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GENTICEL REPORTS 18 MONTH INTERIM ANALYSIS OF GTL001 PHASE 2 TRIAL IN HPV16/18 INFECTED WOMEN

- **No statistical difference seen between treatment and placebo**
- **GTL001 development plan is under review**
- **Strategic pipeline development activities remain on track**
- **Agreement with Serum Institute of India on Vaxiclase is progressing to plan**

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 interim results at 18 months in the phase 2 trial of its HPV16/18 immunotherapeutic candidate GTL001.

This phase 2 trial is an ongoing randomized double-blind, placebo controlled study conducted at 39 investigational sites in seven Western Europe countries. 233 patients positive for HPV 16/18 at baseline were evaluable for efficacy analysis, with a treated arm of 117 patients and a placebo arm of 116 patients. Enrolled patients were required to be HPV 16 and/or 18 positive with normal (NILM[1]), or abnormal (ASCUS or LSIL[1]) cytology. Per protocol, two intra-dermal injections were planned, either 600 µg of GTL001 or 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.

All patients receiving at least one dose of vaccine or placebo were assessed for viral clearance. Results at 12 months announced in January 2016 showed no difference in viral clearance between treatment and placebo overall, but a trend towards significant difference in subgroup analyses was noted, notably in the NILM[1] group. While this new interim analysis at 18 months showed no new unexpected safety events, viral clearance in the treated total population or in the sub groups did not differ statistically from the natural clearance in the placebo group.

Further study results on secondary endpoints, including the difference in progression to high-grade lesions or cancer between treatment and placebo - the primary endpoint considered for a phase 3 program - will become available in the first quarter of 2017 after the trial final analysis at 24 months.

Benedikt Timmerman, PhD, Chief Executive Officer of Genticel commented: *"These results did not meet our expectations and GTL001 development plan is being reviewed accordingly. However, these interim outcomes will not affect the key strategic direction we have taken to further grow our portfolio with innovative immunotherapies and to validate our Vaxiclase proprietary technology for other vaccine applications, notably through our on-going agreement with Serum Institute of India Ltd."*

[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.*

About GTL001 Phase 2 (RHEIA-VAC) Clinical Trial

The phase 2 trial is an ongoing randomized double-blind, placebo controlled study conducted at 39 investigational sites in seven Western Europe countries 233 patients positive for HPV 16/18 at baseline were evaluable for efficacy analysis. The trial consists of a treated arm with 117 patients and a placebo arm with 116 patients.

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 at least one 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 and efficacy at 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 clinical efficacy is being evaluated in a 24-month proof of concept Phase 2 trial in Europe, which will be completed in Q1 2017.

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Offering a promising technological platform.

Genticel's versatile platform, Vaxiclase, is well suited for the development of immunotherapies against multiple infectious or cancerous diseases. A partnership on the use of Vaxiclase has already been established with Serum Institute of India Ltd (SILL), the largest producer of vaccine dose worldwide. This agreement covers territories outside of the USA and Europe, and 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.

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More information 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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