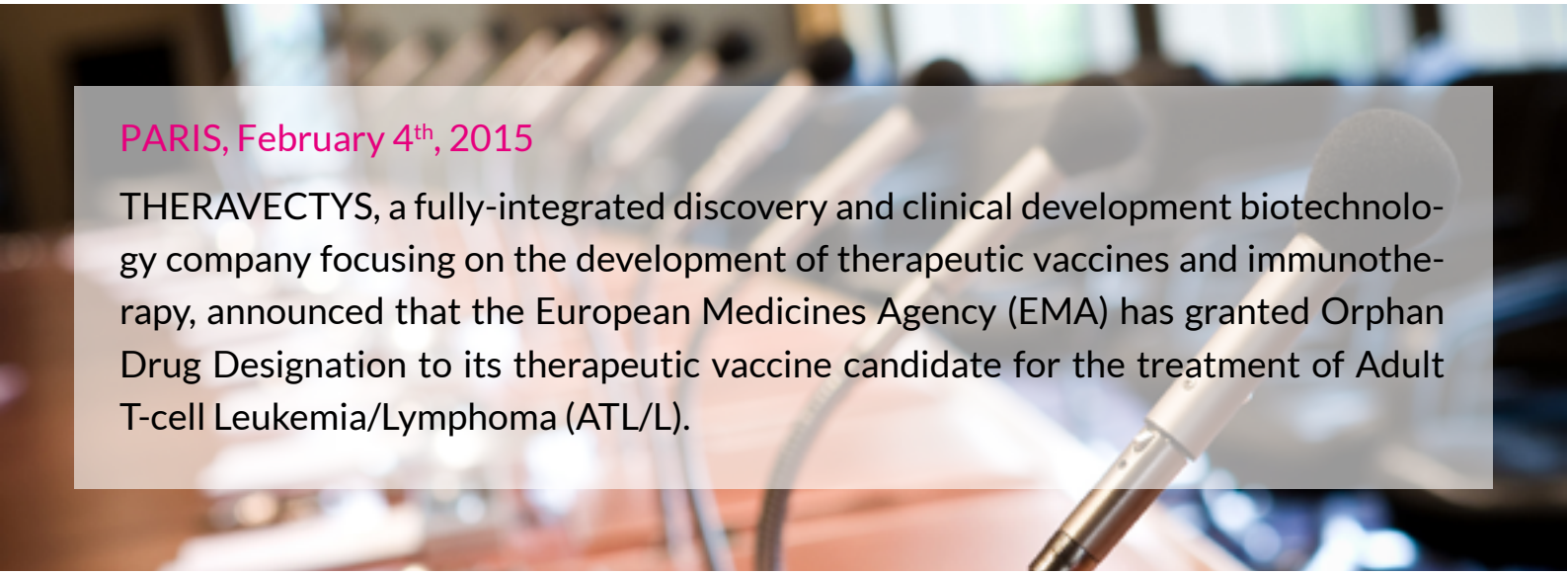
THERAVECTYS OBTAINS ORPHAN DRUG DESIGNATION FROM THE EUROPEAN MEDECINES AGENCY FOR ITS LENTIVIRAL VECTOR-BASED THERAPEUTIC VACCINE AGAINST ADULT T-CELL LEUKEMIA AND LYMPHOMA



PARIS, February 4th, 2015

THERAVECTYS, a fully-integrated discovery and clinical development biotechnology company focusing on the development of therapeutic vaccines and immunotherapy, announced that the European Medicines Agency (EMA) has granted Orphan Drug Designation to its therapeutic vaccine candidate for the treatment of Adult T-cell Leukemia/Lymphoma (ATL/L).

"On world cancer day 2015, we are proud to be one of the most innovative players in the immuno-oncology space, developing a new kind of treatment for more sustainable remission. In our continued effort to improve patient care, we are moving to the next stage in our fight against cancer with the launch of our clinical trial for virally-induced Adult Leukemia/Lymphoma." says ou CEO, **Renaud Vaillant**.

ATL/L is a rare malignancy of a certain type of white cells, T-Lymphocytes, caused by the Human T-Cell Lymphotropic Virus type 1 (HTLV-1) with a prevalence up to 1% of the overall population in Japan. Approximately 5% of all patients infected with HTLV-1 will develop ATL/L, in their lifetime.

Four ATL/L subtypes have been described, with a poor prognosis (less than a year for the two most aggressive forms). Patients are confronted with a lack of well-tolerated and/or performant treatment options which, to-date, include biological treatments with serious adverse reactions as well as aggressive chemo and antiviral therapies or, when eligible, long and uncertain hematopoietic stem cell transplantation.

The biological compound is an investigational therapeutic vaccine aiming at inducing an immune response against HTLV antigens born by ATL/L with the aim of enabling the patients' immune system to fight leukemic cells.

"Preclinical immunogenicity results obtained to-date are very promising and we are really excited by the perspective bringing a safe and better-tolerated alternative to patients who are desperately in need of a treatment" says **Déborah REVAUD**, Senior Scientist in charge of the development project.

In Europe, the Orphan designation is granted to drugs in development intended for the treatment, the prevention or the diagnosis of life-threatening or chronically-debilitating diseases of a prevalence lesser than 5 in 10,000 people. The designation allows sponsors to benefit from an accelerated development process as well as incentives and a 7 years market exclusivity once the drug is placed on the market.

"We are extremely pleased that the European Medicines Agency has granted an Orphan Drug status to our vaccine candidate against ATL/L" says **Emmanuelle Sabbah-Petrover**, Head of Regulatory Affairs. *"This is a significant milestone for THERAVECTYS and we intend to take full advantage of all incentives associated with this designation to pursue and further accelerate the development of the compound. We expect to recruit our first patients towards the end of Q3 2015 in Europe and advance further developments in the U.S. and in Japan in 2016".*

Should the vaccine candidate demonstrate a convincing safety and efficacy profile during its development against ATL/L, the company is already considering the perspective of further developing the same vaccine candidate for HTLV-related infections as a therapy and possibly as a prophylactic approach.

About THV02

THV02 is an experimental treatment composed of two lentiviral vectors to be **used in a prime/boost regimen in ATL/L patients infected by the HTLV-1 virus**. Both investigational drugs encode the same antigens, derived from four proteins of the HTLV-1 virus.

During **preclinical evaluation**, THV02 has **demonstrated to be safe and has presented an unprecedented immunogenicity profile** in several models.

About THERAVECTYS

THERAVECTYS is a Paris-based, privately owned, fully-integrated discovery & clinical development biotech company capitalizing **15 years of fundamental research at the Pasteur Institute** in the field of **lentiviral vectors** and from which the company has secured an **exclusive worldwide patent license agreement** for the use the lentiviral vectors in vaccination and immunotherapy applications.

Strongly supported by **renowned investors** and **former global pharmaceutical executives**, the company rapidly progresses in its R&D activities and in-house production capabilities. THERAVECTYS is determined to lead the vaccination paradigm shift and offer to patients valuable & affordable treatments against cancer and major global infectious diseases for which the induction of a strong cellular immune response is required.

With **promising preliminary safety and immunogenicity results** from its **HIV vaccine candidate** currently in Phase I/II, THERAVECTYS is now accelerating the development of further vaccine candidates in several oncology and infectious disease indications with the aim to **bring to market innovative treatments** with current unmet need, alone or in collaboration with partners.

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