

# PRESS RELEASE

Paris and Toulouse, November 13, 2014

# GENTICEL COMPLETES PROCERVIX PHASE II STUDY ENROLLMENT AHEAD OF SCHEDULE

- A total of 239 subjects infected with HPV 16 and/or 18 enrolled at 39 clinical centers throughout Europe for RHEIA-VAC study of ProCervix
- Patient retention rate exceeds 99% thus far

GENTICEL (Euronext Paris and Brussels: FR0011790542 - GTCL), a French biotechnology company and leading developer of therapeutic vaccines, today announces the completion of patient enrollment of the phase II study of its lead therapeutic vaccine candidate, ProCervix.

## Completion of patient enrollment for the RHEIA-VAC study ahead of schedule

With the last patient enrolled on November 10, 2014, Genticel has reached a significant milestone in the ProCervix development program. Overall, 239 patients were enrolled at 39 sites across seven European countries (Belgium, Finland, France, Germany, the Netherlands, Spain and the UK) in less than ten months.

Since the beginning of 2014, Genticel has been running a double-blind, randomized, placebo-controlled, multicenter trial for ProCervix, a therapeutic vaccine designed for adult women infected with HPV 16 and/or HPV 18, before high-grade cervical lesions or cancer occur. It is the first therapeutic vaccine to address the medical need of this high-risk population since preventive HPV vaccines cannot cure women from an established infection.

Sophie Olivier, the company's Chief Medical Officer, stated, "We are very satisfied with the way the recruitment phase of the study has been carried out. Our RHEIA-VAC study investigators have been extremely efficient in enrolling patients meeting the eligibility criteria. As a result, we were able to complete the enrollment at least four months in advance. So far, only one out of all patients, having received a first vaccination, has decided to withdraw from the trial. This illustrates how determined these women are to get treated when they are infected by HPV 16 and/or HPV 18. It also seems to indicate that ProCervix has an acceptable safety and tolerance profile."

Benedikt Timmerman, Genticel's Chief Executive Officer, added, "The amount of time to recruit patients in a clinical trial often represents the most significant operational uncertainty. With the completion of enrollment of the RHEIA-VAC phase II clinical trial, this uncertainty is behind us; we now have a fixed duration up to the completion of the study. Specifically, this means that the primary end point results by group will become available during the 1<sup>st</sup> half of 2016 instead of during the 2<sup>nd</sup> half, as previously forecasted."





## Upcoming events

### Genticel will take part in various investor events over the coming months:

KBC Biotech & Healthcare Seminar - New York Petercam Healthcare CEO Seminar - Brussels JP Morgan Healthcare Conference - San Francisco November 13, 2014 November 27, 2014 January 12 - 15, 2015

#### 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 Vaxiclase, 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 www.genticel.com

#### About the clinical trial RHEIA-VAC (Research on HPV Eradication In Adults by VAC cination):

RHEIA-VAC is a Phase II study of the ProCervix therapeutic vaccine. ProCervix is being studied in HPV 16 and/or 18 infected women, who have normal cervical cytology or ASCUS(1)/LSIL(2) (mild cervical cellular dyskaryosis). RHEIA-VAC is a double-blind, randomized and placebocontrolled efficacy study. Viral clearance at 12 months is the primary endpoint. In a previous Phase I study, ProCervix showed a favorable safety and tolerability profile.

(1) ASCUS: Atypical Squamous Cells of Undetermined Significance (2) LSIL: Low grade Squamous Intra-epithelial Lesions

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