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Genticel Announces First Patient Treated in U.S. Phase 1 Clinical Trial of GTL001, Company's Therapeutic Vaccine Candidate against HPV 16/18 Infections

Genticel (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 announces that the first patient of the U.S. phase 1 clinical trial has been vaccinated with GTL001, the Company's first-in-class therapeutic vaccine candidate against HPV 16/18 infections.

This first vaccination follows the U.S. Food and Drug Administration's (FDA) clearance last June of Genticel's Investigational New Drug (IND) application to conduct a phase 1 clinical study of GTL001 in patients infected with HPV 16 and/or 18, which cause 70% of cervical cancer cases.

GTL001 already achieved encouraging results in a phase 1 trial on 47 patients in Europe and the first results of the European phase 2 study on 239 patients will be available in the first half of 2016.

In this U.S. phase 1 trial, Genticel is evaluating GTL001's safety and tolerance profile in 20 women aged 25 to 65, a subject population that includes women older than those previously studied in Europe. The study is being conducted at 3 investigational sites in the U.S.

Sophie Olivier, Genticel's Chief Medical Officer, stated, "We are very pleased with the way recruitment has taken off. The investigational study sites have been extremely diligent in enrolling patients meeting eligibility criteria, resulting in the treatment of our first patient today. Recruitment is thus in pace with our objective of delivering the trial results during the first half of 2016."

Martin Koch, Genticel's Chief Executive Officer, added, "The initiation of this study in the U.S. illustrates Genticel's global clinical development strategy for GTL001 in order to validate the vaccine's potential as an effective treatment for the millions of women infected with HPV 16 and/or 18 who currently do not have any therapeutic option."

Furthermore, Genticel recently obtained positive preclinical proof of concept results for the Company's second therapeutic vaccine candidate, GTL002 (Multivalent HPV), which targets the six most oncogenic HPV types. GTL002 will be ready for a phase 1 trial in 2017.

With GTL001 and GTL002, Genticel is the first company to develop a pipeline of HPV vaccine therapeutics for the millions of women infected by the most oncogenic types of this virus and for whom no treatment is currently available.



About Genticel

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 Genticel 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.

Genticel's versatile platform, Vaxiclase, is ideally suited for the development of immunotherapies against multiple infectious or cancerous diseases. Genticel'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 could generate up to \$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 us at www.genticel.com





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