LinKinVax welcomes interim results of the ANRS VRI06 Phase I trial evaluating a novel HIV vaccine candidate

- *First vaccine to target dendritic cells, key activators of the immune system*
- *Novel delivery of the HIV envelope protein potentially critical to future vaccine strategies*
- *Safe and able to induce early, significant and sustained immune response*

These results were presented by Prof. Yves Levy, Executive Director of the VRI and CSMO of LinKinVax, on 21 February 2023 at the 30th Conference on Retroviruses and Opportunistic Infections (CROI) ***held in Seattle from 19 to 22 February 2023.***

Paris, 22 February 2023 - **LinKinVax, a clinical-stage biotechnology company, welcomes the interim results of the ANRS VRI06 Phase I trial evaluating a preventive HIV vaccine and conducted by the sponsor INSERM-ANRS and the Vaccine Research Institute (ANRS and Université Paris-Est Créteil, France). These results show that the vaccine candidate is safe and induces an early, significant and sustained immune response.**

The *CD40.HIVRI.Env* vaccine candidate is developed by the VRI with a technology whose exclusive worldwide license is held by LinKinVax. It is the first vaccine based on this technology, that targets an immune response binding HIV envelope protein to monoclonal antibodies specifically targeting CD40 receptors on the surface of dendritic cells. Once injected, the Env protein is thus delivered directly to the dendritic cells that play a key role in the education and activation of the immune system.

André-Jacques Auberton-Hervé, **Co-founder and CEO of LinKinVax** declared**:** *"We are pleased with these very promising immunogenicity results, which demonstrate the robustness of our DC Targeting vaccine platform and confirm its safety. This important milestone paves the way for the upcoming Phase II/III clinical studies that we will conduct once the final Phase I results have been obtained. These studies will aim to demonstrate the efficacy of the vaccine, the "Everest of vaccine strategies", which has been the elusive goal of HIV research for the past 40 years."*

"*The CD40.HIVRI.Env vaccine candidate has demonstrated both its safety and ability to induce early, potent and sustained responses*," explained **Prof. Yves Lévy, Executive Director of the VRI and CMSO of LinKinVax**. "*The immune response profile generated by this vaccine (antibody response and activation of polyfunctional $CD4^+$ T cells) was the one associated with a reduced risk of HIV infection in the RV144 trial. However, at this early stage of vaccine development, it is important to remember that*

volunteers should continue to protect themselves from any risk of HIV infection, as the efficacy of the vaccine will only be evaluated in the Phase II/III studies."

ANRS VRI06 clinical study

This Phase I study conducted in France and Switzerland included 72 healthy volunteers by the end of its recruitment period in October 2022. An interim analysis of the results was carried out on 36 subjects.

This dose escalation study included three groups: a first group of 12 subjects received a subcutaneous dose of 0.3 mg of vaccine at inclusion and at Weeks 4 and 24; the second and third groups then received doses of 1 or 3 mg, respectively, according to the same schedule. The vaccine is combined with the Hiltonol® adjuvant, designed to enhance its potential action.

This is a double-blind trial and some volunteers are injected with a placebo. The safety and immunogenicity were assessed at Weeks 6, 26 and 48.

Safety and tolerance

The results observed at Week 26 in the first 36 volunteers included (average age 34 years, 64% male), show that the **vaccine candidate is safe and well tolerated**.

Promising induction of an effective immune response to HIV

The vaccine yielded high levels of antibodies directed against HIV envelope : 80-100% at Week 6, 100% at Week 26 in all groups (0.3, 1 and 3 mg). These levels remained stable or dropped slightly until Week 48. Antibodies targeting a specific area of the HIV envelope (V1/V2 region) were also produced. Furthermore, at Week 26, neutralising antibodies were detected in 50% of subjects in the 0.3 mg group and 100% of subjects in the other two groups. The observed counts of $CD4^+$ T cells targeting specifically the HIV envelope protein produced after the vaccination remained stable until Week 48.

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About LinKinVax technology :

LinKinVax's vaccine platform is built around a humanized monoclonal antibody, which is merged 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.

Three products are in or about to enter clinical trials: a prophylactic vaccine for HIV, (currently in phase I led by Inserm/ANRS), a SARS-CoV-2 vaccine covering variants of interest, and a therapeutic vaccine for human papillomavirus-related cancers.

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/ANRS/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