



LinKinVax and Gustave Roussy Collaborate on a Phase I/IIa HPV.DCVax Clinical Trial for the Treatment of Patients with HPV-Positive Oropharyngeal Cancer

CD40HVac, a therapeutic vaccine candidate in immuno-oncology targeting dendritic cells

Paris, January 19, 2023 - LinKinVax, a clinical-stage biotechnology company specialized in innovative protein-based vaccines, and Gustave Roussy, first leading cancer center in Europe, ranked third Best Cancer Hospital in the world, announced a collaboration to conduct a first-in-human Phase I/IIa clinical trial with CD40HVac, a new therapeutic vaccine candidate against head and neck cancer associated with human papillomavirus (HPV).

The objectives of the study (EUCT n° 2022-502930-25-00), sponsored by Gustave Roussy, are to demonstrate **the safety and immunogenicity** of the CD40HVac vaccine candidate with the Poly-ICLC adjuvant (Hiltonol®) against oncogenic HPV in patients with head and neck cancer, and to **determine the recommended Phase 2 dose** based on the safety profile of the vaccine candidate and its ability to induce immune responses. Several exploratory objectives are also planned to estimate progression-free survival and overall survival.

LinKinVax develops CD40HVac, a therapeutic vaccine for HPV-associated malignancies, based on an innovative technology directly targeting dendritic cells (DC), which play a crucial role in the immune system by stimulating and regulating immune responses. A recent U.S. population-based study conducted by the Centers for Disease Control and Prevention (CDC) showed that 66% of cervical cancers, 55% of vaginal cancers, 79% of anal cancers, and 62% of oropharyngeal cancers are attributable to HPV 16 and 18.

Although many HPV-induced tumors can be cured with modern multidisciplinary treatment approaches, it is important to develop new and effective therapeutic vaccines against HPV-associated malignancies to better address the needs of patients.

Prof. Yves Levy, Chief Medical and Scientific Officer LinKinVax, commented: "*This partnership with Gustave Roussy to launch of the first phase 1 study is a crucial step for the development of our CD40HVac vaccine in immuno-oncology. It represents a bridge between basic research and clinical research designed to accelerate innovation for the benefit of patients. Together with Gustave Roussy, we look forward to making what we hope will be a major contribution to the treatment of HPV related cancers*".

Dr. Caroline Even, Department of Head and Neck Oncology at Gustave Roussy (Villejuif- Paris) added: "*Both Gustave Roussy and LinKinVax place innovation at the heart of a human, scientific and technological revolution in the fight against cancer, thereby responding to the ongoing challenge of giving patients access to the most recent treatment advances. We hope that this first project will be inaugural of a long-standing and synergistic collaboration between LinKinVax and Gustave Roussy*".

About LinKinVax technology

LinKinVax's vaccine platform is built around a humanized monoclonal antibody, which is fused with regions of pathogens of interest, targeting the CD40 molecule expressed by dendritic cells, DC, which play a key role in stimulating the immune system. The results obtained demonstrate the benefits of this strategy owing to the small quantity of antigens required to activate the immune system, with or without an adjuvant, and its ability to trigger a lasting cellular and humoral and immune response. The platform also benefits from the experience and safety profile of the protein-based vaccines that have been widely used for over 30 years now.

About LinKinVax

LinKinVax was founded in 2020 and is led by two internationally renowned personalities in the worlds of medicine, industry and business, namely André-Jacques Auberton-Hervé, Honorary Chairman and founder of SOITEC, and Prof. Yves Levy, MD, PhD, immunologist, and Director of the Vaccine Research Institute (VRI/INSERM/UPEC). LinKinVax is developing an innovative protein-based vaccine platform that can accelerate availability of vaccines by leveraging the research conducted at the Vaccine Research Institute (VRI). This DC Targeting-based protein vaccine platform can adapt to changes and mutations in the target pathogens. For further information, please visit www.linkinvax.com

About Gustave Roussy :

Ranked as the leading European Cancer Centre and third in the world, Gustave Roussy is a centre with comprehensive expertise and is devoted entirely to patients suffering with cancer. The Institute is a founding member of the Paris Saclay Cancer Cluster. It is a source of diagnostic and therapeutic advances. It caters for almost 50,000 patients per year and its approach is one that integrates research, patient care and teaching. It is specialized in the treatment of rare cancers and complex tumors and it treats all cancers in patients of any age. Its care is personalized and combines the most advanced medical methods with an appreciation of the patient's human requirements. In addition to the quality of treatment offered, the physical, psychological and social aspects of the patient's life are respected. 4,100 professionals work on its two campuses: Villejuif and Chevilly-Larue. Gustave Roussy brings together the skills, which are essential for the highest quality research in oncology: a quarter of patients treated are included in clinical trials.

For further information: www.gustaveroussy.fr/en, [Twitter](#), [Facebook](#), [LinkedIn](#), [Instagram](#)

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