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Gentical Announces Positive Preclinical Proof of Concept Results of GTL002, its New Multivalent HPV Therapeutic Vaccine Candidate Based on Company's Versatile Vaxiclase Platform

Gentical (Euronext Paris & Brussels: FR00011790542 – GTCL), a French biotechnology company and developer of innovative immunotherapies to prevent cancers caused by the human papillomavirus (HPV), announces today positive preclinical *in vivo* proof of concept results of GTL002, its multivalent HPV therapeutic vaccine candidate based on the Company's versatile Vaxiclase platform.

No treatment options are available for women infected with oncogenic HPV types but who have not yet developed high-grade lesions or cervical cancer: GTL002 seeks to eradicate the 6 most oncogenic HPV types affecting 158 million women worldwide.

As a reminder, GTL001 (known in Europe as ProCervix), Gentical's first-in-class therapeutic vaccine candidate currently in phase 2 in Europe, already targets the 2 most oncogenic HPV types that affect 93 million women.

With GTL001 and GTL002, Gentical is the first company that has established a staged pipeline of HPV therapeutic vaccines for the large female population burdened by this unmet medical need.

The proof of concept data of GTL002 demonstrated that an *in vivo* immune response was induced against each of the 6 HPV-derived proteins present in the therapeutic vaccine. In addition, *in vivo* therapeutic efficacy was shown by tumor eradication in the most widely used and broadly accepted reference model.

"These positive results, coupled with robust manufacturing data that met stringent reproducibility, quality and yield criteria, provide a solid foundation to advance our multivalent HPV vaccine towards clinical development," stated Marie-Christine Bissery, Chief Scientific Officer of Gentical. She added: *"Gentical can now initiate the formal preclinical pharmacology, toxicology studies and GMP clinical lot production required for the preparation of an IND or a phase 1 trial in Europe that could start as early as 2017."*

GTL002 is the first product candidate based on Gentical's proprietary Vaxiclase technology. This next-generation technology platform can be used with many antigens in multiple indications. In February 2015, Gentical signed a first licensing agreement with the Serum Institute of India Ltd. (SIIL), the world's largest producer of vaccine doses, to evaluate Vaxiclase for use in multivalent vaccines containing pertussis antigens. Under the terms of the agreement, Gentical receives up to \$57 million in upfront and milestones payments, plus royalties on sales.

"Achieving in vivo preclinical proof of concept of GTL002 efficacy is an important milestone in strengthening Gentical's HPV therapeutic vaccine pipeline," concluded Benedikt Timmerman, Chief Executive Officer of Gentical. *"These positive data show our ability to deliver a follow-on HPV product candidate and support our confidence in Vaxiclase's substantial value in other therapeutic indications."*

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 GTL001 phase 2 clinical trial.



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 multivalent HPV therapeutic vaccine candidate, GTL002, targets the six most pertinent HPV types in terms of global epidemiology and was designed using the Vaxiclase platform. It is currently in preclinical development.

Focusing on value creation.

GTL001 and GTL002 could generate respectively over €1 billion and €2 billion per year in revenues. Genticel seeks to establish partnerships for these two products as of 2016/2017. The versatility of its technological platform, Vaxiclase, has 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 Genticel, before royalties on sales. It will enable SII to develop acellular multivalent combination vaccines against a variety of conditions, notably whooping cough.

For more information, visit www.genticel.com



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