

## **Vaxon Biotech successfully completes its Phase I/II trial of Vx-001 cancer vaccine, Phase III ready to start in NSCLC**

**Results show Vx-001 vaccine to be safe, strongly immunogenic and clinically active, and provide firm basis for Vx-001 to move to pivotal Phase III trial**

Paris, May 19, 2010—Vaxon Biotech, a specialist in tumor immunotherapy, announces today the successful conclusion of the Phase I/II trial of its Vx-001 therapeutic cancer vaccine. As a result, Vaxon is pursuing the clinical development of Vx-001 by launching a pivotal phase III trial in non-small cell lung cancer (NSCLC) in 2010, and in hepatocellular carcinoma and breast cancer in 2012-2013.

The phase I/II trial was conducted among 116 patients with different types of cancer including 33 patients with NSCLC. The primary objective was to evaluate safety of Vx-001, with a secondary objective to evaluate immune response and clinical response. Results showed that Vx-001 is safe (only grade I vaccine related toxicity was observed) and well tolerated by the patients, that it induces a long lasting vaccine specific immune response in 70 percent of patients, and that it has a significant clinical activity: four patients experienced objective response and 33 patients stabilized their disease for more than six months. Survival of vaccinated patients was related to the immune response; patients who developed immune response had a longer survival than patients who failed to do so. Analysis focused on the thirty-three NSCLC showed that Vx-001 induces long lasting disease control, including objective responses, in more than 42% of patients. Survival of NSCLC vaccinated with Vx-001 was close to 19 months, at least 50 per cent longer than normal in this patient population.

On the basis of this successful phase I/II trial and the very promising results in NSCLC, the European Medicines Agency (EMA) has approved the design of the planned pivotal phase III study and agreed to consider Vx-001 for marketing authorization after the completion of this trial.

“We are delighted that Vaxon will become of the select few biotech companies to have a product in a late stage of clinical development,” said Kostas Kosmatopoulos, CSO of Vaxon Biotech. “If all goes to plan, Vx-001 will be the first vaccine to enter the market for patients with advanced locoregional and metastatic NSCLCs that account for 50 percent of all lung cancers. It will also be one of the first immunotherapeutic anti-cancer products on the market, thus confirming the high potential of this innovative solution.”

50.000 new cases of NSCLC per year in USA and Europe are addressed by Vx-001 for its first NSCLC indication (10% of total number of lung cancer). Vaxon expects to have a marketed product (Vx-001) in 2014-2015 for NSCLC and 2020 for hepatocellular cancer and triple negative breast cancer.

## **About Vaxon Biotech**

Vaxon Biotech is specialized in tumor immunotherapy, a therapeutic approach that consists in stimulating the immune system to target and destroy tumor cells, thus preventing the tumor from progressing. Vaxon Biotech's innovative and unique vaccine technology ("Optimised Cryptic Peptides") significantly improves immune response and hence makes vaccines more effective. Vaccines using this technology target cryptic peptides/antigens present on the tumor cell surface. Cryptic peptides do not induce tolerance of the immune system, unlike dominant peptides, which are tolerated by the immune system and therefore generate a weak immune response.

Vaxon Biotech's most advanced product, Vx-001, is slated to enter a pivotal Phase III clinical trial in non-small cell lung cancer (NSCLC) in 2010 with the aim of a marketing authorization in 2014-2015. This trial follows a large proof of concept Phase I/II trial successfully carried out on patients with advanced cancer. The trial showed that Vx-001 is remarkably safe over a period of more than five years, is strongly immunogenic and induces long-lasting disease control that is correlated with the immune response. The development strategy for Vx-001 and the design of this clinical phase III trial were approved in 2008 by the European Medicines Agency (EMA) further to a protocol assistance process. The product has obtained orphan drug designation for its first indication (NSCLC) from the EMA and from the US Food & Drug Administration (FDA). Vaxon is also developing Vx-001 in other indications including hepatocellular carcinoma, glioblastoma and triple negative breast cancer. Another Vaxon product under development is Vx-006 for prostate cancer and breast cancer.

Vaxon Biotech is headquartered in Paris and was founded in 2004 based on work carried out at Inserm and the Institut Gustave Roussy (IGR) by Dr Kostas Kosmatopoulos (CSO at Vaxon). These two institutes granted three exclusive worldwide patent licenses to Vaxon, which itself has registered five other patent families.

For further information, go to: <http://www.vaxon-biotech.com>

---

### **Contact for Media & Analysts:**

**Andrew Lloyd & Associates**

Agnes Dalosi / Andrew Lloyd

[agnes@ala.com](mailto:agnes@ala.com) / [allo@ala.com](mailto:allo@ala.com)

Tel: +44 1273 675 100

---