

*FOR IMMEDIATE RELEASE:*

## **VAXIMM starts clinical study of first oral cancer vaccine**

*Basel (Switzerland), Mannheim (Germany), 13.12.2011* – VAXIMM AG, a Swiss-German biotech firm and Merck KGaA spin-off, announced today the start of the first clinical trial of its investigational oral therapeutic cancer vaccine VXM01. The placebo-controlled phase I dose escalation study intends to enroll up to 45 pancreatic cancer patients at the Heidelberg University Hospital (Heidelberg, Germany). In addition to standard-of-care treatment, the patients will receive several doses of VXM01, a therapeutic cancer vaccine that targets the tumor vasculature. The results of the initial double blind period of the study are expected in the first half of 2013.

The investigational therapeutic vaccine VXM01 is designed to stimulate the patients' own immune system to destroy tumor-associated blood vessels, which are essential for tumors growth. It is the first therapeutic cancer vaccine in clinical development that does not target the cancer cells directly, but rather the tumor stroma, a structure that is required by solid tumors for their growth. VXM01 is also the first therapeutic cancer vaccine being investigated, which is given orally and which acts in the gut to induce an anti-tumor response of the immune system.

PD Dr. Hubertus Schmitz-Winnenthal, principal investigator of the study, commented: "I am delighted about the transition of this therapeutic cancer vaccine into clinical evaluation. In animal experiments conducted by us and others, VXM01 showed an impressive anti-tumor activity. We are very keen on exploring the safety and potential efficacy of this vaccine in inoperable pancreatic cancer patients, as a first step in the clinical evaluation of VXM01".

Dr. Heinz Lubenau, General Manager of VAXIMM GmbH, a fully owned subsidiary of VAXIMM AG in Germany, commented: "With our lead product VXM01 entering clinical trials, we achieved a very important milestone in the development of this therapeutic cancer vaccine. By characterizing the safety, tolerability, immunogenicity and other clinical parameters of the vaccine in patients, we aim to establish a solid basis for the further development of VXM01 in several different cancer indications. In addition, this trial may pave the way for the use of the technology platform in other potential applications".

Dr. Klaus Breiner, chairman of VAXIMM's board of directors, and a Managing Partner at BB BIOTECH VENTURES added: "We are glad to see VAXIMM's successful transformation into a clinical stage company. We are also grateful to PD Dr. Schmitz-Winnenthal for the pivotal role he played in the spin-off of this project from Merck, and continues to play in bringing this investigational therapeutic vaccine now from the bench to the bedside".

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## *About VAXIMM:*

VAXIMM is a privately held, Swiss- and German-based biotech company that is primarily focused on developing active immunotherapies (vaccines) for patients suffering from cancer. Its initial product candidate VXM01 is targeting the tumor vasculature, which is essential for tumors to grow beyond microscopic size. VXM01 has shown impressive anti-tumor activity in various animal studies and commenced human clinical trials in 2011. VAXIMM was formed in 2008 as a joint venture of BB Biotech Ventures and Merck KGaA to develop VXM01. Merck Serono Ventures, Sunstone Capital, and BioMedPartners joined as investors in 2010. VAXIMM GmbH is a fully owned subsidiary of VAXIMM AG, with offices in Mannheim, Germany. For more information, please see [www.vaximm.com](http://www.vaximm.com).

## *About VXM01:*

VXM01 is a therapeutic oral cancer vaccine in clinical development for the treatment of cancer. It is based on VAXIMM's T-cell vaccination platform that uses modified live attenuated bacteria as a carrier for tumor- and tumor stroma-specific antigens. The carrier itself is a licensed vaccine, which has been safely given to millions of people. To yield VXM01, the bacteria have been modified to carry the genetic information of the vascular endothelium growth factor receptor 2 (VEGFR2), a well-characterized target for anti-angiogenic intervention. VXM01 is designed to stimulate the patients' own immune system in order to destroy the tumor vasculature, which is essential for tumors to grow beyond a microscopic size. In animal studies, an analog vaccine has shown promising anti-tumor activity against different tumor types, including pancreatic cancer, colon cancer, lung cancer, and melanoma. The original work that led to VXM01 was conducted at The Scripps Research Institute. For more information on the clinical trial of VXM01, please see [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier NCT01486329).

## *About how VXM01 works:*

After oral vaccination with VXM01, patients are expected to mount a cellular immune response against fragments of VEGFR2, which are abundantly presented on the surface of the tumor vasculature. The cytotoxic T-cells of the immune system are then targeting and destroying the neovascular endothelial cells that make up the tumor vasculature. This leads to the breakdown of the vessels that nurture the tumor. As a result, the tumor shrinks, and metastasis formation and growth are inhibited. In addition, the immune response triggered by VXM01 is expected to cause an inflammation in proximity to the tumor. This is thought not only to self-sustain the immune response towards the tumor's vasculature, but to also to promote an immune response against the tumor itself.

## *About Heidelberg University Hospital:*

Heidelberg University Hospital is among the largest and most renowned medical centers in Germany. The Medical Faculty of Heidelberg University ranges among the internationally relevant biomedical

research institutes in Europe. The common goal is to develop new therapies and to apply them rapidly for the benefit of the patient. As one of the world's leading clinics for pancreatic disorders, the European Pancreas Centre is an important part of the University Hospital. Extensive research and development projects and new concepts of in-house co-operation and organization keep the facility at a top level. The hospital and the faculty have approximately 11,000 employees and are actively involved in training and qualification. In more than 50 departments, clinics and special departments with about 2,000 hospital beds, approximately 600,000 patients receive inpatient and outpatient treatment each year. All our efforts are geared towards providing the best possible treatment for our patients. For more information, please see [www.klinikum.uni-heidelberg.de](http://www.klinikum.uni-heidelberg.de).

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