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GENTICEL TO EVALUATE ROCHE MOLECULAR SYSTEMS' COBAS® HPV TEST IN PREPARATION FOR PHASE 3 PROGRAM OF GTL001

Genticel (Euronext Paris & Brussels: FR00011790542 – GTCL), a clinical-stage biotechnology company and developer of innovative immunotherapies to prevent cancers caused by the human papillomavirus (HPV), today announces that the Company has signed an agreement with Roche Molecular Systems Inc. to evaluate Roche's cobas® HPV Test in preparation for the planned phase 3 trial of GTL001, Genticel's most advanced therapeutic vaccine candidate against HPV 16/18 infections.

GTL001 is currently being evaluated in a randomized, double-blind phase 2 efficacy study across 7 countries in Western Europe in 236 HPV 16/18 positive patients with normal cytology or minor abnormalities. Interim results are expected early this year with a primary endpoint based on virology. Per protocol, Genticel is using the ISO15189 certified qPCR test from AML, Antwerp, Belgium, a full genotyping test which is also used for the Flemish population based screening program. However, this laboratory-developed test is only performed in Belgium.

In the planned global phase 3 program of GTL001, Genticel intends to measure the non-appearance of high-grade lesions in HPV 16/18 positive women. For this purpose, the Company requires a more broadly available commercial HPV genotyping test to both identify the patient population at risk prior to enrolment and to assess HPV infection status post-treatment. Therefore, Genticel will assess Roche Molecular Systems' cobas® HPV Test by evaluating existing samples from the phase 2 trial at a clinical virology threshold considered for the global phase 3 program of GTL001.

The cobas® HPV Test is currently the only HPV assay which is both EU-labeled and FDA-approved and provides specific genotyping information, notably for HPV 16 and 18, the highest-risk types targeted by GTL001. Since April 2014, the cobas® HPV Test is the only test approved in the U.S. that can be used instead of a Pap smear in first-line, primary screening in women 25 years of age and older. Last October, the cobas® HPV Test was also awarded the tender as first-line, primary screening test in the National Cervical Cancer Screening Program in the Netherlands. These events further support the continuously growing trend both in Europe and in the U.S. towards early screening for the most dangerous types of HPV and highlight the need for a treatment option for the millions of women infected with HPV 16 or 18 worldwide.

"W*e are very pleased to enter into this agreement with Roche Molecular Systems,"* concluded Benedikt Timmerman, PhD, MBA, Chief Executive Officer of Genticel. "*The ability to evaluate the cobas® HPV Test is an important milestone that will help us anticipate requirements for the planned phase 3 program of GTL001 and identify the patient population that will most benefit from treatment."*

About Genticel

Aiming to solve a public health issue.

Among the 300 million women around the world currently infected with HPV, 500,000 new cases of cervical cancer are identified each year and 275,000 women succumb to the disease. 70% of cervical cancer cases are caused by 2 HPV types and Genticel aims to eliminate them at an early stage with GTL001 (known in Europe as ProCervix), its first-in-class immunotherapeutic vaccine candidate. The company has already completed patient recruitment for the phase 2 clinical trial of GTL001 in Europe.

Offering a promising technological platform.

Genticel's versatile platform, Vaxiclase, is ideally suited for the development of immunotherapies against multiple infectious or cancerous diseases. Genticel's second candidate, GTL002, is a multivalent HPV therapeutic vaccine designed with Vaxiclase. It targets the six most relevant HPV types in terms of global epidemiology and is currently in preclinical development.

Focusing on value creation.

Respectively, the peak sales potentials of GTL001 and GTL002 are estimated at over €1 billion and €2 billion per year. In addtion to this attractive HPV product pipeline, Genticel's versatile technological platform, Vaxiclase, has already generated significant interest in the pharmaceutical industry, as illustrated by the partnership agreement signed in 2015 with the Serum Institute of India Ltd. (SIIL), the world's largest producer of vaccine doses. This partnership could generate up to $57 million in revenues for Genticel, before royalties on sales. It will enable SIIL to develop acellular multivalent combination vaccines against a variety of infectious diseases, including whooping cough.

For more information, visit us at www.genticel.com

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