

VAXIMM initiates Phase 1 translational study in glioblastoma with oral T-cell immunotherapy, VXM01

Basel (Switzerland) and Mannheim (Germany), July 12, 2016 – VAXIMM AG, a Swiss/German biotech company focused on developing oral T-cell immunotherapies, announced today the treatment and successful operation of the first patient in a Phase 1 clinical trial. The study, sponsored by VAXIMM, will initially enroll six patients with operable recurrence of a glioblastoma (brain tumor) and is being conducted at the University Hospital in Heidelberg, Germany.

All patients in the study must have recurrence of their disease following at least one prior treatment that must have included radiochemotherapy with temozolomide and be candidates for routine reoperation with a safe option for delaying surgery for 4-5 weeks. Patients will receive four doses of oral VXM01 four to five weeks before surgery, and two safety magnetic resonance images at 3 and 1 weeks, prior to reoperation. Following surgery, patients may receive optional VXM01 administrations every four weeks up to week 48. The primary objectives of the study are safety and tolerability. The trial will also investigate a number of pharmacodynamic endpoints and clinical response. A special focus of the study is the measurement of the VXM01-related cytotoxic T-cell response, the assessment of immune cell infiltration and of changes in the vascularization and the PD-1/PD-L1 status of the tumor, as a response to the treatment.

Prof. Wolfgang Wick, MD, Chairman, Department of Neurology, Heidelberg University Hospital, and principal investigator of the study, said: “This concept has paradigm-changing potential for data-driven development in immunotherapy. Today, the primary goal for brain tumor immunotherapy is to understand its treatment successes and limitations and to prepare for larger, more sophisticated trials. The current trial offers a window to immunotherapy treatment through a clear molecular readout and potential design insights for a new, larger study.”

Prof. Andreas Unterberg, Chairman, Department of Neurosurgery, Heidelberg University Hospital, commented: “I am pleased that the first patient in this study has undergone a successful reoperation. Given the deadly nature of glioblastoma, we are in urgent need of treatments that will help to prevent the recurrence of disease. Vaccination with the oral immunotherapy VXM01 has the potential to be a potent tool in helping to slow or stop the recurrence of the cancer, and I look forward to seeing the results from this study.”

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 (VEGFR2) as the target gene. VXM01 stimulates the patient’s immune system to activate VEGFR2-specific, cytotoxic T-cells (so-called killer cells). These immune killer cells then actively destroy cells in the tumor vasculature leading to an increased infiltration of various immune cells into the tumor. In preclinical studies, a murine analog VXM01 vaccine showed broad anti-tumor activity in different tumor types. This activity was linked to a VEGFR2-specific T-cell response and was accompanied by the destruction of the tumor vasculature and increased immune cell infiltration. In a Phase I double-blind,

randomized, placebo-controlled study in 71 patients with advanced pancreatic cancer, VXM01 appeared to be safe and well tolerated and led to the activation of VEGFR2-specific cytotoxic T-cells, which was associated with significantly improved patient survival. A clinical study in colorectal cancer is ongoing.

About VAXIMM:

VAXIMM is a privately held, Swiss/German biotech company that is developing oral T-cell 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 the tumor. VAXIMM's lead product candidate, oral VXM01, activates killer cells targeting tumor-specific vasculature and certain immune-suppressive cells, thereby increasing immune cell infiltration in solid tumors. VXM01 is currently in clinical development for several tumor types, including pancreatic, colorectal and brain cancer. 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 wholly 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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