

*Paris and Toulouse, January 30, 2017*

## **BUSINESS UPDATE – FOURTH QUARTER 2016**

### **Cash & cash equivalents and liquid investments of €12.9 million at December 31, 2016, in line with Company expectations**

- ▶ **Successful completion of determining milestone in partnership with Serum Institute regarding use of GTL003 in multivalent vaccines**
- ▶ **New patent granted in the USA that protects Vaxiclase and GTL003**
- ▶ **End of HPV therapeutics development program following announcement of final results of GTL001 phase 2 trial**
- ▶ **Entering into strategic combination with Genkyotex, which is developing a pipeline of first-in-class NOX inhibitors in fibrosis and inflammatory pain**

Genticel (Euronext Paris & Brussels: FR00011790542 – GTCL), a clinical-stage biotechnology, today announced its cash & cash equivalents and liquid investments position and its highlights from the fourth quarter of 2016.

### **FINANCIAL HIGHLIGHTS**

On December 31, 2016, Genticel's net cash & cash equivalents and liquid investments position was €12.9 million (vs. €12.4 million on September 30, 2016), fully in line with the Company's expectations.

Cash burn during the fourth quarter (i.e., € 3.8 million) was driven by costs associated with the end of Genticel's clinical development activities (US phase 1 and the European Phase 2 clinical trials led with GTL001). The cash burn also included downsizing costs incurred during the fourth quarter while aligning the organization to its reduced workload. On December 31, 2016, the Company had 7 full-time employees, of which two were on notice period.

The fourth quarter cash burn was largely offset by the payment of the 2015 "Research Tax Credit" (€3.0 million) and by \$1.2 million (i.e.: €1.1 million) received as a milestone payment from Serum Institute of India.

Given its current development stage, Genticel has as of yet no sales turnover to report.

### **BUSINESS HIGHLIGHTS**

- ▶ **Genticel successfully completes determining milestone in partnership with Serum Institute regarding use of GTL003 in multivalent vaccines**

On November 30, 2016, Genticel announced that a determining milestone in its partnership with Serum Institute of India Pvt. Ltd. (Serum Institute), established in February 2015, had been successfully completed. In preclinical in vivo experimentation, Genticel's proprietary reengineered adenylate cyclase, GTL003, fulfilled the predetermined objectives. This was the last preclinical milestone of the agreement, corresponding to a \$1.2 million milestone payment.

If clinical development and commercialization by Serum Institute of the vaccines derived from this program occur, the agreement could generate for Genticel up to \$57 million in milestone payments and then single digit-royalties on further sales.

### ▶ **New patent granted in the USA that protects Vaxicelase and GTL003**

In the fourth quarter, Genticel was granted a new United States patent (No 9,499,809) entitled “CyaA-based chimeric proteins comprising a heterologous polypeptide and their uses in the induction of immune responses.” This patent protects Vaxicelase when used as a product *per se* (GTL003), which is the case in Genticel’s partnership with Serum Institute.

### ▶ **End of HPV therapeutics development program following announcement of final results of GTL001 phase 2**

On December 13, 2016, 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.

As consequence of these disappointing results, Genticel concluded its HPV therapeutics development program and focused on seeking new drug candidates.

### ▶ **Entering into strategic combination with Genkyotex, which is developing a pipeline of first-in-class NOX inhibitors in fibrosis and inflammatory pain**

On December 22, Genticel and Genkyotex, a Swiss privately-held biopharmaceutical company and the leader in NOX therapies, announced that Genticel had signed a contribution agreement with the shareholders of Genkyotex pursuant to which, subject to the approval of Genticel’s shareholders at a meeting expected to be held in the first quarter of 2017, Genkyotex’s shareholders will contribute in kind 100% of the Genkyotex share capital (on a fully diluted basis) to Genticel, which will issue new shares in remuneration for the contribution. Upon completion of the proposed transaction, Genkyotex’s shareholders will hold 80% of Genticel’s share capital and voting rights (on a non-diluted basis).

This transaction successfully completes Genticel’s strategic review process and fulfills the Company’s objective to access the most promising drug pipeline possible. Genkyotex’s therapeutic approach is based on a selective inhibition of NOX enzymes, which drive a broad range of disease processes, including fibrosis, inflammatory pain, angiogenesis, cancer growth, and neurodegeneration. Genkyotex is currently developing two first-in-class NOX inhibitors:

- GKT831, a NOX1 and NOX4 inhibitor for fibrotic diseases, is expected to enter a Phase II clinical trial in primary biliary cholangitis (PBC), an orphan fibrotic liver disease, during the first half of 2017;
- GKT771, a NOX1 enzyme inhibitor identified as factor involved in the development of the angiogenesis, pain and inflammation, is expected to enter a Phase I clinical study during the second half of 2017.

Genkyotex also has several ongoing pre-clinical programs evaluating the therapeutic potential of NOX inhibitors in central nervous system (CNS) diseases, hearing loss and oncology indications.

The combined consolidated cash position of Genkyotex and Genticel should enable the new group to complete both its Phase II study in PBC with GKT831 and its first Phase I study with GKT771.

## **UPCOMING EVENTS**

- ▶ Shareholders meeting on February 28, 2017, scheduled primarily to approve the contribution of Genkyotex and the issue of new shares by Genticel to Genkyotex’s shareholders in remuneration for the contribution of their shares.

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<sup>1</sup> CyaA: Adenylate cyclase, the *Bordetella pertussis*

## About Gentcel

Gentcel's versatile platform, Vaxiclase, is well suited for the development of various immunotherapies. A partnership on the use of Vaxiclase 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 Gentcel, 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.

Genkyotex is developing a portfolio of NADPH oxidase (NOX) oral small molecule inhibitors, which have therapeutic potential for the treatment of multiple significant diseases with substantial unmet need, including fibrosis, inflammatory pain, angiogenesis, cancer growth, and neurodegeneration. Genkyotex is currently developing two clinical stage, first-in-class NOX inhibitors and is conducting research on several other pre-clinical molecules.

More information at [www.gentcel.com](http://www.gentcel.com)



### Forward-looking statements related to Gentcel

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