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## GENTICEL PRESENTS FIRST HALF 2015 FINANCIAL RESULTS, OPERATIONAL PROGRESS & OUTLOOK

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), presents today its financial results for the six-month period ending June 30, 2015 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 Investors. In accordance with applicable law, the Half Year 2015 financial statements were subject to a limited review by the company’s statutory auditors and were approved by the Executive Board (Directoire) on September 10, 2015.

### HALF-YEAR 2015 HIGHLIGHTS

- ▶ Vaxicelase technology license agreement signed with Serum Institute of India Ltd., which could lead to revenue up to US\$57 million before royalties.
- ▶ Promising additional pharmacology *in vivo* results of GTL001 (ProCervix), Company’s first-in-class HPV therapeutic vaccine candidate, presented at AACR Annual Meeting 2015.
- ▶ Positive *in vivo* preclinical proof of concept results of GTL002 (Multivalent HPV), Genticel’s new therapeutic vaccine candidate based on proprietary Vaxicelase platform.
- ▶ Genticel received FDA Clearance of IND application for U.S. Phase 1 Clinical Trial of GTL001.
- ▶ Cash and liquid investments of €25.2 million in line with pipeline development advances and Company’s expectations.

*“Genticel has achieved key milestones that strengthen its HPV therapeutic pipeline during the first half of 2015 and has demonstrated its ability to deliver according to plan, notably with regards to the clinical development of GTL001, our lead therapeutic vaccine candidate, both in Europe and in the U.S.,”* commented Martin Koch, Chief Executive Officer of Genticel. *“The upcoming months will be exciting ones as the top line phase 2 results of our lead candidate become available and as our strategic efforts towards diversification begin to pay off.”*

### HALF-YEAR 2015 FINANCIAL HIGHLIGHTS

In thousands of euros	H1 2015	H1 2014*
Revenues	88	-
Research and Development expenses	-6 075	-4 915
Research Tax Credit (Subsidies)	1 780	1 456
General and Administration expenses	-1 554	-1 328
Operating loss	-5 761	-4 787
Net Loss of the period	-5 663	-4 796
Loss per share (in €)	0.37	0.37
<b>Change in net cash and cash equivalent</b>	<b>-7 755</b>	<b>33 084</b>
<b>Cash and liquid investments</b>	<b>25 164</b>	<b>36 923</b>

\* HY 2014 financial statements have been amended in application of IAS 8 (please refer to HY 2015 financial statements as at June 30, 2015 for details.)

As at June 30, 2015, Genticel's net cash & cash equivalents and liquid investments position was €25.2 million (vs. €29.1 million on March 31, 2015), fully in line with the Company's expectations.

Given the current development stage of its therapeutic vaccines candidates and its value-creation strategy for these assets, Genticel has as of yet no recurrent revenue to report. Under the licensing agreement signed in February 2015 with Serum Institute of India Ltd., the Company received an up-front payment of US\$100,000 (€0.1 million) in the first half of 2015.

The operating loss of €5.7 million is consistent with the Company's expectations.

- ▶ The increase in R&D expenses vs. the first half of 2014 (€6.1 million versus €4.9 million) reflects the expenses incurred to move forward with the Company's lead candidate, GTL001, in its phase 2 clinical trial in Europe, and to prepare the IND application of the phase 1 clinical trial in the U.S. This increase (+24%) is partly offset by Research Tax Credit income amounting to €1.8 million at June 30, 2015.
- ▶ Administrative costs amounted to €1.5 million in the first half of 2015, up €225,919 on the same period in 2014 partly due to a €190,000 increase in professional fees as a Euronext-listed company versus the same period the previous year.

Financial result for the first half of 2015 was €98,401, up €108,250 compared to the same period in 2014, mainly due to interest earned from investing the funds generated by the Company's IPO, in bank deposits and a capitalization contract.

Working capital requirements as at June 30, 2015 amounted to €2.3 million, versus €0.5 million on June 30, 2014. The growth in working capital requirements was mainly due to the increase in research tax credit (CIR) receivables. The credit due in 2014 was received during the first half of 2014, while the credit due in 2015 is expected during the second half of 2015.

## HY 2015 OPERATIONAL HIGHLIGHTS

### **GTL001 (ProCervix)**

In the first half of 2014, Genticel passed several key milestones in its product development, primarily for GTL001, its first therapeutic vaccine candidate. GTL001 is intended for women already infected with HPV 16 and/or 18 before the appearance of high-grade or cancerous lesions. It is a "first-in-class" product as it would be the first therapeutic vaccine that meets the medical needs of this high-risk population, as preventive HPV vaccines are only effective in teenage girls or women who are not yet infected.

The clinical development of GTL001 represented a large part of the Company's activity during these six months, particularly in conducting the multicenter European phase 2 trial in which it is evaluating GTL001 in terms of viral clearance. This trial is proceeding satisfactorily. Half of the 236 vaccinated patients are now at 12 months post-vaccination follow-up. Additionally, patient engagement remains very high with a participant retention rate of 98%. The Data and Safety Monitoring Board (DSMB), which consists of a group of independent experts who review the tolerance data from the trial, twice recommended – in January and June 2015 – that the trial continue as planned. The first data from this trial will be available in the first half of 2016.

Genticel continues to accumulate GTL001 efficacy data, and presented promising results of a new in vivo pharmacological study at the American Association for Cancer Research (AACR) Annual Meeting in April 2015. The results of this study indicate that GTL001 has the potential to eradicate HPV 16 infections in progress, while offering protection against future HPV 18 infections and to eradicate HPV 18 infections in progress, while providing protection against future HPV 16 infections.

In June 2015, the Company obtained an Investigational New Drug (IND) authorization to conduct a phase 1 clinical trial for GTL001 in the U.S. in patients with HPV 16 and/or 18. Investigational sites will initiate recruiting patients during the second half of 2015.

### **GTL002 Multivalent HPV therapeutic vaccine**

The Company's second drug candidate is a therapeutic HPV vaccine that targets HPV 16 and 18 plus four other types of HPV from among the most pertinent HPV genotypes in terms of preventing cervical cancer. The preclinical development of this product continued in the first half of 2015, with a key milestone passed in May 2015, the preclinical proof of concept. The data from this preclinical proof of concept study of GTL002 show that an *in vivo* immune response was induced against each of the six proteins from the HPV viruses present in the therapeutic vaccine. Moreover, *in vivo* therapeutic efficacy was shown by tumor eradication in the most widely used and broadly accepted reference model.

Gentical can now initiate pharmacological and toxicological studies as well as the production of clinical batches, which are all necessary for the preparation of an IND or a phase 1 clinical trial in Europe, which may begin in 2017.

### **Vaxiclase technology platform**

Vaxiclase is Gentical's proprietary technology platform used in the development of its multivalent HPV drug candidate, GTL002. Vaxiclase is the result of optimizations made to the native structure of *Bordetella pertussis* adenylate cyclase. With these optimizations, it is possible to insert larger antigens or multiple antigens into Vaxiclase, which occurs in the case of the multivalent HPV vaccine. Tripling the carrying capacity of the vector opens up the possibility of new applications such as the creation of vaccines against many diseases in multiple indications.

In February 2015, Gentical granted a license to use its Vaxiclase technological platform to Serum Institute of India Ltd. (SIIL), the largest producer of vaccine doses in the world. Under this license, SIIL will evaluate the Vaxiclase platform for the development of multivalent acellular prophylactic vaccines containing whooping cough antigens, for emerging markets.

In return for access to and use of the Vaxiclase platform in the authorized indication and countries, Gentical could receive up to US\$57 million in initial payments and stage payments on development and sales, as well as royalties as a percentage of net sales. The detailed financial terms of the agreement have not been disclosed. The agreement also allows Gentical to benefit from all the production improvements that SIIL could bring to the Vaxiclase platform. Given the Serum Institute's expertise and its results in the field of industrial-scale vaccine production, this agreement represents a major strategic asset for Gentical.

## **POST-CLOSE EVENTS AND OUTLOOK**

On July 2, 2015, the Company announced that, upon the proposal of Benedikt Timmerman, Gentical's Supervisory Board appointed Martin Koch, CFO, as the Company's CEO for 3 months during Mr. Timmerman's recovery from several accidental lower limb fractures. Mr. Timmerman remains on Gentical's Executive Management Board and provides strategic counsel to the team. The Supervisory Board foresees extending Mr. Koch's mandate as CEO beyond its initial 3-month term, most likely until year-end, to give Mr. Timmerman the time needed to fully complete his rehabilitation program.

Lastly, on September 8, 2015, a new U.S. Patent No. 9,095,537, entitled "Therapy of cancer based on targeting adaptive, innate and/or regulatory component of the immune response," has been granted in the United States that encompasses the use of the Company's CyaA-based vectors and their derived products such as GTL001 in the treatment of cancer, notably in combination therapy with TLR agonists. This new patent expands the Company's potential to progress in therapeutic areas beyond early stage disease and protects its technology for use in multiple indications - from viral infection to cancer - in all major markets.

Given the satisfying progress to date of its HPV program, the Company intends, as planned, to intensify its business development efforts beginning in the second half of 2015 in order to benefit from new strategic options in 2016. These efforts could take the form of a diversification of the Company's portfolio of products or indications, through in-house development, co-development or acquisition. New calls to the market may be required to fund this future expansion program<sup>1</sup>. Their schedule, terms or conditions cannot yet be discussed given the very early stage of the implementation of this strategy.

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<sup>1</sup> Please refer to section 4.1.4. Risks related to the commercial and strategic development of the Company's registration document 2014, filed with the AMF on March 31, 2015 under number R.15-015.

## UPCOMING EVENTS

**2015 Third Quarter Business Update**  
(after Euronext stock exchange closing)

October 23, 2015

### Upcoming meetings

- ▶ Large & Midcap Event, Paris – Palais Brongniart October 7 & 8, 2015
- ▶ KBC Biotech & Healthcare Seminar, New York November 10, 2015
- ▶ Salon Actionaria, Paris – Palais des Congrès November 20 & 21, 2015
- ▶ JP Morgan Healthcare Conference, San Francisco January 11 to 15, 2016

## 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 (known in Europe as ProCervix), its first-in-class immunotherapeutic vaccine candidate. The company has already completed patient recruitment for the phase 2 clinical trial of GTL001 in Europe.

### Offering a promising technological platform.

Genticel's versatile 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 therapeutic vaccine designed with Vaxiclase. It targets the six most relevant HPV types in terms of global epidemiology and is currently in preclinical development.

### Focusing on value creation.

Respectively, the peak sales potentials of GTL001 and GTL002 are estimated at over €1 billion and €2 billion per year. In addition to this attractive HPV product pipeline, Genticel's versatile technological platform, Vaxiclase, has already generated significant interest in the pharmaceutical industry, as illustrated by the partnership agreement signed in 2015 with the Serum Institute of India Ltd. (SIIIL), the world's largest producer of vaccine doses. This partnership is expected to generate \$57 million in revenues for Genticel, before royalties on sales. It will enable SIIIL to develop acellular multivalent combination vaccines against a variety of infectious diseases, including whooping cough.

For more information, visit us at [www.genticel.com](http://www.genticel.com)



### Disclaimer

This press release and the information it contains does not constitute an offer or solicitation to buy, sell or hold Genticel shares in any country. This press release may contain forward-looking statements by the company with respect to its objectives. These statements are based on the current estimates and forecasts of the company's management and are subject to risks and uncertainties such as the company's ability to implement its chosen strategy, customer market trends, changes in technologies and in the company's competitive environment, changes in regulations, clinical or industrial risks and all risks linked to the company's growth. These factors as well as other risks and uncertainties may prevent the company from achieving the objectives outlined in the press release. No guarantee is given on forward-looking statements which are subject to a number of risks, notably those described in the [registration document](#) filed with the French Markets Authority (the AMF) on 1 April 2015 under number R.15-015 and those linked to changes in economic conditions, the financial markets, or the markets on which Genticel is present. Genticel products are currently used for clinical trials only and are not otherwise available for distribution or sale.

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