

# THERAVECTYS FINALIZES THE RECRUITMENT OF PATIENTS FOR THE PHASE I/II CLINICAL TRIAL OF ITS ANTI-HIV THERAPEUTIC VACCINE CANDIDATE

World-first use of lentiviral vector technology in the field of vaccines

Paris, February 5, 2014

THERAVECTYS, a French biotechnology company specializing in the development of vaccines based on lentiviral vector technology, announced today the finalization of recruitment of patients for the first anti-HIV therapeutic vaccination trial, currently in progress in France and Belgium.

This study of the first administration to humans aims to study the safety, tolerance and immunogenicity of its vaccine candidate in patients infected with HIV, undergoing highly active antiretroviral therapy (HAART).

36 patients were included in the study. Preliminary results will be available from June 2014 onwards and definitive results over the next 12 months.

Odile Launay, the clinical trial coordinator, indicated: "I would like to offer my most sincere thanks to all of the centres taking part in this world-wide premiere of a vaccine trial using lentiviral vectors. The search for a vaccine-based solution for patients infected with HIV remains a priority and the ongoing trial will contribute to the achievement of this objective."

Paul GINESTE, Director of Clinical Development, indicated: "*With the aid of the centres taking part in this trial, THERAVECTYS has just reached an important stage. It allows us to plan the analysis of the results that will certainly lead THERAVECTYS to pursue the development of its candidate vaccine for a registration of this indication*".

The United Nations estimates that around 34 million individuals are infected with HIV throughout the world. Sub-Saharan Africa is by far the part of the world where the impact is highest, representing 69% of global cases.

Within Europe and on the American continent, the number of infected individuals is estimated to be 2.3 million and 3 million respectively. Associations of antiretroviral treatments have enabled to delay the

AIDS phase. These treatments must nevertheless be continued for life, in order to keep the infection in a quiescent state for as long as possible.

The stimulation by a vaccine of the immune system of infected individuals could either permit patients to stop the antiretroviral treatment, or significantly reduce the number and doses of these antiretroviral treatments, while maintaining control of the infection.

### The vaccine candidate

The therapeutic anti-HIV vaccine, the first candidate to emerge from THERAVECTYS' research, uses its proprietary lentiviral vector technology for vaccine use.

Unlike other gene transfer vectors, lentiviral vectors are capable of inducing a cellular and humoral immune response, which is simultaneously strong, durable and diversified. This induced immune response is specific to HIV and to cells infected by the virus. It participates in the control of this infection by the immune system.

## About THERAVECTYS

THERAVECTYS is a French biotechnology company engaged in the development of a new generation of vaccines based on the lentiviral vector technology, a breakthrough technology originating from fundamental research at Pasteur Institute.

It is expected to enable the prevention or the treatment of cancers and major global infectious diseases where the induction of a strong and effective cellular immune response is required: viral diseases (HIV), bacterial or parasitic diseases, cancers, etc. By way of a worldwide exclusive agreement with the Pasteur Institute and the financial

support from public authorities (Bpifrance, i.e. the former OSEO, and ANR), THERAVECTYS continues to invest in research and development to fight against major pathologies.

Alone or in collaboration with other partners, THERAVECTYS plans to shortly begin the clinical development of further vaccine candidates.

Since its creation, THERAVECTYS has been pursuing the development of a therapeutic anti-HIV vaccine and a phase I/II clinical trial is currently underway.

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