

## THERAVECTYS TO PRESENT DETAILED PHASE I/II RESULTS FROM THE FIRST-EVER LENTIVIRAL-VECTOR BASED THERAPEUTIC VACCINE TRIAL AT THE 2015 TOWARDS AN HIV CURE SYMPOSIUM

PARIS, July 18<sup>th</sup>, 2015

THERAVECTYS, a Paris-based, fully-integrated discovery & clinical development company specialized in lentiviral vector-based therapeutic vaccines and T-cell therapies announced that detailed results from its phase I/II study will be presented at the 2015 Towards an HIV Cure Symposium in Vancouver, Canada, on 18 & 19 July 2015, immediately preceding the 8<sup>th</sup> IAS Conference on HIV Pathogenesis, Treatment & Prevention (IAS 2015).

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The **randomized, placebo-controlled trial** (ClinicalTrials.gov Identifier: NCT02054286) currently enrolled **38 HIV-positive patients** under HAART and aimed at comparing the **safety, tolerability and immunogenicity** of the therapeutic vaccine candidate at **3 different doses** ( $5.10^6$ ,  $5.10^7$  or  $5.10^8$  TU) **versus placebo**. The treatment regimen consisted of **two intramuscular injections 8 weeks apart** with non-replicative and self-inactivating lentiviral vectors encoding for immunogenic regions of the HIV GAG, POL and NEF proteins. Vaccine-induced HIV-1-antigen-specific T-cell in peripheral blood were characterized by intracellular cytokine staining in all patients, placebo included, before and after HAART interruption 24 weeks after the first injection.

*“We are very pleased to present the clinical data of this **first-ever lentivector based therapeutic vaccine trial**”* says Dr. H el ene TOUSSAINT, senior scientist in charge of the HIV vaccine program.

With the absence of any serious adverse events on all 38 patients and no safety concerns related to the treatment, the clinical data **confirmed both safety and tolerance of the lentiviral-based therapeutic vaccine**. In addition, the analysis of the immunological data demonstrated the

**ability of the vaccine candidate to elicit multi-specific and poly-functional CD8 and CD4 T-cell responses** in most of the vaccinated patients.

«These data provide further evidence that THERAVECTYS' regimen vaccine is safe and well tolerated, and can **induce intense, broad and long-lasting cellular immune responses** in vaccinated patients regardless their preexisting immune profile» says Dr. Cécile BAUCHE, Chief Scientific Officer of the Company.

In this trial, a high frequency, from 0.097 to 0.874%, of **functional T-cells able to produce at least 2 or 3 cytokines among IFN- $\gamma$ , TNF- $\alpha$  and IL-2** was evidenced across patients. A **dose effect** was also observed when comparing the 3 groups, with **greater magnitude with the highest dose**.

«The clinical data of this trial supports **the potential of the lentiviral vector platform** developed by THERAVECTYS for the future development of therapeutic vaccines and immunotherapies in oncology and infectious diseases.» says Renaud VAILLANT, Chief Executive Officer, THERAVECTYS.

For a complete review of THERAVECTYS' technologies & programs, please visit the company's website.

## About THERAVECTYS

THERAVECTYS is a fully-integrated discovery and clinical development biotech company originating from the Pasteur Institute. Based on its lentiviral vector technology platform, THERAVECTYS develops therapeutic vaccines and immunotherapies to fight cancers and infectious diseases, including a proprietary and differentiated CAR T-cell technology platform.

Capitalizing over 15 years of fundamental research in the field of lentiviral vectors, the company has built a broad and robust intellectual property position in addition to worldwide and exclusive licenses secured from institutions including Institut Pasteur and Institut Curie.

The company's lead infectious disease lentivector vaccine has successfully completed a Phase I/II safety & immunogenicity human proof-of-concept study in HIV. THERAVECTYS lead oncology lentivector vaccine will enter clinical trials in 2015 while the company's CAR T-cell therapies are in the preclinical stage.

Alone or with partners, THERAVECTYS plans to advance its pipeline of oncology and infectious disease therapies using the company's integrated set of discovery, clinical development, and GMP manufacturing capabilities specialized in lentiviral vector technologies.

**For more information:**

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