

**PRESS RELEASE** 

Paris and Toulouse, September 22, 2016

# GENTICEL PRESENTS FIRST HALF 2016 FINANCIAL RESULTS AND UPDATES ITS OPERATIONAL OUTLOOK

Genticel (Euronext Paris & Brussels: FR00011790542 – GTCL), a clinical-stage biotechnology company and developer of innovative immunotherapies to fight infectious diseases and cancer presents today its financial results for the six-month period ending June 30, 2016 prepared in accordance with IFRS as endorsed by the European Union. The full interim financial report (regulated information) is available on Genticel's website under <a href="Investors/Financial information">Investors/Financial information</a>. In accordance with applicable law, the Half-Year 2016 financial statements were subject to a limited review by the Company's statutory auditors and were approved by the Executive Management Board (*Directoire*) on September 15, 2016.

# **HALF-YEAR 2016 BUSINESS HIGHLIGHTS**

- Rémi Palmantier appointed Chief Scientific Officer to accelerate the Company's development
- ▶ Evaluation of the HPV cobas② test from Roche Molecular Systems in preparation for phase 3 program of GTL001
- Initial results at 12 months from phase 2 trial of HPV immunotherapeutic candidate GTL001
- Publication of the 2015 annual financial report and strategic update for 2016
- Additional results at 12 months from phase 2 trial of HPV immunotherapeutic candidate, GTL001
- Publication of the phase 1 trial results of GTL001 in 'Clinical Cancer Research'
- ▶ Completion of the 5-year stability assays for GTL001 and of the evaluation of HPV cobas test.
- Presentation of clinical results for GTL001 and preclinical results for GTL002 at the EUROGIN 2016 Congress
- ▶ 18-month interim analysis of GTL001 phase 2 trial

# **HALF-YEAR 2016 FINANCIAL HIGHLIGHTS**

euros in thousands	HY 2016	HY 2015
Revenues	220	88
Research & Development expenses	- 4,873	- 6,075
Research & Tax Credit (subsidies)	1 ,943	1,780
General & Administration expenses	-2,063	-1,554
Operating Loss	- 4,772	-5,761
Net Loss of the period	-4,751	-5,663
Loss per share (in euros)	0.31	0.37
Change in net cash and cash equivalent	-7,023	-7 <i>,</i> 755
Cash and liquid investments	14,825	25,164

As at June 30, 2016, and consistent with the Company's expectations, cash and liquid investments amounted to €14.8M (versus €18.8 as at March, 31 2016). The Research Tax Credit for 2015, expected in the 2<sup>nd</sup> half of 2016 for €3,000K, is not included in this cash position.

Given its present state of development, the Company has no recurrent revenue from the sales of its products. Under the license agreement with Serum Institute of India Ltd (SIIL), the Company has invoiced during the first half of 2016 an amount of 250 K\$ (220 K€) for the delivery of additional testing services requested by SIIL.

The Company's operating loss of €-4,722K was consistent with the Company's expectations.

- The reduction in R&D expenses versus the first half of 2015 (€4,873K versus €6,075K) is related to the first reduction of development activities for GTL001, in particular the hold on the investments planned for the preparation of GTL001 phase 3 clinical lots. The decrease in these expenses (-20%) has not affected the Research Credit Tax amount (€1,943K as at June 30, 2016), as eligible expenses in the first half of 2016 were similar to those in the first half 2015.
- Administrative costs amounted to €2,062K in the first half of 2016, up €508K on the same period the previous year. This increase was largely due to €367K in restructuration costs during the first half of 2016.

Financial profit for the first half of 2016 was €21K, down €77K on the same period the previous year. This was mainly due to a general decrease in cash and a very significant decrease in the return yielded by liquid investments.

Working capital requirement was €2,521K versus €2,317K as at June 30, 2015. As in the first half of 2015, the reimbursement of 2015 Research Tax Credit receivables is expected during the second half of 2016, which tends to increase the working capital requirement of the Company during the first half of the year.

# **HALF-YEAR 2016 OPERATIONAL HIGHLIGHTS**

HPV immunotherapeutic candidates GTL001 and GTL002

The first half of 2016 was marked by the initial results from the Phase 2 study in Europe of GTL001, the Company's most advanced immunotherapeutic candidate against HPV 16 and 18 infections.

The analysis at 12 months, released in January 2016, showed no statistical difference in viral clearance between the treated group and the placebo group in the total population. However, this difference was significant in two predefined subgroups, the patients with normal cytology and the patients aged less than 30 years. Given the mechanism of action of GTL001, it was considered at this stage, that the data at 18 months were needed to decide on the feasibility of a Phase 3 program.

The Company has, therefore, announced in March 2016 that it was limiting its investments in this therapeutic vaccine candidate to the continuation of the two ongoing clinical trials and that it was suspending the planned investments for the preparation of a phase 3 GTL001 and for preclinical activities in GTL002, its second candidate (multivalent HPV). It also restructured its operations to preserve cash pending further 18-month results.

However, the interim analysis of data at 18 months, made public late June 2016, still showed no statistical difference in viral clearance between the treated group and the placebo group.

These results, which do not meet expectations, led the Company to reconsider the preclinical and clinical development plans for its HPV program including GTL001 and GTL002 candidates. Please refer to next section "Post-quarter close and operational outlook" for updated perspectives.

Partnership with SIIL

The second-generation technology platform of the Company, Vaxiclase, can be used not only as an antigen delivery vector, as is the case for GTL002, but also as the antigen of pertussis in the development of prophylactic vaccines, since the protein is the causative agent of whooping cough ("Bordetella pertussis").

Genticel has granted in February 2015 to Serum Institute of India Ltd (SIIL), the largest producer of doses of vaccines in the world, a license to use its technology platform Vaxiclase as an antigen. Under this license, SIIL evaluates Vaxiclase as an antigen in the development of acellular multivalent prophylactic vaccines including a pertussis antigen for emerging markets. When Vaxiclase is used as an antigen, it will now be considered as a new product candidate called GTL003.

In return for access to and use of GTL003 in the authorized indication and countries, Genticel could receive up to USD 57 million in upfront payments and milestone payments on development and sales, as well as 1-digit royalties on net sales. First revenues generated by the partnership with Serum Institute of India Ltd. were registered in 2015 and 2016.

Work in collaboration with SIIL continued satisfactorily in H1 2016.

#### POST-PERIOD CLOSE AND OPERATIONAL OUTLOOK

The Company considers that results at 12 and 18 months in GTL001 phase 2 trial no longer make possible a partnership to finance a straightforward phase 3 of this candidate.

The ongoing clinical studies of GTL001 will be completed, without further investment to prepare a Phase 3 program of GTL001. Moreover, as the development plans of the Company's' two HPV candidates, GTL001 and GTL002, had much in common - such as the adjuvant or the administration protocol - the Company has decided not to pursue the preclinical development of GTL002.

Modifications in the development modalities of GTL001 or GTL002, such as a change in the adjuvant or in the vaccination protocol, may help lead to convincing clinical results. They would be more distant than initially envisaged, given the need to validate the considered modifications at the preclinical stage. On this basis, the Company wishes to assign all or part of its HPV franchise to a partner.

Furthermore, the Company's finances enable:

- The continuation of its collaboration with Serum Institute of India Ltd. and the exploration of further extension of this partnership; the completion of a critical milestone in furthering the collaboration is expected in Q4 2016.
- An acceleration in the diversification of the Company's activities; as such, the Company has announced on July, 6, 2016 that it has retained Eumedix, a recognized European specialist in corporate finance, as a strategic advisor in its search for new innovative drug candidates, through a merger or an acquisition if appropriate.

In addition to this search for new opportunities, the Company continues, during the second half of 2016, its cash preservation policy and the alignment of its resources with the decreasing workload associated with GTL001 and GTL002 project management. In particular, and in accordance with French law, the Company has engaged with the personnel representatives of GENTICEL in new discussions on further downsizing its workforce for economic reasons as ongoing tasks are completed over time.

### **UPCOMING PUBLICATION**

October 27, 2016

Business & Cash Position Update 3rd Quarter 2016

# **About Genticel**

# 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.

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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