

THERAVECTYS is granted authorization from the French and Belgian regulatory agencies to launch a Phase I/II clinical trial for its anti-HIV therapeutic vaccine candidate

The world's first use of lentiviral vector technology in the vaccine field

Paris, 30 November 2012

THERAVECTYS, a French biotechnology company currently developing a new generation of vaccines, today announced it was granted authorization by the National Security Agency for Medicines and Health Products in France (Agence Nationale de Sécurité du Médicament et des produits de santé) and the Federal Agency for Medicines and Health Products in Belgium (Agence Fédérale des Médicaments et des Produits de Santé) to launch a phase I/II clinical trial for its anti-HIV therapeutic vaccine candidate based on lentiviral vector technology.

Renaud VAILLANT, Chief Executive Officer of THERAVECTYS states *“This authorization marks a key step in the company’s development. THERAVECTYS will be the first company in the world to initiate an anti-HIV therapeutic vaccination clinical trial with lentiviral vectors.”*

About the trial sponsored by THERAVECTYS

This double-blind placebo controlled study will include 36 patients in 6 clinical centers: 4 in France and 2 in Belgium.

Pr. Odile LAUNAY, coordinator at the Cochin-Pasteur Clinical Investigation Center based at the Cochin Hospital in Paris, France, will be the coordinating investigator of the trial. *“This study should confirm the preclinical data and the ability of the vaccine candidate, based on the result of fundamental research conducted at the Pasteur Institute, to induce an immune response against HIV”* says Pr. Odile LAUNAY.

A phase I/II clinical trial

With this first human trial, THERAVECTYS not only intends to evaluate the safety and tolerance of its therapeutic vaccine candidate but also to measure the quality and intensity of the induced immune response.

The anti-HIV therapeutic vaccine developed by THERAVECTYS should allow patients treated with antiretroviral drugs to stop taking them on a sustainable and perhaps permanent basis once vaccinated. *“We expect to enroll our first patient before the end of the year”*, says Dr. Emmanuelle SABBAH-PETROVER, in charge of THERAVECTYS’ Regulatory Affairs and Clinical Trials who adds: *“Our early interactions with the French, Belgian and European regulatory agencies facilitated their investigations on our clinical trial applications.”*

Lentiviral vectors supporting anti-HIV vaccination

THERAVECTYS uses lentiviral vector technology to develop a new generation of vaccines. Unlike other gene transfer vectors, lentiviral vectors have the unique ability to induce a strong, sustainable and diversified cellular immune response, which should help remove infected cells.

Dr. Cécile BAUCHE, Chief Scientific Officer of THERAVECTYS states: *“In 12 months, THERAVECTYS should be able to demonstrate safety and immunogenicity in humans. This expected confirmation will not only bring tremendous hope for all HIV positive patients, but it will also open a path for new developments.”*

About THERAVECTYS

THERAVECTYS, a biotechnology company, has developed a new generation of vaccines based on lentiviral vector technology. Built on the result of fundamental research conducted at the Pasteur Institute, this breakthrough technology is expected to enable preventing or effectively treating many diseases in which the induction of effective cellular immune response is required: viral diseases (HIV), bacterial or parasitic diseases, cancers...

Since its creation, THERAVECTYS has been working on the development of a therapeutic vaccine against HIV. This vaccine, for which

the Phase I/II clinical trial is set to begin in the second half of 2012, should allow HIV-positive patients under combination therapies to discontinue and perhaps even permanently stop taking any antiretroviral treatment once vaccinated.

Benefitting from an exclusive worldwide license with the Pasteur Institute and from financial support from public institutions (OSEO, ANR), THERAVECTYS is continuing its research and development efforts to combat other diseases. It plans to soon be developing new vaccine candidates, either alone or in collaboration with other pharmaceutical laboratories.

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