

**PRESS RELEASE** 

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## **GENTICEL ANNOUNCES 2015 ANNUAL RESULTS AND STRATEGIC UPDATE FOR 2016**

- Cash position of € 21.8 million as at December 31, 2015
- First income from partnership with Serum Institute of India Ltd recorded in 2015
- Operating expenses in line with 2015 clinical milestones
- Strategic focus on GTL001 clinical activities and business development
- Cash runway extended into 2018

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 presents its 2015 full year results in accordance with International Financial Reporting Standards (IFRS) and provides a strategic update for 2016.

## **2015 ANNUAL RESULTS**

euros in thousands	2015	2014*
Revenues	178	0
Research & Development expenses	(10,935)	(11,190)
Research & Tax Credit (subsidies)	2,940	2,904
General & Administration expenses	(3,599)	(2,763)
Operating Loss	(11,417)	(11,049)
Net Loss of the period	(11,193)	(10,944)
Loss per share (in euros)	(0.72)	(0.79)
Change in net cash and cash equivalent	(11,010)	28,831
Cash and liquid investments	21,836	32,803

<sup>\* 2014</sup> financial statements have been amended in application of IAS 8 (please refer to half-year 2015 financial statements for detailed information)

## 2015 FINANCIAL REVIEW (SEE APPENDIX FOR DETAILED INFORMATION)

## ▶ Income statement

In 2015, the Company recorded its first income for a total of € 0.18 million, resulting from an up-front payment (US\$100K) and a technical milestone payment (US\$100K) under its agreement with Serum Institute of India Ltd (SIIL).

SIIL is evaluating the use of Vaxiclase in the development of acellular multivalent combination vaccines against a variety of infectious diseases, including whooping cough. The license agreement, limited to the authorized indication in emerging markets, includes upfront and milestones payments for potentially up to \$57 million, as well as single digit royalties on sales.

As at December 31, 2015, Genticel had an operating loss of € 11.4 million compared with a loss of € 11 million in 2014. This is fully in line with pipeline development advances and reflects:

- Stable investment in R&D (€ 10.9 million in 2015 versus € 11.2 million in 2014), as the decreased costs of the continuation of GTL001 Phase 2 clinical trial in Europe were partially offset by the set-up and initiation costs of GTL001 Phase 1 trial in the US. However, a large part of these costs will be non-recurring.
- As a consequence of stable investment in R&D, the 2015 Research Tax Credit of € 2.9 million (*Crédit d'Impôt Recherche* in France) is almost equal the 2014 Research Tax Credit;
- An increase in general and administrative expenses from € 2.7 million in 2014 to € 3.6 million for 2015 was mainly due to onetime recruitment costs (€ 0.2 million); an ad-hoc market access studies (€ 0.3 million), and onetime increase in Intellectual Property management (€ 0.2 million).

After taking into account the 2015 financial revenues, the 2015 net loss of (€ 11.2 million) is consistent with the Company's expectations.

## ▶ Balance sheet and cash at the end of 2015

In comparison to the € 32.8 million held on December 31<sup>st</sup>, 2014, Genticel completed 2015 with cash & cash equivalents and liquid investments of € 21.8 million consisting of € 5.1 million in non-current financial assets, € 5.1 million in current financial assets and € 11.6 million in cash and cash equivalents.

This change reflects € 11.8 million cash consumed for Company operations, in line with expectations.

The financial position with cash & cash equivalents and liquid investments of € 21.8 million as at December 31<sup>st</sup>, 2015 enables cash runway through Q4 2017.

### **2015 CORPORATE HIGHLIGHTS**

- Vaxiclase platform licensed to Serum Institute of India Ltd (SIIL) for use in pertussis vaccines (Q1 2015)
- Pipeline development presented at EUROGIN Sevilla, Spain (Q1 2015)
- Valerie Leroy appointed Senior Director, Corporate Communications and Investor Relations (Q2 2015)
- Positive preclinical proof of concept for GTL002, Genticel's multivalent HPV immunotherapeutic candidate (Q2 2015)
- Additional pharmacology in-vivo results of GTL001 showing potential to both treat and protect, presented at AACR Annual Meeting 2015 Philadelphia, PA, USA (Q2 2015)
- Investigational New Drug (IND) approval by the US Food & Drug Administration (FDA) for GTL001 Phase 1 clinical study in the US (Q2 2015)
- Genticel CFO, Martin Koch, appointed CEO to replace Benedikt Timmerman during temporary medical leave of absence (Q2 2015)
- Independent Data Safety Monitoring Board Recommends Continuation per protocol of Phase 2 clinical trial of GTL001 in Europe (Q3 2015)
- US patent granted for use of Genticel's antigen delivery vectors in combination therapy to treat cancer (Q3 2015)
- Enrollment of 1<sup>st</sup> patient in the US Phase 1 clinical trial of GTL001 (Q4 2015)
- Benedikt Timmerman resumes CEO position at Genticel (Q4 2015)

## **2015 OPERATING REVIEW**

In 2015, Genticel continued to deliver on the operational calendar of the IPO and reached all key milestones in its development programs.

## Vaxiclase

Vaxiclase is Genticel's next-generation, proprietary platform based on the native CyaA protein derived from *Bordetella pertussis*, the causative agent of whooping cough. In February 2015, Genticel licensed Vaxiclase to Serum Institute of India Ltd (SIIL), the world's largest producer of vaccine doses. Under this agreement, SIIL is evaluating the use of Vaxiclase in the development of acellular multivalent combination vaccines against a variety of infectious diseases, including whooping cough in all cases. The license agreement, limited to emerging markets, includes upfront and milestones payments for up to \$57 million, as well as single digit royalties on sales. This partnership progressed smoothly in 2015 and a preclinical milestone is scheduled to be reached in the second half of 2016.

## ▶ GTL001

GTL001 is intended for women already infected with HPV 16 and/or 18 before the appearance of high-grade or cancerous lesions. It is the first immunotherapy that aims to meet the medical needs of this large high-risk population, as preventive HPV vaccines are only effective in women who are not yet infected.

The recruitment of a 2-year multi-center Phase 2 trial to evaluate the efficacy of GTL001 in clearing the viral infection was completed in November 2014, 4 months ahead of schedule. Thirty-nine investigation sites in seven Western European countries are actively participating in this clinical trial. The Data and Safety Monitoring Board (DSMB), a group of independent experts that reviews the tolerance data from the trial every six months, twice recommended continuing the trial unchanged after its scheduled meetings in January and July 2015. Patient and physician engagement remained very high throughout 2015 with retention rate of 97% of the enrolled population. *Please refer to the post year close section for information about GTL001 Phase 2 trial 12-months results, released in January 2016.* 

The company presented its pipeline development in February 2015 at EUROGIN in Sevilla, Spain. In April 2015, Genticel also presented additional in-vivo pharmacology results of GTL001 at the AACR Annual Meeting 2015 - Philadelphia, PA, USA. These promising results open the possibility to both protect and treat patients with several different antigens for a given cancer.

In preparation of GTL001 Phase 3 programs, intended to run both in Europe and in the US, Genticel submitted an IND file to the FDA and was granted IND status in June 2015, which triggered the initiation of a Phase 1 study in the US. The first of the 20 patients planned for this study was treated in October 2015 and results are expected in Q3 2016.

### **▶** GTL002

The Company's second drug candidate, GTL002, is a multivalent HPV immunotherapy that targets 6 of the most relevant HPV types including HPV 16 and 18 which collectively cause 85% of cervical cancer. Preclinical results obtained in 2015 were very encouraging. Specifically, Genticel announced in May 2015 that GTL002 had achieved its pharmacological proof of concept, demonstrating simultaneous delivery of multiple antigens of several oncogenic HPV types using the Vaxiclase technology, with in vivo induction of antigen-specific T cell responses and E7-oncoprotein-specific tumor regression.

## **▶** Intellectual property

Genticel enriched its intellectual property portfolio in 2015, notably with an additional US patent granted in September 2015 for use of Genticel's antigen delivery vectors in combination therapy to treat cancer. Genticel now holds multiple patents layers protecting both its drug candidates and its technology platforms across the key mature and emerging markets.

## Corporate events

In order to increase the Company's profile and visibility in the financial community, Genticel appointed Valerie Leroy as Senior Director, Corporate Communications and Investor Relations in April 2015.

In July 2015, the Company announced the appointment of Genticel CFO, Martin Koch, as CEO to replace Benedikt Timmerman during temporary medical leave of absence. Mr. Timmerman resumed his position in December 2015.

## **POST YEAR CLOSE NEWS**

## ▶ Genticel appoints Rémi Palmantier, PhD, as Chief Scientific Officer to accelerate its development

On January 5, 2016, Genticel announced the appointment of a seasoned scientist with broad international experience, Rémi Palmantier, PhD, as Chief Scientific Officer. Dr. Palmantier joins Genticel from GSK Vaccines, where he was most recently Senior Director, R&D, for the global portfolio of immunotherapies for chronic diseases. Dr. Palmantier will support the Company's strategy to expand its pipeline of innovative immunotherapies and to target various types of infectious diseases and cancers, beyond its advanced program of HPV immunotherapeutics.

# ▶ Genticel to evaluate Roche Molecular System's cobas® HPV test in preparation for Phase 3 program of GTL001

On January 7, 2016, the Company announced an agreement with Roche Molecular Systems Inc. to evaluate Roche's cobas® HPV Test in preparation for the planned Phase 3 trial of GTL001. The cobas® HPV Test is currently the only HPV assay which is both EU-labeled and FDA-approved and provides specific genotyping information, notably for HPV 16 and 18, the highest-risk types targeted by GTL001. The ability to evaluate this broadly available commercial test is an important milestone that will help the Company anticipate requirements for the planned Phase 3 programs of GTL001 and identify the patient population that will benefit most from treatment.

# ▶ Genticel reports initial results at 12 months from Phase 2 trial of HPV immunotherapeutic candidate, GTL001

On January 27, 2016, Genticel announced initial results from the ongoing randomized, double-blind, placebo controlled Phase 2 clinical study of its immunotherapeutic candidate, GTL001, designed to clear HPV 16 and/or 18 infection. While there was no statistical difference in viral clearance between treatment and placebo in the overall study population at 12 months, there was a clear separation in 2 predefined subgroups, namely patients with normal cytology and patients less than 30 years old at baseline. The independent DSMB (Data Safety and Monitoring Board) recommended on January, 26, 2016, the continuation of the study per protocol. The positive result obtained in the subgroup of patients with normal cytology is particularly interesting to Genticel because it corresponds to the population evaluated in the Phase 1 study that already showed a trend of efficacy and because this group represents at least 70% of the overall target population. Further data will be collected at 15, 18 and 24 months. The next information will be reported in Q3 2016 and will provide viral clearance data at 15 and 18 months.

### **2016 STRATEGIC UPDATE**

Genticel's most advanced candidate, GTL001, is today more than halfway through its 24-month proof of concept Phase 2 trial. The data at 15, 18 and 24 months will confirm the design of further clinical developments, either in the overall population before high grade lesions, or in subgroups including the largest target group, HPV 16 / 18 positive patients with normal cytology (NILM). Phase 3 preparation activities will consequently begin only once these data have been obtained and analyzed.

As a result, the Company will defer by 12 months the industrial GMP production at commercial scale planned for GTL001 Phase 3 and the semi-industrial production planned for GTL002 Phase 1 trial. Investments will be focused on the ongoing GTL001 clinical trials, the Phase 2 study in Europe and the Phase 1 study in the United States.

Production process operations and related activities including analytical immunology are associated with a significant use of resources, both human and financial. The implementation of the proposed measures could result in a workforce reduction of approximately 30% in the Company's Labège laboratories and in support functions. Genticel is complying with French law, notably with respect to its legal obligation to duly inform and consult its employee representatives on the workforce reduction plan.

The shift of investments including postponing production and focusing on GTL001 clinical activities will extend the Company funding well into 2018.

Benedikt Timmerman, Chief Executive Officer of Genticel commented: "The Phase 2 study with GTL001 showed very encouraging results at 12 months in predefined subgroups which represent by themselves a huge market. We are now waiting for the read-outs set at 18 and 24 months post treatment to define the suitable clinical path going forward. We believe that it is reasonable, in this context, to take a number of cash preservation measures while maintaining our core assets and our ability to quickly initiate phase 3 activities. In the meantime, we are actively pursuing our business development efforts with the primary objectives to select an appropriate partner for our HPV therapeutic candidates and to expand our pipeline."

## **UPCOMING EVENTS H1 2016**

March 14	Paris, France	SFAF meeting on 2015 annual results and 2016 outlook (French Society of Financial Analysts)
March 22	Brussels, Belgium	KBC 6 <sup>th</sup> Healthcare conference
March 21-23	Washington, DC, USA	Targeted Anticancer Therapies (TAT) 2016 Congress
April 4-6	Stockholm, Sweden	Bio-Europe Spring 2016
April 11-12	Paris, France	Small & Midcap Event
April 16	Antwerp, Belgium	VFB Happening 2016 (Flemish Federation of Investors)
June 3-7	Chicago, IL, USA	American Society Of Clinical Oncology (ASCO) 2016 Annual Meeting
June 6-9	San Francisco, CA, USA	2016 BIO International Convention
June 15-18	Salzburg, Austria	EUROGIN 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, its first-in-class immunotherapeutic candidate. GTL001 is more than halfway through a 24-month proof of concept Phase 2 trial 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 immunotherapeutic candidate designed with Vaxiclase. It targets the six most relevant HPV types in terms of global epidemiology and is currently in preclinical development.

#### Focusina 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. (SIIL), the world's largest producer of vaccine doses. This partnership 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.

For more information, visit us at 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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## **APPENDIX: DETAILED FINANCIAL INFORMATION 2015**

The financial statements have been prepared in accordance with IFRS, as adopted by the European Union. The financial information included in this press release is an extract from the full IFRS consolidated financial statements that will be published with the 2015 Annual Financial Report.

IFRS financial statements for the year ending on December 31, 2015 have been audited by Grant Thornton and Sygnatures.

INCOME STATEMENT	31/12/2015	31/12/2014	31/12/2014
		revised*	published
(Amounts in euros)	12 months	12 months	12 months
Sales	-	-	-
Cost of sales	-	-	-
Gross margin	-	-	-
Other income	177,742	-	-
Net R&D expenses			
R&D expenses	(10,935,343)	(11,189,788)	(10,793,686)
Subsidies	2,940,037	2,904,002	2,785,172
General and administrative expenses	(3,599,155)	(2,762,748)	(2,762,749)
Operating profit (loss)	(11,416,719)	(11,048,534)	(10,771,263)
Financial expenses	(64,535)	(85,167)	(85,167)
Financial income	287,931	189,882	189,882
Pre-tax profit (loss)	(11,193,323)	(10,943,819)	(10,666,547)
Tax expense	_	_	_
Net income	(11,193 323)	(10,943,819)	(10,666,547)
Group share	(11,193,323)	(10,943,819)	(10,666,547)
Non-controlling interests	-	-	-
Earnings per share			
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Weighted average number of outstanding shares	15,463 263	13,801,002	13,801,002
Basic earnings per share (€/share)	(0.72)	(0.79)	(0.77)
Diluted earnings per share (€/share)	(0.72)	(0.79)	(0.77)

STATEMENT OF COMPREHENSIVE INCOME	31/12/2015	31/12/2014 revised*	31/12/2014 published
(Amounts in euros)	12 months	12 months	12 months
Profit (loss) for the year	(11,193,323)	(10,943,819)	(10,666,547)
Actuarial gains (losses)	122,504	(82,027)	(82,027)
Items not recyclable in income	122,504	(82,027)	(82,027)
Items recyclable in income	-	-	-
Other items of comprehensive income (net of tax)	122,504	(82,027)	(82,027)
Comprehensive income	(11,070,819)	(11,025,846)	(10,748,574)
Group share	(11,070,819)	(11,025,846)	(10,748,574)
Non-controlling interests	-	-	-

<sup>\*</sup> Please refer to HY 2015 financial statements for detailed information

STATEMENT OF FINANCIAL POSITION	31/12/2015	31/12/2014	31/12/2014
(Amounts in euros)		revised*	published
ASSETS			
Intangible assets	54,017	19,131	19,131
Property, plant and equipment	155,874	94,863	94,863
Other non-current financial assets	5,290,657	10,189,293	10,189,293
Total non-current assets	5,500,549	10,303,287	10,303,287
Inventories	52,560	31,469	31,469
Other receivables	3,653,694	3,140,066	3,021,235
Current financial assets	5,021,938	12,557,243	12,557,243
Cash and cash equivalents	11,659,829	10,170,051	10,170,051
Total current assets	20,388,021	25,898,828	25,779,998
Total Assets	25,888,570	36,202,115	36,083,284
LIABILITIES			
Shareholders' equity			
Capital	1,554,109	1,544,024	1,544,024
Additional paid-in capital	48,420,039	48,112,032	48,112,032
Other comprehensive income	4,948	(117,555)	(117,555)
Reserves - Group share	(18,451,210)	(8,377,776)	(8,377,776)
Result - Group share	(11,193,323)	(10,943,819)	(10,666,547)
Shareholders' equity, Group share	20,334,563	30,216,905	30,494,177
Non-controlling interests		0	0
Total shareholders' equity	20,334,563	30,216,905	30,494,177
Non-current liabilities			
Employee benefit obligations	322,060	379,718	379,718
Non-current financial debt	1,900,781	1,645,793	1,645,793
Total non-current liabilities	2,222,842	2,025,510	2,025,510
Current liabilities			
Current financial debt	621,347	511,841	511,841
Trade payables and related accounts	1,886,424	2,662,777	2,266,675
Tax and social security liabilities	821,340	784,358	784,358
Other creditors and miscellaneous liabilities	2,055	723	723
Total current liabilities	3,331,166	3,959,699	3,563,597
Total Liabilities	25,888,570	36,202,115	36,083,284

<sup>\*</sup> Please refer to HY 2015 financial statements for detailed information

CASH FLOW STATEMENT	Notes	31/12/2015	31/12/2014 revised*	31/12/2014 published
(Amounts in euros)		12 months	12 months	12 months
Cash flow from operating activities				
Net income		(11,193,323)	(10,943,819)	(10,666,547)
(-) Elimination of amortization of intangible assets	3	(4,240)	(7,645)	(7,645)
(-) Elimination of depreciation of property, plant and equipment	4	(51,716)	(27,606)	(27,606)
(-) Provision additions	13	(64,847)	(46,676)	(46,676)
(-) Expenses linked to share-based payments	11	(840,695)	(924,637)	(924,637)
(-) Subsidies posted to profit and loss	12.2	-	128,532	128,532
(-) Capitalised interest	12.3	-	(27,374)	(27,374)
(+) interest from investments	18	280,090	132,897	132,897
(-) Discounting / unwinding of advances	12.2	(33,730)	(2,044)	(2,044)
Self-financing capacity before cost of net financial debt and taxes		(10,478,184)	(10,169,267)	(9,891,995)
(-) Change in working capital requirements (net of impairment of trade receivables and inventories)		1,265,995	(321,805)	(44,534)
Cash flow from operating activities		(11,744,179)	(9,847,462)	(9,847,462)
Cash flow from investing activities				
Acquisitions of intangible assets	3	(39,126)	-	-
Acquisitions of property, plant and equipment	4	(112,727)	(73,201)	(73,201)
Redemption of term deposits recorded in other current & non-current		12,500,000	_	_
financial assets		12,300,000		
Subscription of term deposits recorded in other current & non-current financial assets		-	(17,500,000)	(17,500,000)
Subscription to a capitalisation contract posted to other non-current financial assets		-	(5,000,000)	(5,000,000)
Interest from investments		236,956	-	-
Cash flow from investing activities		12,585,103	(22,573,201)	(22,573,201)
Cash flow from financing activities				
Capital increase net of conversion of bonds to shares	10	-	38,858,170	38,858,170
Capital increase transaction expenses	10	-	(2,944,403)	(2,944,403)
BSA & BSPCE subscriptions		-	43,621	43,621
BSPCE exercised		318,092	-	-
Encashment of conditional advances and subsidies (1)	12.2	853,099	830,874	830,874
Issuance of share-convertible bond	12.3	-	2,451,628	2,451,628
Repayment of conditional borrowings and advances	12.2	(495,600)	(288,240)	(288,240)
Bond repayments	12.2	(26,798)	-	-
Other flows from financing activities (change in liquidity contract)		-	(200,000)	(200,000)
Cash flow from financing activities		648,793	38,751,650	38,751,650
Increase (decrease) in cash & equivalents		1,489,716	6,330,987	6,330,987
Cash & cash equivalents – beginning of the period (including bank overdrafts)	8	10,169,940	3,838,953	3,838,953
Cash & cash equivalents – end of the period (including bank overdrafts)	8	11,659,656	10,169,940	10,169,940
Increase (decrease) in cash		1,489,716	6,330,987	6,330,987
Cash & cash equivalents	8	11,659,829	10,170,051	10,170,051
Bank overdrafts	12	(174)	(111)	(111)
Cash & cash equivalents at period-end (including bank overdrafts)		11,659,656	10,169,940	10,169,940

<sup>\*</sup> Please refer to HY 2015 financial statements for detailed information