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VAXIMM Announces Data from Phase I Trial in Glioblastoma with Oral T-cell Immunotherapy VXM01 to be Presented at ASCO 2017 Annual Meeting

- Results include one objective response, three patients with stable disease

Basel (Switzerland) and Mannheim (Germany), May 18, 2017 – VAXIMM AG, a Swiss/German biotech company focused on developing oral T-cell immunotherapies, today announced that the first clinical data in glioblastoma with its lead product candidate, oral VXM01, are being presented at the upcoming American Society of Clinical Oncology (ASCO) 2017 Annual Meeting being held June 2-6, 2017 in Chicago, IL, USA.

A poster entitled, "VXM01 phase I study in patients with operable progression of a glioblastoma," will be presented during the Central Nervous System Tumors Session on Sunday, June 5th, 1:15-4:45 PM CDT.

The Phase I trial was designed to evaluate the safety and tolerability, as well as clinical and immunogenic response, to VXM01 in patients with recurrent glioblastoma whose disease had progressed following treatment with at least radiochemotherapy including temozolomide, which is the standard of care. The data being reported are from eight patients. Patients were given a single dose of VXM01 on days 1,3,5 and 7 before the planned surgery on day 35. Following surgery, patients could then receive a single administration every four weeks during the follow-up period. Median dosage was seven vaccinations.

Of the eight patients treated, surgery was performed on seven. One patient experienced an objective and durable response, and three other patients had stable disease. Additionally, peripheral immune responses were observed, and five of seven patients had an increase in CD8+ T-cells in tumor tissue following re-operation compared to the primary tumor tissue. Four out of eight patients showed a specific T-cell response. In addition, in four patients a relevant increase in cerebral blood volume and apparent diffusion coefficient on post-vaccination MRI was observed. VXM01 was shown to be well tolerated.

Prof. Wolfgang Wick, MD, Chairman, Department of Neurology, Heidelberg University Hospital, and principal investigator of the study, said: "We are very pleased with the first results we have seen with VXM01 in glioblastoma. This trial provides insights that will be helpful in designing future clinical trials in this disease with VXM01 and other immunotherapies. These early results with VXM01 support advancing the development of this promising immunotherapy to treat brain tumors, where there is a major need to find more effective treatments to help prevent recurrence of this deadly disease."

Due to the promising early results in this trial, the study has been expanded to include an additional patient cohort.

Dr. Matthias Schroff, Chief Executive Officer of VAXIMM, added: “We are very excited to see such promising first data with VXM01 in this challenging-to-treat cancer. With such compelling, albeit early, results and following the advice of the clinicians participating in the study, we have decided to increase the number of patients in the trial. In addition to glioblastoma, Additional trials with VXM01 are ongoing or planned in various cancer, including in combination with avelumab.”

The abstract (#191829) is now available online at http://abstracts.asco.org. A copy of the poster will be available on VAXIMM’s website after it is presented at the ASCO Annual Meeting on June 5th.

About VXM01:

VXM01 is an oral T-cell immunotherapy that is designed to activate T-cells to attack the tumor vasculature, and, in several tumor types, attack cancer cells directly. It is based on a live attenuated, safe, orally available, bacterial vaccine strain, which is modified to carry vascular endothelial 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 several tumor types, including brain cancer, VEGFR2 is highly over-expressed on the cancer cells themselves. 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. Clinical studies in colorectal cancer and glioblastoma are 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 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 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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