VAXIMM

VAXIMM Presents Data from Phase I Trial in Pancreatic Cancer with Oral T-cell Immunotherapy VXM01 at ASCO 2016 Annual Meeting

- Continued treatment with VXM01 shown to induce a prolonged specific T-cell response
- VXM01 generally well tolerated
- T-cell response to VXM01 was correlated with significantly improved overall survival
- Potential opportunities in variety of solid tumors - additional trials already underway

Basel (Switzerland) and Mannheim (Germany), June 6, 2016 – VAXIMM AG, a Swiss-German biotech company focused on developing oral T-cell immunotherapies, today announced that data on its lead product candidate VXM01 in pancreatic cancer were presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Illinois.

The poster, entitled, *A phase 1 trial extension to assess immunologic efficacy and safety of prime-boost vaccination with VXM01, an oral T cell vaccine against VEGF-receptor 2, in patients with advanced pancreatic cancer (Abstract 3091),* discussed findings from a 26-patient study extending the randomized, double-blind, placebo-controlled Phase 1 dose-escalation trial in 45 patients with advanced pancreatic cancer[i]. The poster is available in the Publications section of the VAXIMM website at www.vaximm.com.

The purpose of the study extension was to explore if continuous treatments with VXM01 could be safely administered and maintain the increased specific T-cell levels previously observed after VXM01 induction treatment (four administrations within one week). In the extension part of the trial, 26 patients with locally advanced, inoperable, Stage IV pancreatic cancer were treated with either VXM01 (N=18) or a placebo (N=8). Two different doses of VXM01 were tested. Patients received the induction treatment, followed by six monthly treatments beginning on Day 38. All patients were allowed to receive standard of care gemcitabine up to Day 38 and any treatment thereafter.

Dr. Jarl Ulf Jungnelius, Chief Medical Officer at VAXIMM, commented: "The results presented at ASCO demonstrate the importance of continued boost administration of VXM01 to optimize the outcome in patients. We are seeing a relation between increase in overall survival and response to VXM01 on the T-cell level. We plan to further evaluate this innovative oral immunotherapy in a variety of solid tumors. A Phase 2a trial in advanced colorectal cancer is already underway."

In the study, VEGFR2-specific T-cell responses were detected in a large proportion of the VXM01-treated patients. After the induction period, pronounced (≥ grade 2) T-cell responses were observed in about half the patients who received at least one additional administration. In the VXM01 group, specific T-cell responses peaked after three months, with an average four-fold increase compared to baseline; at completion of dosing after six months, these levels were still increased.

VXM01 was shown to be generally well tolerated, with some mild to moderate decreases in platelets and lymphocytes and an increase in diarrhea, confirming the findings of the previous study[i]. The frequency of drug-related adverse events was comparable after induction treatment and further

administrations, indicating that continued dosing with VXM01 did not aggravate the side effect profile of this immunotherapy.

While there were no significant differences between placebo and VXM01-treated patients in overall survival, due to the very small number of patients in the study, VXM01-treated patients who responded to vaccination with increased T-cell reactivity towards VEGFR2 showed a significantly improved survival compared to non- or low-grade responders. Notably, all VXM01-treated patients with a grade ≥2 response survived the entire vaccination and up to Month 8. In the placebo group and in the previous study with induction treatment only, no association between grade of response and significantly improved survival was found.

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 pre-clinical 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 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 and 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. 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.

VAXIMM

Contact:
Dr. Heinz Lubenau
Tel.: +49 621 8359 687 0
Email: info@vaximm.com

Media Inquiries:
MC Services AG
Katja Arnold, Shaun Brown
Email: vaximm@mc-services.eu
Tel: +49 89 210228-0

---

[i] *Schmitz-Winnenthal, F.H. et al., OncoImmunology 2015, 4(4), p.e1001217.*