

Vaxon Biotech randomizes the 110th patient in its oncology vaccine phase IIB clinical study in NSCLC

Oncology vaccine Vx-001 is the only one in the world to use optimized cryptic peptides. It has a high therapeutic potential for indications such as NSCLC, breast cancer and pancreatic cancer

The study, launched in 2012, randomizes 220 patients across 65 sites in eight European countries

Results are expected in Q4 2016

Paris, France, December 1, 2014 – Vaxon Biotech, a company specialized in anti-tumor immunotherapy, today announces the recruitment of the 110th patient in its multicenter phase IIB study of the Vx-001 vaccine in Non-Small-Cell Lung Cancer (NSCLC).

The 110th patient was randomized in October. A total of 220 patients will be randomized in 65 sites across Italy, Spain, Germany, Greece, Poland, France, Romania and the Czech Republic.

The Vx-001-201 trial is applicable to patients with metastatic NSCLC who do not progress after platinum based first line chemotherapy. Vx-001 is the most advanced product in the Vaxon Biotech portfolio. It is a peptide-based vaccine for HLA-A2-positive patients with TERT-expressing tumors. Vx-001 is composed of two peptides that are administered separately: the native cryptic peptide ARG-Vx001 and its optimized variant TYR-Vx001 that is strongly immunogenic. Vx-001 can treat almost all tumors, irrespective of their histological origin. The antigen target (Telomerase reverse transcriptase, TERT) is a universal tumor antigen expressed by more than 85 per cent of tumors.

Vaxon Biotech's approach is innovative as it consists of targeting cryptic epitopes by using optimized cryptic peptides. Targeting cryptic tumor epitopes tackles the immune tolerance to tumor antigens. Vaxon Biotech is the only company in the field of tumor immunotherapy to propose this approach.

"A successful phase IIB study with the Vx-001 will validate our innovative approach to tumor vaccination, which involves the targeting of cryptic tumor epitopes by using optimized cryptic peptides," said Kostas Kosmatopoulos, chief scientific officer and founder at Vaxon Biotech, "In this study, we aim to prove that, when treated with Vx-001, those patients who have metastatic NSCLC and do not progress after first line chemotherapy will have a prolonged survival rate."

At a phase I/II clinical trial stage, Vx-001 showed remarkable efficacy and absence of toxicity at five years plus, with a strong correlation between immune response and clinical response on various advanced stage cancers.

As the successful phase IIB trial with Vx-001 will give rise to a phase III study in NSCLC, it will also open the way for the clinical development of this vaccine in other indications, such as breast, pancreatic and head and neck cancers.

With a successful phase IIB, Vx-001 will also dramatically hasten the development of new generation vaccines composed of multiple optimized cryptic peptides, to target several universal tumor antigens at the same time. Examples include Vx-006 (currently in phase I) which is dedicated to patients expressing HLA-A2 (40-45 per cent of patients), Vbx-016 to HLA-B07 patients (20 per cent of patients) and Vbx-026 to HLA-A24 patients (25 per cent of patients).

Eight patents have been granted in the US, Europe, Japan, China and Canada to cover Vx-001. The EMA granted Vx-001 orphan medicinal product designation for its first indication (NSCLC) in 2007, with the FDA doing likewise in 2009.

The results of the Vx-001-201 trial are expected in Q4 2016.

About optimized cryptic peptides

Vaxon Biotech has developed a unique and innovative vaccine technology that uses 'optimized cryptic peptides' that significantly improve immune response and therefore the efficacy induced by vaccines. The vaccines derived from this technology target the cryptic peptides (antigens) that are present on the surface of tumor cells. These peptides are 'quiet'; they are not involved in immune tolerance and when they are optimized they induce a strong antitumor immunity. In contrast, the dominant tumor peptides (antigens) are tolerated by the immune system and therefore trigger a weak immune response.

About Vaxon Biotech

Vaxon Biotech specializes in anti-tumor immunotherapy through an innovative therapeutic approach which aims to stimulate the immune system to target and destroy tumor cells and halt tumor development.

The company is currently developing four products, two in clinical development and two at the preclinical stage. The most advanced product in its portfolio, Vx-001, is a peptide based vaccine for HLA-A2-positive patients with TERT-expressing tumors. It has been in phase IIB trials for non-small-cell lung cancer (NSCLC) since 2012 (underway in eight European countries).

Vaxon Biotech is also developing another product, Vx-006, a polypeptide designed to treat solid tumors. This product is currently in a phase I clinical study that aims to evaluate toxicity and measure the immune response induced by Vx-006. The results of the study will be unveiled in early 2015.

Based in Paris and Evry, France, Vaxon Biotech was founded in 2004 on the basis of work undertaken by Dr Kostas Kosmatopoulos at Inserm, France's national institute of health and medical research, and the Institut Gustave Roussy (IGR), a leading cancer research institute. The two institutes have granted Vaxon Biotech an exclusive worldwide license for three patents, with the company having subsequently filed seven more patents in its own name.

ANR (French Agence Nationale de la Recherche) has subsidized the initial R&D for Vbx-016 and Vbx-026. GENOPOLE-Evry and INSERM-Transfert have supported



Vaxon Biotech since its inception; they are both historical shareholders in the company. <http://www.vaxon-biotech.com>

Media & Analysts Contacts

Andrew Lloyd & Associates

Sarah Morgan / Sandra Régnavaque

sarah@ala.com - sandra@ala.com

+44 (0)1273 675 100

@ALA_Group
