

## **VAXIMM Announces Final Results from Phase I Trial in Recurrent Glioblastoma with Oral T-cell Immunotherapy VXM01 to be Presented at 2018 ASCO Annual Meeting**

- Results from 14 patients include one objective and durable response
- 7 of 14 patients still alive: all for more than one year
- Survival appears correlated to higher CD8/Treg ratio, which further increased following VXM01 treatment

*Basel (Switzerland) and Mannheim (Germany), May 24, 2018* – VAXIMM AG, a Swiss/German biotech company focused on developing oral T-cell immunotherapies, today announced that the final results from a Phase I study in recurrent glioblastoma with its lead product candidate, oral VXM01, are being presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting being held June 1-5, 2018 in Chicago, IL, USA.

### **Abstract #2017, Poster Board #175**

A poster entitled, “VXM01 phase I study in patients with progressive glioblastoma: final results,” will be presented during the Central Nervous System Tumors Session on Saturday, June 2<sup>nd</sup>, 1:15-4:45 PM CDT, as well as during a poster discussion session that day, 4:45 PM - 6:00 PM CDT. The abstract (#2017) is available on the ASCO website [here](#).

The Phase I trial was designed to evaluate the safety and tolerability of VXM01, as well as clinical and immunogenic response, in patients with recurrent glioblastoma whose disease had progressed following treatment with radiochemotherapy including temozolomide, which is the standard of care. Fourteen patients were treated with VXM01, including three who were also treated with the anti-PD-1 checkpoint inhibitor, nivolumab. Patients were given VXM01 on days 1, 3, 5 and 7. Tumor resection was then performed on eight patients. During the follow-up period, patients could receive oral VXM01 every four weeks. Median dosage was eight vaccinations. VXM01 appeared to be well tolerated, both as monotherapy or in combination with nivolumab. ELISpot analysis showed detectable VEGFR-2-specific T-cell responses.

Of the fourteen patients treated, one patient experienced an objective response with VXM01 monotherapy and a durable response with the addition of nivolumab. During the observation period of up to 20 months, seven patients were still alive, all of them living for more than one year. Survival seemed to be correlated with a higher CD8/Treg ratio in the progressive and primary tumors. The ratio further increased after VXM01 treatment. In patients with prolonged survival, a decrease in intratumoral PD-L1 was observed, which supports the rationale for combining VXM01 with an anti-PD-L1 checkpoint inhibitor.

Prof. Wolfgang Wick, MD, Chairman, Department of Neurology, Heidelberg University Hospital, Heidelberg, Germany, and principal investigator of the study, said: “The results of this trial are promising and support advancing the development of VXM01 for the treatment of glioblastoma, a deadly form of brain cancer, where there is an urgent need to find more

effective treatments to help prevent recurrence. We are particularly excited about the early clinical signals we have seen with VXM01 and we look forward to the start of a planned trial combining VXM01 with a PD-L1 inhibitor.”

In 2017, VAXIMM entered into a collaboration agreement with Merck KGaA, Darmstadt, Germany and Pfizer Inc. to evaluate VXM01 in combination with avelumab, a human anti-PD-L1 antibody. The clinical combination trial in glioblastoma is expected to be initiated this year.

#### ***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.

#### ***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 operations. For more information, please see [www.vaximm.com](http://www.vaximm.com).

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