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GENTICEL REPORTS ADDITIONAL RESULTS AT 12 MONTHS FROM PHASE 2 TRIAL OF HPV IMMUNOTHERAPEUTIC CANDIDATE, GTL001

POST-HOC ANALYSES SHOW STATISTICALLY SIGNIFICANT VIRAL CLEARANCE IN A COMBINED SUBGROUP REPRESENTING OVER 80% OF GTL001 TARGET POPULATION

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 reports additional results at 12 months from the phase 2 clinical study of the Company's immunotherapeutic candidate, GTL001, designed to clear HPV 16 and/or 18 infection.

Initial results at 12 months of the GTL001 phase 2 study, announced on January 27, 2016, showed clear statistical separation (p=0.018) in the predefined subgroup of patients with normal cytology (NILM[1]), which comprises about 75% in GTL001's target population[2]. In addition, *post-hoc* analyses demonstrated a trend towards statistical significance in the subgroup of patients with undetermined cellular anomalies (ASCUS[1]).

Based on these results, the combined group of patients with normal cytology (NILM[1]) and patients with undetermined cellular anomalies (ASCUS[1]) also demonstrates a statistically significant separation (p= 0.0029). This combined group of patients who do not yet have low-grade lesions (LSIL[1]) comprises the vast majority (over 80%) of the HPV-positive women GTL001 aims to treat.

"*These very encouraging complementary data are indicative of the potential of GTL001 to provide a therapeutic solution to a large majority of the women infected with the two most dangerous types of HPV. While these results are subject to confirmation by data at 18 and then 24 months, they are extremely encouraging and validate the biologic activity of GTL001 in HPV 16/18-positive subjects prior to the onset of low-grade lesions,"* said Benedikt Timmerman, PhD., MBA, CEO of Genticel.

He added, "*These phase 2 study results provide us with the opportunity to appropriately refine our clinical development plan for GTL001, going forward. We now confidently await the conclusion of this study, which is expected during the first quarter of 2017.*"

Summary of Subgroup Analyses

Viral clearance at 12 months	GTL001	Placebo	p-value
Normal cytology (NILM) – *predefined group*	20/32 (62.5%)	12/30 (40%)	0.018*
Undetermined cellular anomalies (ASCUS) – *post-hoc*	17/31 (54.8%)	12/34 (35.3%)	0.067*
Total NILM and ASCUS – *post-hoc*	**37/63 (58.7%)**	**24/64 (37.5%)**	**0.0029***
Low-grade lesions (LSIL) – *post-hoc*	20/54 (37.0%)	22/51 (43.1%)	0.560*
Overall population – *predefined primary endpoint*	57/117 (48.7%)	46/116 (39.7%)	0.188**

** : Cochran-Mantel-Haenszel test controlling stratification factors : HPV type, cytology and age. **: Fisher exact test.*

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1 ***NILM:*** *Negative for Intraepithelial Lesion or Malignancy;* ***ASCUS:*** *Atypical Squamous Cells of Undetermined Significance;* ***LSIL:*** *low-grade squamous intraepithelial lesion.*

2 *Wright et al. Primary cervical cancer screening with human papillomavirus: End of study results from the ATHENA study using HPV as the first-line screening test. Gynecol Oncol 2015: 136; 189-197.*

About GTL001 Phase 2 (RHEIA-VAC) Clinical Trial

The phase 2 trial is an ongoing randomized double-blind, placebo controlled study which enrolled 239 HPV 16/18-positive patients at 39 investigational sites in 7 Western Europe countries. The trial consists of a treated arm with 117 patients and a placebo arm with 116 patients. A total of 233 evaluable patients are included in the topline results per protocol efficacy analysis.

Enrolled patients are required to be HPV 16 and/or 18 positive with normal, LSIL or ASCUS cytology. Patients with CIN2+ were excluded by colposcopy/histology. All patients received either 2 inter-dermal injections of 600 µg of GTL001 or 2 inter-dermal injections of placebo 6 weeks apart, and in both cases 2 applications of imiquimod cream 5%, 15 minutes and 24 hours after each injection of vaccine or placebo. The patients in both arms who received the full dose of vaccine or placebo were assessed for viral clearance at 12 months as the primary endpoint, and for secondary endpoints including maintenance of viral clearance and progression to CIN2+.

Viral clearance is assessed using a type specific, sensitive and quantitative HPV PCR assay. All patients in the trial continue to be followed for safety at 18 and 24 months and efficacy at 15, 18 and 24 months after their second injection. Additional data, including maintenance of viral clearance, viral load dynamics, and progression to CIN2+ will be evaluated. Additional study details are available at https://clinicaltrials.gov/ct2/show/NCT01957878.

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. (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.

More information at *www.genticel.com*

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