PRESS RELEASE

ViciniVax announces first patient treated in Phase I study with immunotherapy Vvax001 for HPV-related precancers and cancer

Groningen, the Netherlands - 3 February 2017 - ViciniVax, a Dutch biopharmaceutical company in Groningen, announced today the treatment of the first patient with Vvax001 in a Phase I study in patients with a history of cervical intraepithelial neoplasia (CIN) 2 and 3 or cervical cancer. The Phase I study is an investigator-initiated Phase I clinical trial conducted by the Department of Obstetrics and Gynaecology in close collaboration with the Department of Medical Microbiology and the Department of Clinical Pharmacy and Pharmacology at the University Medical Center Groningen in The Netherlands.

"We are very excited about the initiation of this Phase I study" said Janneke Meulenberg, CEO of ViciniVax. "This is the first time a Semliki Forest virus based vaccine is tested in humans and a major advancement in our Vvax001 development program. Given our strong preclinical data with Vvax001, we are looking forward to see the translation to humans". The interventional, open-label, dose-escalation study is designed to evaluate the safety and immunological effects of Vvax001. Twelve patients will be divided into four dose escalation cohorts. Each patient receives three intramuscular doses of the Vvax001 immunotherapy. The primary endpoint is to assess its ability to induce HPV16 E6,7-specific T-cell immunity. The secondary endpoint is to evaluate the safety of the intervention.

Cervical cancer is the second largest cause of cancer deaths in women worldwide. Human papilloma virus (HPV) infection has been recognized as the necessary cause of cervical intraepithelial neoplasia (CIN1/2/3) and cervical cancer. HPV infection is the most common sexually transmitted disease, affecting about 400 million women worldwide. Persistent HPV infection can lead to CIN2/3 and then to cervical cancer. Worldwide, CIN2/3 hits 7 million women, while cervical cancer affects 500,000 women each year leading to more than 270,000 deaths. Current treatment for CIN2/3 relies primarily on surgery, which is highly discomforting and carries a risk of serious complications like bleeding, cervical stenosis and cervical incompetence, leading to infertility. Above all, it does not eradicate the underlying HPV infection.

Dr. Refika Yigit, M.D., and principal investigator for the study, commented "Therapeutic vaccination with Vvax001 may offer an attractive alternative to the current surgical options for treatment of precancerous lesions and cervical cancer: it targets the underlying HPV infection and all HPV-associated lesions regardless of location, while inducing long-lasting immunity, thus preventing recurrence".

About ViciniVax
ViciniVax is a Dutch biopharmaceutical company, spin-off from the University Medical Center Groningen, The Netherlands. ViciniVax' leadproduct is Vvax001, an immunotherapeutic cancer vaccine against HPV-related premalignant lesions and cancer. It is a replication deficient recombinant Semliki Forest virus (rSFV) vector, expressing a fusion protein of HPV E6,7. Vvax001 elicits a strong immunological anti-tumor response after vaccination.

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