



## **Positive results from AELIX' HIV therapeutic vaccine clinical study published in Nature Medicine**

**Article describes positive results of AELIX' therapeutic HIV vaccine, leading to prolonged period without AntiRetroviral Treatment (ART), and supporting the use of HTI vaccine for combination cure strategies for HIV**

**Second clinical trial combining vaccine therapy with Gilead Sciences' investigational, Toll-Like Receptor 7 (TLR7) agonist, vesatolimod, underway. Enrollment completed and results expected early next year**

**Barcelona, Spain, November 2, 2022** – AELIX Therapeutics S.L. (AELIX), a clinical-stage biotechnology company specialized in the discovery and development of immunotherapies for HIV infection, today announces the publication in Nature Medicine of [the results of its AELIX-002 clinical study](#) (NCT03204617).

"We are excited to have published the data on this important study in such a prestigious journal, reaching a wide readership. Our T-cell vaccine approach has the potential to play a critical role in strategies to cure HIV infection. AELIX is a leader in developing vaccine-based solutions for HIV cure," said Dr Christian Brander, co-founder and chief scientific officer at AELIX and principal investigator at IrsiCaixa.

The AELIX-002 study was conducted in collaboration with Gilead Sciences at the IrsiCaixa AIDS Research Institute, a centre jointly promoted by the "la Caixa" Foundation and the Department of Health of the Generalitat de Catalunya. It evaluated the safety, tolerability, immunogenicity and efficacy of AELIX' HTI T-cell therapeutic HIV vaccine (DNA.HTI, MVA.HTI and ChAdOx1.HTI), in early treated people living with HIV. The study achieved its primary and secondary endpoints of safety, tolerability and immunogenicity.

The trial also evaluated the efficacy of the vaccination and showed that the use of the AELIX HTI vaccine can enable a prolonged period without AntiRetroviral Therapy (ART). The strength of the vaccine-induced T-cell response significantly correlated with prolonged periods off ART. The results support the development of combination strategies based on the HTI vaccine to control HIV without the need for ongoing ART.

"The positive results from this trial show that it is possible to induce an immune response in a person living with HIV which enables them to improve the suppression of the virus in the absence of antiretroviral medication," said Dr [Beatriz Mothe](#), principal investigator of the study at the Fight Against Infections Foundation and associate researcher at the IrsiCaixa AIDS Research Institute, where the study was conducted from 2017 to 2021. "A safe and effective HTI vaccine could become the backbone of combination strategies to achieve complete viral suppression, which ultimately is our common goal."

A second clinical study, AELIX-003 ([NCT04364035](#)), is being conducted in collaboration with Gilead. This active Phase 2 study is designed to evaluate the HTI vaccine in combination with Gilead's investigational Toll-Like Receptor 7 (TLR7) agonist, vesatolimod, in people with HIV on antiretroviral therapy. Vesatolimod is an immune modulator being evaluated as part of an investigational combination regimen that could potentially lead to



viral remission. In this study, vesatolimod is expected to enhance the vaccine-induced immune response leading to the elimination of virus-infected cells.

“Illuminating the pathways to an HIV cure is an incredibly complex scientific challenge and collaboration is key to catalysing the research,” said Devi SenGupta, MD, Executive Director, HIV Clinical Development, Gilead Sciences. “The AELIX-003 study aims to build upon these positive results published in Nature Medicine and may help inform future directions for HIV cure research. We look forward to presenting the findings from this Phase 2 study at a future HIV congress.”

The HIV epidemic affects a projected 38.4 million people worldwide, with 650,000 deaths and 1.5 million new infections in 2021. Globally, it is estimated that 28.7 million people are currently accessing antiretroviral therapy. New innovations, like AELIX’ T-cell vaccine, leading to a prolonged period without ART, could be a gamechanger in HIV cure strategies as a combination approach to treating the disease.

### **About the HTI immunogen**

The HTI immunogen was designed at IrsiCaixa by Dr Christian Brander, chief scientific officer at AELIX and head of the IrsiCaixa Host Genetics and Cellular Immunity Group, and his colleagues. It is based on the observation that T-cell responses to certain parts of HIV are enriched in individuals with a non-progressor clinical phenotype. The HTI immunogen combines these regions in a vaccine immunogen. The HTI sequence design is driven by functional immune data from close to 1,000 individuals from four different cohorts on three continents ([Mothe et al. 2011](#)). It does not rely solely on sequence conservation, density of HLA binding motifs or gene expression levels and kinetics. The predictive power of HTI directed T-cell responses on *in vivo* virus control has been validated in unrelated cohorts and through sub-studies in samples from earlier vaccine trials, including the STEP trial.

### **About AELIX Therapeutics**

AELIX, a clinical-stage biotechnology company based in Barcelona, Spain, is focused on the development of a therapeutic HIV vaccine to be included in cure/eradication strategies. AELIX is a spin-off of HIVACAT, the Catalan public-private consortium conducting cutting-edge research in this field. AELIX holds a worldwide, exclusive license for the development and commercialization of the HTI immunogen. The company is backed by a syndicate of experienced Spanish and international investors including Ysios Capital, Caixa Capital Risc, 10K Lakes Capital, and the Centro para el Desarrollo Tecnológico e Industrial (CDTI).

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