains Professor Olivier Graesslin, M.D., Head of the Reims University Hospital's Gynecology-Obstetrics unit and coordinator of this study.**

The IDAHO study will comprise two phases:

- The first, cross-sectional phase, will involve the recruitment of 3,500 patients for 3 years beginning in December 2015 with an aim to show that the integration of HPV is a biomarker for diagnosing high-risk precancerous lesions that require immediate care and treatment.
- The second phase will follow patients who have tested positive for HPV infection with low-grade precancerous lesions for three years, in order to confirm that the integration of HPV DNA is a biomarker for the progression of precancerous lesions.

Aaron Bensimon, Ph.D., Genomic Vision's co-founder and Chairman, concludes: "*This clinical study involving 11 leading French hospitals is the largest one that Genomic Vision has participated in, and reflects the medical community's need for the development of more efficient cervical cancer screening tests. The quality of this consortium's partners makes us particularly optimistic regarding the outcome of our collaboration. Once it has been validated, our HPV test should increase the efficacy of the diagnosis and thus enable patients to be steered towards the most suitable treatment, therefore avoiding the need for unnecessary, invasive and expensive colposcopies."*

Upcoming financial publication

- Annual Revenue for 2015, Monday, January 18, 2016* (after trading)

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

ABOUT GENOMIC VISION

Founded in 2004, Genomic Vision is a molecular diagnostics company that specializes in the development of diagnostic tests for genetic diseases and cancers based on molecular combing. Using this 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, 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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