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Gentical Receives FDA Clearance of IND Application for U.S. Phase 1 Clinical Trial of GTL001 (ProCervix), Company's First-in-class HPV Therapeutic Vaccine Candidate

Gentical (Euronext Paris & Brussels: FR00011790542 – GTCL), a French biotechnology company and developer of innovative immunotherapies to prevent cancers caused by the human papillomavirus (HPV), today announced that the U.S. Food and Drug Administration (FDA) has cleared Gentical's Investigational New Drug (IND) application to conduct in the U.S. a phase 1 clinical study 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.

Today, no treatment options are available for the 93 million women worldwide infected with HPV 16 and/or 18 who have not yet developed high grade lesions or cervical cancer.

[Diane M. Harper](#), MD, MPH, MS, will lead the U.S. phase 1 study of GTL001 as principal investigator. Dr. Harper is the Gradie and Mary Rowntree Endowed Chair and professor of the department of Family and Geriatric Medicine and Obstetrics and Gynecology at the University of Louisville, KY, and is an internationally recognized researcher, teacher and clinician in the prevention, diagnosis and treatment of HPV-associated diseases.

The U.S. phase 1 study is designed to evaluate the tolerability and safety of GTL001 as a therapeutic vaccine in 20 women aged 25 to 65 infected with HPV 16 and/or 18. Three investigational sites will be recruiting these patients during the second half of 2015.

"This trial will provide important insights into the tolerability of GTL001 by enrolling patients over a broader age range than in our European studies," stated Sophie Olivier, Chief Medical Officer at Gentical. She continued: "Results from the U.S. phase 1 study, together with those from the fully-recruited phase 2 study in Europe, will serve to design the subsequent clinical development studies for GTL001 in Europe and in the U.S."

Gentical previously obtained encouraging safety, tolerability and immunogenicity results from the European phase 1 study of GTL001 in 47 patients. Based on these results, in 2014 the company initiated a European phase 2 trial to evaluate the efficacy and safety of GTL001 in clearing HPV infection in 239 women aged 25 to 50. All patients were recruited by November 2014. The initial efficacy data from this phase 2 trial will be available in the first half of 2016.

"This IND clearance represents a significant advance for Gentical, as the upcoming phase 1 clinical trial for GTL001 will be our first study conducted in the U.S." added Benedikt Timmerman, Chief Executive Officer of Gentical. "It reinforces our confidence in the strength of our clinical strategy and further demonstrates Gentical's ability to deliver on key aspects of its pipeline development plan."

Gentical's follow-on multivalent HPV candidate, GTL002, recently generated positive *in vivo* proof of concept results for all six oncogenic HPV types targeted and could be tested in a phase 1 trial as early as 2017. With GTL001 and GTL002, Gentical is the first company to establish a staged pipeline of HPV therapeutic vaccines for the millions of women burdened by this unmet medical need.

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.

Gentice's versatile platform, Vaxiclase, is ideally suited for the development of immunotherapies against multiple infectious or cancerous diseases. Gentice'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, Gentice'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. (SII), the world's largest producer of vaccine doses. This partnership is expected to generate \$57 million in revenues for Gentice, before royalties on sales. It will enable SII to develop acellular multivalent combination vaccines against a variety of infectious diseases, including whooping cough.

For more information, visit www.gentice.com



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