

Paris and Toulouse, France – January 26, 2015

## Genticel to continue per protocol its Phase 2 clinical study with ProCervix after 2<sup>nd</sup> review by the DSMB

**The Data and Safety Monitoring Board (DSMB) identified no safety concerns that would require making changes to the conduct of the study**

Genticel (Euronext Paris and Brussels: FR0011790542 - GTCL), a French biotechnology company and leading developer of therapeutic vaccines, announces today that the Data and Safety Monitoring Board (DSMB), an independent committee of experts which monitors safety data every six months during the study, met as scheduled on January 22<sup>nd</sup> and recommended the RHEIA-VAC study proceed without any modifications. The DSMB had already made the same recommendation during the first review on July 1<sup>st</sup>, 2014.

RHEIA-VAC (**R**esearch on **HPV** **E**radication **I**n **A**dults by **V**ACCination) is a double-blinded, randomized, placebo-controlled Phase 2 efficacy study of the ProCervix therapeutic vaccine. ProCervix is used for HPV 16 and/or 18 infected women, who have normal cervical cytology or ASCUS<sup>(1)</sup> /LSIL<sup>(2)</sup> (mild cervical cellular dyskaryosis). The absolute risk of these women developing high grade lesions within 4 years is about 34%<sup>(3)</sup> i.e. approximately 1 in 3 persons.

On November 13<sup>th</sup> 2014, Genticel had announced achieving the full enrollment of all 239 patients in this study more than 4 months ahead of schedule and retaining 99% of participating subjects in the trial. As a reminder, viral clearance, the primary endpoint of this Phase 2 trial, is set 12 months after first vaccination. With patient enrollment being completed sooner than anticipated, Genticel should be able to communicate on this primary endpoint, by treatment group, during the first half of 2016 rather than in the second, as was initially planned.

Dr Sophie Olivier, Chief Medical Officer of Genticel, said, “*We are very satisfied with the progress of the RHEIA-VAC study and with the continuing commitment of all our investigators, whose motivation has been a cornerstone in the recruitment and retention of women in this trial.*” She added: “*It is also reassuring that the DSMB, which has now evaluated safety, tolerance and compliance data on almost all patients enrolled in this clinical study, has again allowed the trial to pursue per protocol.*”

(1) ASCUS: Atypical Squamous Cells of Undetermined Significance

(2) LSIL: Low-grade Squamous Intra-epithelial Lesions

(3) Naucler et al. *British Journal of Cancer*, 2007



**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's most advanced candidate therapeutic vaccine, ProCervix, is currently in a Phase 2 clinical trial. ProCervix is designed to induce the elimination of 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 "Prix Biotech d'Avenir" (Most Promising Biotech) in the SW France category of the Deloitte Technology Fast 50 Benchmark in 2014.*

*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](http://www.genticel.com)*



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