Genticel (Euronext Paris and Brussels: FR0011790542 - GTCL), a French biotechnology company and leading developer of therapeutic vaccines, presents today its semi-annual financial report as of June 30, 2014. In accordance with applicable law, the financial statements were subjected to a limited review by the statutory auditors. They were approved by the Executive Board (Directoire) on September 10, 2014.

In both clinical and financial results, the first half of 2014 was a very positive period. Genticel emerges ideally equipped to continue developing its therapeutic vaccines program, aimed at preventing cancers caused by the human papilloma virus (HPV) in persons infected with the virus.

Benedikt Timmerman, the founder and CEO of Genticel, commented, “During the first half of 2014, Genticel achieved several significant milestones. We successfully launched the Phase II RHEIA-VAC trial for ProCervix, our therapeutic vaccine candidate. To date, more than 50% of patients have been recruited, which is exactly in line with projections. In human resources, we strengthened our management team by recruiting Dr. Sophie Olivier, a gynecologist, to the key post of Chief Medical Officer. We also continued the preclinical study of our second therapeutic vaccine candidate, Multivalent HPV. Finally, our successful initial public offering equipped us with the financial resources to develop our portfolio for the coming years.”

Six-month outlook
- Complete recruitment for Phase II trial for ProCervix;
- Second meeting of Data and Safety Monitoring Board (DSMB) to review the safety data from ProCervix’s current Phase II trial;
- Continue preclinical studies with Multivalent HPV.

Reminder: Genticel will announce the main outcome of the current Phase II ProCervix trial (demonstration of ProCervix’s ability to eliminate the HPV virus) during the first six months of 2016.
Scientific developments

Phase II trial of ProCervix is off to an excellent start, with rapid recruitment

Genticial has achieved a major milestone in the development of its flagship product with the launch of a Phase II clinical trial for ProCervix, its most advanced therapeutic vaccine candidate.

The multi-center Phase II trial, which is evaluating the viral clearance efficacy of ProCervix, received a favorable opinion from the European Medicines Agency (EMA). Thirty-nine investigation sites in seven European countries participate in this clinical trial. On June 30, 2014, Genticial had recruited more than half of the patients for its Phase II trial, in line with its projections. The plan to complete recruitment of all patients in the first half of 2015 has been confirmed.

Furthermore, the DSMB, a group of independent experts that reviews the trial safety data every six months, recommended the continuation of the trial with no change.

Satisfactory progress with Multivalent HPV

The preclinical results during the first half of 2014 for the Company’s second vaccine candidate, Multivalent HPV, are very encouraging. The vaccine targets six of the most pertinent HPV genotypes that lead to cervical cancer (including HPV 16 and 18).

Management team strengthened

To run its clinical development pipeline, and the Phase II ProCervix trial in particular, Genticial has strengthened its management team by recruiting Dr. Sophie Olivier, a gynecologist, as Chief Medical Officer. At its most recent meeting, the Supervisory Board appointed Dr. Olivier to the Executive Board in recognition of the central role she plays in the strategy and implementation of ProCervix’s clinical development plan.

Intellectual property portfolio enriched

During the first half of 2014, Genticial was granted five patents in various regions. These patents bolster protection of Genticial’s portfolio of products on key mature and emerging pharmaceutical markets in the United States, Europe, Japan, South Korea and India.
Financial position

During the first half of 2014, the Company was admitted to trade on the Euronext regulated market in Paris and Brussels. Genticel successfully raised gross proceeds of €34.7 million and net proceeds of €31.7 million, helping it to continue actively developing its therapeutic vaccine portfolio.

As of June 30, 2014, Genticel had an operating loss of €4.6 million, compared with a loss of €2.9 million for the same period of the previous year. This change reflects:

- Increased investment in research and development (+61% to €4.7 million), essentially due to the set-up and startup of the Phase II clinical trial of ProCervix. These costs are crucial for ProCervix’s development, and are mostly non recurrent. During the first half of 2014, Genticel booked €1.4 million of operating income in research tax credit (Crédit Impôt Recherche [CIR]) and subsidies, up 22% from the first half of 2013;
- An increase in general and administrative expenses from €0.6 million to €1.3 million. Half of this increase is due to costs from the initial public offering as well as non-recurring personnel costs.

After taking financial items into account, the net loss for the first six months of 2014 was €4.6 million, compared with a net loss of €2.3 million for the same period in 2013.

Genticel completed the first half of 2014 in a very robust financial position, with cash and cash equivalents of €36.9 million versus €3.8 million on December 31, 2013. In part, the change reflects:

- Payment of €2.4 million for the issuance of a share-convertible bond;
- Numerous capital increases, for a net amount of €35.9 million (including €31.7 million from the IPO);
- Payment of €200,000 for a liquidity contract administered by Oddo Corporate Finance;
- Cash used up in the amount of €4.9 million for Company operations, in line with expectations.

On August 27, 2014, the Company received €349,000 from Bpifrance in the form of subsidies and redeemable advances as part of a collaborative project on the preclinical development of Multivalent HPV.

Furthermore, the Company submitted to Bpifrance a project completion report for a redeemable advance provided during the preparation of ProCervix’s Phase II trial. The project’s success led Bpifrance to accept the final report and provided the Company with €481,000 on September 4, 2014. This amount is slightly less than the amount sought for in the initial agreement (€38,000) because the total cost to complete the project was less than the budget initially presented to Bpifrance.

During the year 2014, the Company is receiving €2.7 million in the form of non-dilutive financing, including €1.9 million in the form of research tax credit for the year 2013.

Genticel announces that its Semi-Annual Financial Report, for the six months ended June 30, 2014, is now available to the public and filed it with the French financial markets authority (Autorité des Marchés Financiers). The document may be viewed online at www.genticel.com, under the tab “Investors.”

Upcoming financial announcements (after Euronext stock exchange closing):

2014 Third Quarter Business Update October 23, 2014

Genticel will participate in several meetings with investors during the coming months:

European Midcap Event – Paris October 2 and 3, 2014

About Genticel

Genticel is a French biopharmaceutical company specialized in the development of therapeutic vaccines aimed at eliminating, at an early stage, the human papillomavirus (HPV) responsible for cervical cancer.

Genticel is developing ProCervix, a first therapeutic vaccine in Phase II clinical trials, designed to eliminate cervical cells infected with HPV 16 and/or HPV 18. The Company has also established Vaxiclace, a technology platform ideally adapted for use in early-intervention immunotherapies against multiple infectious or cancerous diseases. This platform is being used to develop a second therapeutic vaccine candidate, now in its preclinical stage, targeting six of the most pertinent HPV strains in terms of global epidemiology.

Genticel is based in Paris and Toulouse and was awarded the 2013 Innovation Prize by the ‘Grands Prix de l’Economie’.

Since April 4, 2014, Genticel shares have been listed on the regulated Euronext markets in Paris and Brussels.

For more information, please visit Genticel’s website www.genticel.com

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