

THERAVECTYS GRANTED AUTHORIZATION BY THE FRENCH NATIONAL AGENCY FOR MEDICINES TO PRODUCE LENTIVIRAL VECTORS FOR CLINICAL USE AND CAR-T CELL THERAPIES UNDER GMP STANDARDS

PARIS, March 23th, 2015

THERAVECTYS, a clinical development biotechnology company focusing on the development of **therapeutic vaccines and immunotherapies**, proudly announces that its manufacturing plant has been granted the **status of a GMP pharmaceutical manufacturing establishment**, by the French National Agency for Medicines and Health Products Safety (ANSM). The new facility will be used to produce lentiviral vectors for clinical development purposes, from phase I through phase III, and will also be used to manipulate human cells in the context of Chimeric Antigen Receptors (CARs) and T-Cell Receptor (TCR)-based cell therapies.

Following the completion by THERAVECTYS of the **first vaccination trial ever performed in humans with lentiviral vectors**, this newly granted authorization further strengthened THERAVECTYS' leadership in the immunotherapy field. Over the last 10 years, the company has established a **unique expertise in lentiviral vector-based therapy**. This breakthrough technology is further supported by THERAVECTYS innovative and complementary R&D activities including the development and the use of a synthetic humanized nanobody library and a **proprietary and differentiated CAR T-cell technology**.

*"Obtaining the status of a pharmaceutical manufacturing establishment is a major achievement for THERAVECTYS. We are proud of the team's dedication to this project, which has allowed us to carry out the work and obtain **the opening approval in only 12 months**,"* said Chief Operating Officer, **Amel Hadri**.

The new facility will be used to fulfill the company's internal **clinical development program** needs, in addition to those of strategic pharmaceutical partners. In the coming months, THERAVECTYS will produce cGMP lentiviral vectors for its **first phase I/II clinical trial in oncology** (adult T leukemia/lymphoma induced by HTLV-1) and for its differentiated CART-cell-based immunotherapy upcoming clinical trial.

Besides the control of its manufacturing costs and timelines, the self-operation of its manufacturing and quality control processes will allow the company to **best leverage and mutualize a common production process** for both research and clinical development material requirements as well as protect **its unique proprietary know-how and trade secrets**.

The production site is designed in compliance with **GMP and ISO standards** and consists in several independent production suites, including upstream and downstream process rooms, an aseptic filling suite, and a logistic zone that allows for GMP storage at various temperatures ranging from -80°C to 25°C. Additionally, the installation includes a quality control laboratory.

The plant has a full **annual capacity of 24 active batches**. Human cells will be cultured in suspension in **up to 1,000 liter bioreactors**, using synthetic medium and disposable materials. THERAVECTYS proprietary specific quality controls have been developed, such as **RCL** (replication-competent lentivirus – the validation of the non-replicative nature of the vector), lentiviral vector titration, and **residual DNA characterization**. These controls have been fully internalized for better product qualification and more efficient batch releases.

THERAVECTYS has continued to improve its industrial processes to strengthen its trade secrets and Intellectual Property (IP). Major accomplishments include **the development of a stable cell line to increase production yield**, the implementation of an **improved lyophilization process** leading towards a more stable final product, as well as the **design and the validation** of new, **specific and proprietary quality controls**. These achievements, and the company's unique and unrivaled expertise, offer a significant competitive advantage in the field of immunotherapy.

“With the opening of our GMP manufacturing plant, based on the exclusive worldwide IP license from the Institut Pasteur, THERAVECTYS is the only company in the world to offer a fully-integrated and protected cutting-edge lentiviral vector technology platform,” said Chief Executive Officer of THERAVECTYS, Renaud Vaillant.

About THERAVECTYS

THERAVECTYS is a privately-owned, fully-integrated discovery and clinical development biotech company originating from the Pasteur Institute.

The company capitalizes on over 15 years of fundamental research in the field of lentiviral vectors and has secured worldwide exclusive rights to Pasteur Institute intellectual property.

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.

The company is strongly supported by renowned investors and former global biopharmaceutical executives and is rapidly progressing in its R&D activities and in-house GMP production capabilities.

Alone and in collaboration with partners, THERAVECTYS is accelerating its clinical development programs and is planning to initiate two additional phase I/II clinical trials in oncology in 2015.

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