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GENTICEL ANNOUNCES PUBLICATION IN ‘CLINICAL CANCER RESEARCH’ OF PHASE 1 TRIAL RESULTS SUPPORTING SAFETY, TOLERABILITY AND IMMUNOGENICITY 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 announced the publication of results from the Phase 1 trial of GTL001 in which the Company’s lead candidate was observed to be generally safe and well-tolerated and to induce a specific immune response in women with normal cytology (NILM¹) infected with HPV16 or HPV18. In addition, the study provided initial evidence that GTL001 could promote clearance of HPV16 and HPV18 in this population². The peer-reviewed publication authored by Prof. Pierre Van Damme, MD, PhD, chairman of the Vaccine & Infectious Disease Institute of the University of Antwerp (Belgium) and entitled “*GTL001, a therapeutic vaccine for women infected with human papillomavirus 16 or 18 and normal cervical cytology: results of a Phase 1 clinical trial*” is available online in [Clinical Cancer Research](#) (Clin Cancer Res).

“GTL001 is the only therapeutic vaccine candidate in development for women infected with HPV16 or HPV18 before the onset of cervical cellular anomalies or lesions. This Phase 1 study indicated that, in this population, GTL001 had a satisfactory safety profile and induced an antigen-specific cellular immune response,” said Prof. Pierre Van Damme, principal investigator of the Phase 1 trial and senior author of the publication.

Currently, there is no treatment option for the 93 million women worldwide infected with HPV16 and 18, prior to the onset of cervical lesions or cancer. This therapeutic gap is certainly central to the sustained engagement of both patients and physicians; no dropouts were reported throughout this Phase 1 study despite a demanding enrollment and follow-up examination schedule.

GTL001 was generally safe and well tolerated, a key requirement for further clinical development in this infected yet asymptomatic population. Although this tolerability study was not designed to perform statistical analysis², results also showed the induction of a specific immune response against HPV16 and HPV18 and indicated that GTL001 could promote and sustain viral clearance.

“We are very pleased to share this publication of these encouraging GTL001 phase 1 data which formed the basis for our decision to initiate our ongoing pan-European Phase 2 trial,” commented Benedikt Timmerman, PhD., MBA, CEO of Genticel. *“The recently released positive results at 12 months in the normal cytology¹ predefined subgroup of the phase 2 study are consistent with the observations of the phase 1 trial in the same population. Together, they strongly suggest that Genticel’s antigen delivery technology is effective in these subjects who represent the large majority of HPV 16/18 positive women.”*

About GTL001 Phase I Clinical Study (EudraCT No. 2010-018629-21)

The Phase 1 trial objectives were to examine the safety, the tolerability, and the immunogenicity of GTL001 solution and GTL001 powder, with or without imiquimod topical cream application, in women infected by HPV 16, HPV 18 or both, who have normal cytology¹.

The study enrolled 47 HPV 16/18 positive women at the Vaccine and Infectious Disease Institute (VAXINFECTIO, University of Antwerp, Belgium), after two consecutive normal cytology examinations, in three open-label cohorts and one randomized, placebo-controlled, double-blind cohort.

The overall patient retention rate was 100 %.

Results showed that intradermal vaccination with GTL001 plus topical imiquimod has an acceptable safety profile, with local reactions, mostly mild to moderate, being the most reported events. All reactions were transient and the interventions needed were occasionally oral over-the-counter analgesics. The systemic and local reactions induced by GTL001 plus imiquimod were consistent with the pharmacological effects of a vaccine inducing a T-cell response.

Consistent with preclinical studies, GTL001 was found able to induce an E7-specific T-cell response. In post-hoc analyses, HPV16/18 clearance² rates were highest in the subjects treated with GTL001 plus imiquimod. Sustained clearance assessed in subjects with virology data after an initial clearance, was highest in treated subjects.

In this Clinical Cancer Research publication, Prof. Van Damme and colleagues concluded that these results were promising, thereby enabling the initiation of the ongoing phase 2 trial of GTL001. Prof. Van Damme is the lead investigator of this 24-month phase 2 trial, which has enrolled 236 women in 39 European centers and is more than halfway through completion.

Please refer to the [online publication](#) for detailed results of the phase 1 trial.

¹ Normal cytology (NILM): *Negative for Intraepithelial Lesion or Malignancy*, cytological classification of a normal pap smear, without cellular anomalies or lesions.

² This phase 1 trial was not designed to detect significant differences in viral clearance and no statistical analysis was performed.

About Clinical Cancer Research

Clinical Cancer Research is a peer-reviewed journal from the American Association for Cancer Research (AACR). It publishes articles that focus on innovative clinical and translational research bridging the laboratory and the clinic.

More information on www.aacr.org and clincancerres.aacrjournals.org

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. (SIIIL), 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 SIIIL to develop acellular multivalent combination vaccines against a variety of infectious diseases, including whooping cough.

For more information, visit us at 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.

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