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

- **12- month primary endpoint not met in the overall population**
- **Statistical difference in viral clearance rates in 2 predefined key subgroups**
- **DSMB recommends continuation of the study per protocol**
- **18-month data on viral clearance, expected Q3 2016, to trigger phase 3 preparation**

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 initial results from the ongoing randomized, double-blind, placebo controlled phase 2 clinical study of its immunotherapeutic candidate, GTL001, designed to clear HPV 16 and/or 18 infection. While there was no statistical difference in viral clearance between treatment and placebo in the overall study population at 12 months, there was a clear separation in 2 predefined subgroups, namely patients with normal cytology and patients less than 30 years old at baseline. Statistically significant viral clearance data at 18 months in the overall population will be determinant to trigger phase 3 preparation. These data will be reported in Q3 2016. The independent DSMB (Data Safety and Monitoring Board) recommended on January, 26, 2016, the continuation of the study per protocol.

"The clinical goal of an HPV immunotherapy is to induce a long-lasting immune response in order to clear infection and prevent the progression to high-grade intraepithelial cervical lesions and cancer," said Margaret Stanley, Professor at the University of Cambridge, UK, renowned HPV immunology expert and advisor to Genticel. *"It has been noted with both other experimental and licensed onco-immune therapies, including the autologous cellular immunotherapy, Sipuleucel, that clinical activity is observed following a significant lag period. Therefore, I look forward to the availability of the 18-month clearance data."*

The 24-month trial enrolled 239 patients (of which 232 were evaluable for the primary endpoint) and is evaluating the efficacy of GTL001, plus imiquimod, to clear HPV 16 and 18 infections, as compared to placebo in infected women 25 to 50 years old with normal (NILM), LSIL or ASCUS[1] cytology and exclusion of CIN2+[1] by colposcopy/histology. Previous studies indicate a natural viral clearance of 40 to 50% at 12 months in HPV 16/18 positive women. An interim analysis at 12 months following the last injection shows no statistical difference in viral clearance rates between placebo and treatment. However, there is a statistically significant separation between the treated group compared to the placebo group in 2 prospectively defined subpopulations: women with normal cytology and women younger than 30. Data are summarized in the table below:

Viral clearance at 12 months	GTL001	Placebo	
	n = 117	*n = 116*	
Primary endpoint (overall population)	57 (48.7%)	46 (39.7%)	p=0.110
	n = 32	*n = 30*	
Normal cytology at baseline	20 (62.5%)	12 (38.7%)	**P=0.018**
	n = 29	*n = 28*	
< 30 years old at baseline	17 (58.6%)	9 (32.1%)	**P=0.049**

These results strongly suggest that Genticel's antigen delivery technology is effective in these 2 subgroups of patients.

While HPV positive women with normal cytology represent only 25% of the study population, they account for over 70% of the women infected with HPV 16/18 in the general population[2]. The results are also consistent with those of the phase 1 study of GTL001, in which the study population comprised exclusively women with normal cytology (NILM).

In addition, it has been observed that it takes longer to clear infection in women with abnormal cervical cytology than in women with normal cytology[3,4]. It has also been shown that higher viral loads at baseline are associated with longer time to complete clearance[5]. Because abnormal cytology, which represents over 70% of this phase 2 study population, is usually associated with higher viral load, it can be expected that viral clearance will take longer.

GTL001 viral clearance data collected at 18 months may therefore demonstrate a statistically significant therapeutic effect in the overall population at a later time point than 12 months. The phase 2 study continues to collect additional data that will be reported at 18 and 24 months.

"*The analysis to date shows clear separation in the viral clearance rates in two key subgroups and support our expectations to see superiority in viral clearance in the treated group at 18 months," said* Benedikt Timmerman, Chief Executive Officer of Genticel. *"We are excited to see how the trial develops and look forward to further analyzing these additional data."*

"With € 21.7 million in cash & equivalents at year's end, Genticel has enough financial resources to complete this 24-monh duration study" concluded Mr. Timmerman.

In this phase 2 study, GTL001 appears to be generally safe and well-tolerated with the expected transient local reactions at injection site identified as the most common adverse events. There is no unexpected safety signal has been observed in the study.

[1] *NILM: Negative for Intraepithelial Lesion or Malignancy - ASCUS: Atypical Squamous Cells of Undetermined Significance - LSIL: Low-grade Squamous Intraepithelial Lesion – CIN: Cervical Intraepithelial Neoplasia, graded from 1 to 3 in increasing order of severity.*

[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*

[3] *Bulkmans NW et al. High-risk HPV type-specific clearance rates in cervical screening. Br J Cancer 2007; 96: 1419-1424.*

[4] *Xi LF et al. Human Papillomavirus (HPV) Type 16 and Type 18 DNA Loads at Baseline and Persistence of Type-Specific Infection during a 2-Year Follow-Up. J Infect Dis 2009; 200:1789–1797.*

[5] *Muñoz N et al. Persistence of HPV infection and risk of high-grade cervical intraepithelial neoplasia in a cohort of Colombian women. Br J Cancer 2009; 100:1184-1190.*

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 seven Western Europe countries. The trial consists of a treated arm with 117 patients and a placebo arm with 116 patients. A total of 232 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

Genticel is a clinical-stage biotechnology company and developer of innovative immunotherapies to fight infectious diseases and cancer. 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, HPV 16 and 18. Genticel aims to eliminate them at an early stage with GTL001, its first immunotherapeutic candidate.

Genticel's antigen delivery 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. Vaxiclase has already generated 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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