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GENTICEL REPORTS FINAL RESULTS OF GTL001 PHASE 2 TRIAL IN HPV16/18-INFECTED WOMEN

- **No statistical difference in viral clearance between treatment and placebo groups at any time point over 2 years**
- **No difference in incidence of subjects progressing to high-grade cervical lesions between groups**
- **Company concludes HPV therapeutics development program; remains focused on seeking new drug candidates**

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 final results (24-month time point) of the phase 2 trial of its HPV16/18 immunotherapeutic candidate, GTL001.

The final data at month 24 showed no statistical differences in viral clearance rates between the GTL001 and placebo groups. No consistent statistical differences between groups were demonstrated in any of the secondary endpoints (confirmed and sustained clearance) over the 2-year duration of the trial. The incidence of subjects progressing to high-grade lesions was identical in both groups. A significant increase in anti-CyaA¹ antibodies following treatment was observed in the GTL001 group, but not in the placebo group. The significant increase in anti-CyaA titers in the treated group persisted during the entire course of the study.

The 12-month results announced in January 2016 showed no overall difference in viral clearance between the treatment and placebo groups, but a trend towards a significant difference in sub-group analyses was observed, most notably in the NILM² sub-group. The interim analysis at 18 months demonstrated that overall viral clearance, or by sub-group, did not statistically differ from the natural clearance observed in the placebo group.

Other than the first days following each vaccination, GTL001 and imiquimod were generally well tolerated with no unexpected safety signal identified at any point during the study.

This phase 2 trial was a randomized double-blind, placebo controlled study conducted at 33 investigational sites in 7 Western European 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) or abnormal (ASCUS or LSIL³) cytology. All patients receiving at least one dose of vaccine or placebo were assessed for viral clearance. Compliance was excellent, with 218 subjects completing the study (112 in the treated group and 106 in the placebo group).

¹ CyaA: Adenylate cyclase, the *Bordetella pertussis*

² NILM: Negative for Intraepithelial Lesion or Malignancy

³ ASCUS: Atypical Squamous Cells of Undetermined Significance - LSIL: Low-grade Squamous Intraepithelial Lesion

Sophie Olivier, MD, Chief Medical Officer of Genticel, commented: *“The positive safety and tolerance data, as well as the strong and lasting induction of anti-CyaA antibodies, observed in this trial are positive indicators for our partnership with the Serum Institute of India⁴. I wish to thank all of the investigators and clinical teams, as well as all the women, who participated in this trial, which will hopefully contribute scientifically to identifying improved therapies for the millions of women infected with dangerous human papilloma virus types.”*

Benedikt Timmerman, PhD, MBA, Chief Executive Officer of Genticel, added: *“Genticel will now end its HPV therapeutics development program and the Company remains focused on seeking new drug candidates, as well as moving forward with our partnership with the Serum Institute, which recently resulted in a \$1.2 million milestone payment to Genticel based on the successful completion of the last preclinical milestone.”*

About Genticel

Genticel’s versatile platform, Vaxicase, is well suited for the development of various immunotherapies. A partnership on the use of Vaxicase as an antigen per se (GTL003) has been established with Serum Institute of India Pvt. Ltd. (Serum Institute), the largest producer of vaccine dose worldwide. This agreement covers territories in emerging markets only, and could generate up to \$57 million in revenues for Genticel, before royalties on sales. It will enable Serum Institute to develop acellular multivalent combination vaccines against a variety of infectious diseases, including whooping cough. In November 2016, the last preclinical milestone was reached, opening the path to formal preclinical testing prior to clinical development and subsequent commercialization.

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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⁴ Serum Institute of India Pvt. Ltd.