

*Paris and Toulouse, June 13, 2016*

## **GENTICEL ANNOUNCES COMPLETION OF TWO MAJOR MILESTONES IN PREPARATION FOR PHASE 3 PROGRAM OF GTL001**

- ▶ **ABILITY TO USE CLINICALLY VALIDATED HPV TESTS**
- ▶ **FIVE-YEAR STABILITY OF GTL001 DRUG PRODUCT**

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 it has confirmed the ability to use widely available genotyping HPV tests in the planned phase 3 program of GTL001, Genticel's most advanced therapeutic vaccine candidate against HPV 16/18 infections. The Company also reports that GTL001 drug product has completed stability assays demonstrating a five-year shelf life.

As announced on January 7, 2016, Genticel evaluated Roche Molecular Systems' cobas® 4800 test, commercially available both in Europe and in the US, in order to confirm whether the globally validated cobas® HPV Test could be used for the recruitment and post-treatment analysis of patients in the planned Phase 3 program of GTL001. This evaluation was conducted by assessing existing samples from the Phase 2 trial at the clinical virology threshold planned in the global phase 3 program of GTL001. The results obtained with the cobas® HPV test, which has undergone extensive clinical validation worldwide, were equivalent to those generated with the clinical laboratory test used per protocol in the Phase 2 trial on the same samples.

*"The ability to use a clinically validated and globally available test such as the cobas® HPV test and the demonstration of GTL001 five-year stability were two critical milestones towards partnering and registration studies for GTL001,"* said Benedikt Timmerman, PhD., MBA, and Chief Executive Officer of Genticel. *"We are very pleased with these achievements and continue to move forward with preparations for the GTL001 Phase 3 program."*

GTL001 is currently being evaluated in a randomized, double-blind phase 2 efficacy study in Western Europe in HPV 16/18 positive patients with normal cytology (NILM), borderline (ASCUS) or with low -grade lesions (LSIL). Virology results at 12 months were reported earlier this year<sup>1</sup>, with encouraging results in the study subpopulation of women who have not yet developed cellular lesions<sup>2</sup>. This subpopulation represents over 80% of HPV 16/18 positive women, the target population of GTL001. In this phase 2 study, Genticel is using, per protocol, the ISO15189 certified qPCR test from AML (Antwerp, Belgium), a full genotyping test that is used in the Flemish population-based cervical cancer screening program. However, this laboratory-developed test is only performed in Belgium.

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<sup>1</sup> Please refer to the press releases issued by the Company on January 27 and April 20, 2016.

<sup>2</sup> Post-hoc analysis (Cochran-Mantel-Haenszel test) of the combined subgroups of NILM (normal cytology) and ASCUS (undetermined cellular anomalies) cytology status :  $p=0.0029$ .

## 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, its first-in-class immunotherapeutic candidate. GTL001 is more than halfway through a 24-month proof of concept Phase 2 trial 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 immunotherapeutic candidate 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 addition 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. (SII), 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 SII to develop acellular multivalent combination vaccines against a variety of infectious diseases, including whooping cough.

For more information, visit us at [www.genticeL.com](http://www.genticeL.com)



### Forward Looking Statement

This press release contains forward-looking statements that are not promises or guarantees and involve substantial risks and uncertainties. The Company's product candidates have not been approved for sale in any jurisdiction. Among the factors that could cause actual results to differ materially from those described or projected herein are uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals, the risk that historical preclinical results may not be predictive of future clinical trial results, and the risk that historical clinical trial results may not be predictive of future trial results. A further list and description of these risks, uncertainties and other risks can be found in the Company's regulatory filings with the French "Autorité des Marchés Financiers", including in the Company's Annual Report for the year ended December 31, 2015 and future filings and reports by the Company which are available on the Company's website. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. GenticeL undertakes no obligation to update or revise the information contained in this Press Release, whether as a result of new information, future events or circumstances or otherwise.

GENTICEL	US INVESTORS	MEDIA
Valerie Leroy Investor Relations & Corporate Communications + 33 6 33 34 37 30 <a href="mailto:investors@genticeL.com">investors@genticeL.com</a>	Life Sci Advisors Brian Ritchie +1 212 915 2578 <a href="mailto:britchie@lifesciadvisors.com">britchie@lifesciadvisors.com</a>	ALIZE RP Caroline Carmagnol et Florence Portejoie +33 6 64 18 99 59 / +33 6 47 38 90 04 <a href="mailto:genticeL@alizerp.fr">genticeL@alizerp.fr</a>