

VAXIMM initiates Phase 2a study in advanced colorectal cancer with oral T-cell vaccine VXM01

- Single-arm study will assess safety, immune responses, clinical responses and immune biomarker changes in tumor biopsies -

Basel (Switzerland) and Mannheim (Germany), May 4, 2016 – VAXIMM AG, a Swiss-German biotech company focused on developing oral T-cell vaccines, announced today the enrollment of the first patient in a Phase 2a clinical trial. The study will enroll 24 patients with metastatic colorectal cancer whose disease has progressed following one or two prior therapies. The study is being conducted at the National Center of Tumor Diseases (NCT) in Heidelberg, Germany, in cooperation with the University Hospital in Heidelberg.

All patients in the study will receive four doses of oral VXM01 in the first week followed by a single dose every four weeks up to week 64. Patients will also receive standard chemotherapy. The primary objectives of the study are safety and tolerability. The trial will also assess immunological response to VXM01, objective response rate, progression-free survival and overall survival. Immune biomarker changes in tumor tissue as a response to VXM01 will also be measured.

“There remains a major need in colorectal cancer for new, more effective treatment options. Immunotherapies have already achieved major breakthroughs in several cancer indications such as melanoma and non-small cell lung cancer. This is the first time an oral immunotherapy will be used for the treatment of colorectal cancer,” said PD Dr. Carsten Grüllich, University Heidelberg, Department of Medical Oncology, and principal investigator of the trial. “This Phase 2a trial should significantly increase our understanding of the oral immunotherapy VXM01 in this important indication.”

“We have seen encouraging data in several preclinical colorectal cancer models,” said Dr. Heinz Lubenau, VAXIMM’s Chief Operating Officer and General Manager of VAXIMM GmbH. “The results from this new clinical trial will be important in adding to our knowledge base and guiding the development of VXM01 in metastatic colorectal cancer patients. This is the second clinical trial with VXM01, following the successful completion of a larger Phase 1 trial in pancreatic cancer patients.”

About VXM01:

VXM01 is an oral T-cell immunotherapy that targets the tumor-specific vasculature and certain immune-suppressive cells. It is based on a live attenuated, safe, orally available, bacterial vaccine strain, which is modified to carry vascular endothelium growth factor receptor-2 (VEGFR-2) as the target gene. VXM01 stimulates the patient’s immune system to activate VEGFR-2-specific, cytotoxic T-cells (so-called killer cells). These immune killer cells then actively destroy the cells in the tumor vasculature leading to an increased infiltration of various immune cells into the tumor. In pre-clinical studies, a murine analog VXM01 vaccine has shown broad anti-tumor activity in different tumor types. This activity was linked to a VEGFR-2 specific T-cell response and was accompanied by the destruction of the tumor vasculature and increased immune cell infiltration. In pre-clinical

studies, VXM01 appeared to be safe and well tolerated. A double-blind, randomized, placebo-controlled study in 72 patients with advanced pancreatic cancer confirmed that VXM01 was safe and well tolerated and demonstrated the activation of VEGFR-2 specific cytotoxic T-cells after VXM01 treatment, which was associated with improved patient survival.

About VAXIMM:

VAXIMM is a privately held, Swiss and German biotech company that is developing oral T-cell vaccines as immunotherapies for patients suffering from cancer. VAXIMM's product platform is based on a live attenuated, safe, orally available bacterial vaccine strain, which is modified to stimulate patients' cytotoxic T-cells (so-called killer cells) to target specific structures of their tumor. VAXIMM's lead product candidate, oral VXM01, activates killer cells targeting tumor-specific vasculature and certain immune-suppressive cells, increasing immune cell infiltration in solid tumors. In addition to VXM01, VAXIMM has a pipeline of complementary development candidates targeting different tumor structures. VAXIMM's investors include BB Biotech Ventures, Merck Serono Ventures, Sunstone Capital and BioMed Partners. VAXIMM AG is headquartered in Basel, Switzerland. Its fully owned subsidiary, VAXIMM GmbH, located in Mannheim, Germany, is responsible for the Company's clinical operations. For more information, please see www.vaximm.com.

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