AELIX Therapeutics enrolls first patient in company's initial therapeutic HIV vaccine clinical trial

AELIX-002 phase I study will focus on evaluating the safety and immunogenicity of the HTI vaccine

Barcelona, Spain, September 5, 2017 - AELIX Therapeutics, a drug development company specialized in the discovery and development of immunotherapies for HIV infection, today announces that it has enrolled the first patient in its phase I clinical trial for the assessment of its proprietary HTI vaccine.

The HTI immunogen brings together specific HIV antigenic regions. There is usually an enriched T-cell immune response towards these regions in those individuals who can control the virus without taking antiretroviral drugs.

AELIX-002 is a phase I randomized, double-blind, placebo-controlled safety, tolerability, and immunogenicity study of the HTI vaccine. The vaccine will be administered in a prime-boost regimen, using first a DNA vector and then a Modified Vaccinia Ankara virus (MVA) vector. This combined administration is expected to strongly enhance immune responses to HIV.

Only individuals diagnosed less than six months after their initial HIV infection and immediately treated with antiretroviral therapy (ART) will be included in the study. The enrollment of early diagnosed, early treated HIV-infected individuals in the trial should optimize the expansion of vaccine-associated immune responses. The trial is taking place at the University Hospital Germans Trias i Pujol (HUGTIP) in Badalona (Catalonia, Spain), and is performed by investigators from the IrsiCaixa AIDS Research Institute and the Fight AIDS Foundation. Results are expected in 2018.

"*The AELIX-002 study builds upon our previous experience with therapeutic HIV vaccine trials. It will allow us to evaluate an exciting new HIV vaccine*", said Dr. Beatriz Mothe, principal investigator of the study at HUGTIP. "*The vaccine has been designed with the goal of refocusing patients´ immune response to especially vulnerable sites of HIV so that they can control their HIV infection without further antiretroviral therapy.*"

"*Developing a safe and effective therapeutic HIV vaccine that frees patients from the burden of antiretroviral therapy could be considered as the final frontier in HIV research*" said Dr. Ian McGowan, chief medical officer at AELIX Therapeutics. "*We are very pleased to be able to partner with Dr. Mothe and her colleagues in evaluating the safety and immunogenicity of our HTI vaccine.*"

According to WHO estimates, today about 36.7 million people are living with HIV and in 2015, more than one million people died of AIDS-related illnesses.

Further trial details can be found at https://clinicaltrials.gov/ct2/show/NCT03204617

About the HTI immunogen

The HTI immunogen was designed by Dr. Christian Brander, Chief Scientific Officer of AELIX Therapeutics and head of the IrsiCaixa Host Genetics and Cellular Immunity group, and colleagues. It is based on the observation that T-cell responses to certain regions 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. Preclinical data shows that immunization with HTI in mice and macaques elicits strong and broad T-cell responses (Mothe *et al.* 2015).

About AELIX Therapeutics

AELIX Therapeutics is a biotechnology company based in Barcelona, Spain. It is focused on the development of a therapeutic HIV vaccine to be included in a cure/eradication strategy. AELIX Therapeutics 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 was incorporated in November 2015 and completed an €11.5M ($12.5M) Series A funding shortly thereafter.
www.aelixtherapeutics.com

Media Contacts & Analysts
Andrew Lloyd & Associates
Agnes Stephens - Sandra Régnavaque
agnes@ala.com - sandra@ala.com
@ALA_Group
