



## **Vaxon Biotech Receives European Orphan Medicinal Product Designation for Vx-001**

**Evry-Genopole, France, November 16<sup>th</sup> 2007** - Vaxon Biotech, a biopharma company specialising in the discovery and development of innovative anticancer immunotherapies, today announced that the Committee for Orphan Medicinal Products (COMP) at the European Medicines Agency (EMA) has granted orphan drug status to Vx-001 for treatment of TERT-positive non-small cell lung cancer (NSCLC) in HLA-A2 positive patients. The EMA's Orphan Medicinal Product Designation is intended to promote the development of drugs which may provide significant benefits to patients suffering from life-threatening or very serious conditions which affect less than five in 10,000 persons in the European Community.

“There is a real need for innovative new treatment options (such as Vx-001) for patients with lung cancer”, commented Dr Nadège Le Roux, Vaxon's Director, Drug Development. She added, “This orphan drug designation is a significant step forward in Vx-001's clinical development plan and offers potential benefits for approval of the drug in the European Union. These patients deserve the hope of greater life expectancy and better quality of life through innovative therapeutics”.

In the very short term, the company's goal is to consolidate its initial clinical results for Vx-001 (by launching phase II trials in NSCLC and hepatocarcinoma) and then tackle new oncological indications.

### **About Orphan Drug Designation**

Under EMA guidelines, Orphan Medicinal Product Designation provides economic incentives for biotechnology and pharmaceutical companies to develop drugs for serious "orphan" conditions, i.e. those affecting fewer than 5 out of 10,000 people in the European Union. Orphan drug designation will entitle Vaxon Biotech to ten years of potential market exclusivity if the product candidate is approved for marketing. Orphan status also permits EMA assistance in optimizing the product's clinical development via participation in clinical protocol design and in preparation of the marketing application. Additionally, a drug candidate designated by the EMA as an Orphan Medicinal Product may qualify for a reduction in regulatory fees, as well as a European Union-funded research grant.

### **About Vx-001**

Vx-001 is a peptide-based vaccine containing hTERT572Y, a single optimized cryptic peptide that activates HLA-A2 cytotoxic T lymphocytes (CTLs) to target tumours expressing the telomerase antigen. In a pilot clinical trial, Vx-001 was well tolerated and induced a strong and broad immune response in cancer patients. This specific immune response was correlated with long-standing disease stabilisation or a clinical response.

### **About Non-Small Cell Lung Cancer**

Approximately 80 percent of all lung cancer cases worldwide are classified as non-small cell lung cancer (NSCLC). According to the American Cancer Society, only about 15 percent of people diagnosed with NSCLC survive the disease after five years. The choice of treatments for NSCLC depends upon the size, location and extent of the disease. Primary approved

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treatments are chemotherapy, radiation and surgical removal of the diseased tissues. For most patients with NSCLC, currently available treatments do not cure the cancer.

### **About Vaxon Biotech**

Vaxon Biotech is a pioneering player in the development of novel anticancer products. Located on the Evry Genopole® campus since 2004, Vaxon Biotech is developing innovative products - optimized cryptic peptides - based on original research findings by Dr Kostas Kosmatopoulos. The company holds an international patent portfolio covering processes for identifying, processing and producing optimized cryptic peptides as well as the products themselves. Currently, two product candidates are in clinical development: Vx-001 is pursuing phase II studies in non-small cell lung cancer (NSCLC) and hepatocellular cancer, whereas Vx-006 is entering phase I/II for prostate cancer.

Since its incorporation, Vaxon Biotech has been strengthening its strategy of discovering, developing and commercializing innovative, efficacious immunotherapy products, with the goal of improving patients' quality of life and life expectancy. Strongly-held values such as ethics and the exploitation of research results are guiding the Vaxon Biotech management team in its mission to provide patients with rapid access to its innovative products. By confirming its pioneering position through strategic alliances and/or equity stakes, Vaxon Biotech intends to become a leading European player in anticancer immunotherapy.

*Disclaimer: the future therapeutic success of the Vx-001 vaccine depends on a multiplicity of factors. The results presented above - whilst implying a high probability of antitumor efficacy - must be confirmed by the randomized, multicenter studies that Vaxon Biotech is set to perform.*

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