



PRESS RELEASE

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Independent Data Safety Monitoring Board Recommends Continuation per Protocol of Gentical's Phase 2 Clinical Trial of GTL001 (ProCervix), Company's First-in-class HPV Therapeutic Vaccine Candidate

- *Half of the 236 vaccinated patients have reached the 12-month follow-up milestone*
- *Patient and physician engagement remains very strong with 98% retention rate**

Gentical (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 announced that the independent Data Safety Monitoring Board (DSMB) recommends the continuation, per protocol, of its phase 2 clinical trial of GTL001 (known in Europe as ProCervix) in patients infected with HPV 16 and/or 18, the two HPV types responsible for 70% of cervical cancer cases. Half of the 236 vaccinated patients have now reached 12 months post-vaccination. In addition, patient and physician engagement remains extremely strong, with a 98 percent retention rate of the participants in the study.

"We are very pleased that GTL001 continues to be well tolerated in all phase 2 participants. We have also been able to keep a high retention rate in this large study, which reflects the strong unmet medical need for a treatment for HPV-infected women with early-stage disease," commented Sophie Olivier, Chief Medical Officer at Gentical. "The DSMB found no safety issues that warranted any changes in the conduct of the phase 2 trial of our lead candidate."

GTL001 previously obtained encouraging safety, tolerability and immunogenicity results from a European phase 1 study in 47 patients. Based on these results, in 2014 Gentical initiated the current European phase 2 clinical trial to evaluate the efficacy and safety of GTL001 in clearing HPV infection in women aged 25 to 50. Recruitment was completed by November 2014 and all vaccinations were administered by December 2014. The initial 12-month efficacy data from this phase 2 trial will be available in the first half of 2016.

Gentical also received in June 2015 the FDA clearance to conduct a US phase 1 study of GTL001 in 20 patients aged 25 to 65 to evaluate its safety profile in a broader age range. Patient recruitment in this study will begin in the second half of 2015.

** Number of patients still in the study / number of randomized patients*

About Gentical

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 Gentical 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.

Gentical's versatile platform, Vaxiclase, is ideally suited for the development of immunotherapies against multiple infectious or cancerous diseases. Gentical'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. (SIIL), 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 SIIL to develop acellular multivalent combination vaccines against a variety of infectious diseases, including whooping cough.

For more information, visit www.genticel.com



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