



## PRESS RELEASE

### **Results from a Phase I clinical trial of a dendritic cell targeting prophylactic HIV vaccine published in the Journal *eClinical Medicine***

- *Provides important validation of the safety and immunogenicity of EnnoDC's technology*
- *The ANRS VRI06 trial, carried out by Inserm, ANRS MIE and the VRI, shows that the CD40.HIVRI.Env vaccine, is safe and induces early and sustained humoral and cellular immune responses against HIV*
- *The first clinical trial results in humans with this novel type of vaccine, which consists of a monoclonal antibody fused to the HIV envelope, targeting the CD40 molecule expressed at the surface of dendritic cells*
- *Results were published in the Journal *eClinical Medicine*, an open access clinical journal, published by *The Lancet**

**Paris, France, 2 October 2024** – EnnoDC\* (or “the Company”), a clinical-stage biotech company pioneering the development of first-in-class dendritic cell-targeting immunotherapies, today notes the publication of positive results from a Phase I trial of its novel Dendritic Cell (DC) targeting prophylactic HIV vaccine in the Journal *eClinical Medicine*, an open access clinical journal, published by *The Lancet*.

The multicentre, double-blind placebo-controlled dose-escalation trial was conducted at clinical sites in France and Switzerland. The results, published by scientists from the Vaccine Research Institute of Inserm and the Université Paris-Est Créteil, the CHUV in Lausanne and the University of Bordeaux, show that the vaccine, CD40.HIVRI.Env, is safe and induces early and sustained humoral and cellular immune responses against HIV. No serious side effects were observed. General and local reactions at the injection site were mainly mild to moderate. Two severe adverse events were reported, which were found to be unrelated to vaccination after analysis.

EnnoDC's first-in-class approach combines the power of vaccines and immunotherapies to provide targeted immune responses for both cancer and infectious diseases. CD40.HIVRI.Env combines a humanized anti-CD40 monoclonal antibody fused with HIV envelope antigens to stimulate DCs through CD40 and deliver a targeted immune response.

**Pr. Yves Lévy, co-founder, Chief Medical and Scientific Officer at EnnoDC and Principal Investigator of the trial commented:** *“These are exciting results for EnnoDC from the first clinical study using our novel dendritic cell targeting technology. The results show that this vaccine is safe and well tolerated and that humoral and cellular immune response were activated against HIV. The results support further development of the program. In addition, the results show that this type of treatment, which specifically targets antigens to the dendritic cells via the CD40 molecule, may be potent in inducing protective immunological responses in prime-boost vaccination strategies.”*

**Christophe Hubert, Chief Executive Officer of EnnoDC, added:** *“These are very encouraging results which provide further validation of our technology with positive read across to our new immunotherapies, in development for HPV-induced cancers, prostate cancer and infectious diseases.”*



Last week [EnnoDC unveiled](#) the next generation of DC-targeting immunotherapies supported by new leadership and an evolved strategy. EnnoDC has an extensive pipeline of clinical and preclinical stage assets in HPV-induced cancers, prostate cancer and in infectious diseases.

Further information on the ANRS VRI06 trial is available in a press release issued by the Vaccine Research Institute (VRI) of Inserm and the Université Paris-Est Créteil (Unit 955 Mondor Institute for biomedical research), the CHUV in Lausanne and the University of Bordeaux through the link below: [Preventive vaccine against HIV: promising results in healthy volunteers with a new vaccine technology – Vaccine Research Institute \(vaccine-research-institute.fr\)](#)

The full paper, published in the October 2024 issue of *eClinical Medicine*, can be accessed through the following link: <https://doi.org/10.1016/j.eclinm.2024.102845>.

Further details about the trial can be found online at <https://clinicaltrials.gov/study/NCT04842682>.

\*EnnoDC is the trading name of LinKinVax Europe SAS.

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**About EnnoDC**

EnnoDC, the trading name of LinKinVax, is a clinical-stage biotech company pioneering the development of first-in-class Dendritic Cell (DC)-targeting immunotherapies. Through our versatile DC-targeting immunotherapy platform we are developing CD40-specific monoclonal antibodies fused with pathogenic antigens to induce a highly specific, safe, broad, and long-lasting immune response to combat diseases like cancer and infectious diseases. The Company currently has three active clinical trials in various stages of clinical development, addressing oncology and infectious disease indications. Its lead asset, CD40HVac is currently in a Phase I/IIa clinical trial for HPV16+ oropharyngeal cancer patients.

EnnoDC is a spin out from the Vaccine Research Institute (VRI), an institute of INSERM (the French National Institute of Health and Medical Research) and is supported by longstanding investors and internationally renowned key opinion leaders who contribute their expertise in the clinical development of EnnoDC's assets and help explore the expansive therapeutic potential of its innovative platform.

Find out more online at: <http://www.EnnoDC.com>



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#### **About ANRS MIE**

ANRS Emerging Infectious Diseases is an autonomous agency of Inserm (the French National Institute for Health and Medical Research). Its mission is to facilitate, evaluate, coordinate and fund research into HIV/AIDS, viral hepatitis, sexually transmitted infections, tuberculosis and emerging and re-emerging infectious diseases.

For more information: <https://anrs.fr/en/>

#### **About the VRI and Inserm**

The Vaccine Research Institute (VRI), Laboratory of excellence, was established by Inserm (French National Institute of Health and Medical Research) and the University of Paris-Est Créteil (UPEC) to conduct research to accelerate the development of effective vaccines against HIV/AIDS and (re-)emerging infectious diseases. The VRI's structure strengthens the links between basic research and translational research, patient associations and the socio-economic world. The VRI extends a network of internationally renowned scientists and research teams with multidisciplinary expertise in system biology and clinical immunology, a network of clinical centres, and shared platform.

For more information: <https://vaccine-research-institute.fr/>

Founded in 1964, Inserm is a public scientific and technological institute dedicated to biomedical research and human health and is involved in the entire range of activities from the laboratory to the patient's bedside. It also partners with the most prestigious research institutions in the world that are committed to scientific challenges and progress in these fields.

For more information: <https://www.inserm.fr/en/home/>

#### **About Université Paris-Est Créteil:**

With 14 faculties, schools and institutes, 1 observatory and 32 research laboratories, Université Paris-Est Créteil has been active in all fields of knowledge since 1970. Each year, UPEC trains over 42,000 students and working professionals of all ages.

A major player in the dissemination of academic, scientific and technological knowledge, the university offers more than 500 training courses in all disciplines and at all levels. UPEC offers personalized support for all successes, thanks to undergraduate and graduate training, recognition of prior learning and lifelong learning opportunities. Furthermore, the university runs a growing number of apprenticeship programs in order to stimulate entrepreneurship and ease professional integration.

Université Paris-Est Créteil has built its strategic plan around three strategic orientations: UPEC is an engaged university that aims to match academic excellence with societal relevance. It encourages and supports all paths of students' success with dedicated programs. UPEC masters its trajectory and is a university open to the world and its diversity.

For more information: <https://www.en.u-pec.fr/>



**About the University of Bordeaux**

With more 54,000 students, 3,200 researchers and teachers, and 2,800 staff members, the University of Bordeaux is one of the leading French public research and higher education institutions, located in a dynamic and culturally rich, fast-developing region.

Ranked among the top universities in France, the University of Bordeaux is renowned for the quality of its academic courses and research. It is a multi-disciplinary, research-focused institution with a strong ambition to develop as a leading, international campus. The University of Bordeaux is leading an ambitious, competitive development program in partnership with local higher education institutes and national research organizations, in order to promote Bordeaux as a “Campus of Excellence”.

For more information: <https://www.inserm.fr/en/home/>