



## **LinKinVax and Gustave Roussy announced first patient dosed in Phase I/IIa clinical study on HPV.DCVax in HPV-positive oropharyngeal cancer**

### ***CD40HVac, a therapeutic vaccine candidate for malignancies targeting dendritic cells***

**Paris, France, September 18, 2023** - LinKinVax, a clinical-stage biotechnology company focusing on innovative protein-based vaccines, and Gustave Roussy, the leading cancer centre in Europe ranked third Best Cancer Hospital in the world, announced the treatment at Gustave Roussy of the first patient in a Phase I/IIa clinical study with CD40HVac, a new therapeutic vaccine candidate for HPV-positive oropharyngeal cancer.

**The objectives of the study (EUCT N° 2022-502930-25-00 - NCT06007092), sponsored by Gustave Roussy, include:**

- **To assess the immunogenicity and safety** of CD40HVac with the Poly-ICLC adjuvant (Hiltonol®) against oncogenic HPV in patients with HPV-positive oropharyngeal cancer, and
- **To determine the recommended dose for the Phase II study**, based on the vaccine candidate's safety profile and ability to induce immune responses.

Several exploratory objectives are also planned to estimate progression-free survival and overall survival.

This multicentre study will test 2 doses of CD40HVac using a dose escalation regimen. Up to 24 patients will be recruited in this double-blind, randomised and placebo-controlled study.

**Valérie Bouchara, Head of Clinical Operations at LinKinVax**, commented: *"This first administration is a major milestone in the development of our therapeutic cancer vaccine CD40HVac. Our teams are committed to uniting their efforts to bring significant innovations to patients with limited therapeutic options, particularly those with recurrent and/or metastatic HPV-positive cancers."*

**Dr Caroline Even, Head of the Head and Neck Medical Oncology Unit at Gustave Roussy** added: *"The CD40HVac therapeutic vaccine candidate will provide a promising addition to the existing therapeutic arsenal, once its benefit and safety have been demonstrated in patients with HPV-positive oropharyngeal cancer. We are delighted to be conducting this study."*

### **About CD40HVac**

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.

### **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](http://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](http://www.gustaveroussy.fr/en)

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