

FOR IMMEDIATE RELEASE:

VAXIMM reports positive follow-on data from oral cancer vaccine trial

- Phase I study evaluating safety and tolerability of VXM01 in pancreatic cancer -

Basel (Switzerland), Mannheim (Germany), December 4th, 2014 – VAXIMM AG, a Swiss-German biotech company focusing on oral cancer vaccines, announced today follow-on data from the first clinical trial of its investigational oral T-cell vaccine VXM01. Data of a trial extension of the randomized, placebo-controlled, double-blind Phase I dose escalation study show that the safety profile to date is manageable, and indicate that VXM01 has a potential to trigger a strong targeted T-cell-mediated immune response in pancreatic cancer patients.

The study code-named VXM01-01-DE enrolled 27 additional patients with inoperable pancreatic cancer at the Heidelberg University Hospital (Heidelberg, Germany). Previously, 45 patients received four doses of VXM01 within a week or placebo, on top of standard-of-care treatment. In the trial extension, patients in the treatment arm received monthly follow-on vaccinations (boosting) for up to six months in addition to the previous four-vaccinations-within-a-week schedule.

The study extension shows that the main adverse event was a decrease in platelet count, which was observed in about half of the vaccinated patients. No dose-limiting toxicities were observed at the two doses levels tested. Initial findings with regard to specific T-cell response and changes in tumor perfusion and other angiogenesis-related biomarkers were reproduced. Importantly, two thirds of the patients showed a strong T-cell mediated immune response against the target (VEGFR-2) after the initial vaccination with VXM01 or after boosting. In an interim analysis, median overall survival in the treatment arm was 10.3 months, and the data show the effect is higher in patients with a target specific T-cell response after VXM01 treatment (12.3 months for responders versus 5.4 months for non-responders). More detailed results from the trial will be submitted for presentation at upcoming scientific meetings and for publications in peer-reviewed journals. Initial data from VXM01-01-DE were presented at the 2013 Annual Conference of the American Society of Clinical Oncology.

“We are enthusiastic about the high immunological response rate and the improved survival of patients responding to VXM01 treatment,” said PD Dr. Hubertus Schmitz-Winnenthal, one of the principal investigators of the study, “This is especially exciting given the patients’ life expectancy and the observed safety profile, even under continued treatment.”

“These are very encouraging data,” added Dr. Heinz Lubenau, General Manager of VAXIMM GmbH, a fully owned subsidiary of VAXIMM AG in Germany. “We are planning to continue the development of VXM01 for the treatment of pancreatic cancer and potentially other solid tumor diseases.”

Dr. Klaus Breiner, Executive Chairman of VAXIMM AG commented: “We are extremely pleased with these results. In the end, it is improved survival that matters.”

About VAXIMM:

VAXIMM is a privately held, Swiss-German biotech company that is primarily focused on developing active immunotherapies (vaccines) for patients suffering from cancer. Its initial product candidate VXM01 is targeting the tumor vasculature, which is essential for tumors to grow beyond microscopic size. VXM01 has shown anti-tumor activity in various animal studies and commenced human clinical trials in 2011. In addition to VXM01, VAXIMM is developing a pipeline of complementary immunotherapies. VAXIMM was formed as a spin-out of Merck and as a joint venture between BB Biotech Ventures and Merck in 2008. Sunstone Capital and BioMedPartners joined as investors in 2010. The investments by Merck are managed today through MS Ventures, the strategic corporate venture arm of Merck Serono, the biopharmaceutical division of Merck. VAXIMM GmbH is a fully owned subsidiary of VAXIMM AG, with offices in Mannheim, Germany. For more information, please see www.vaximm.com.

About VXM01:

VXM01 is an oral T-cell vaccine that targets the tumor vasculature. VXM01 uses VAXIMM's proprietary oral T-cell vaccination platform technology and carries vascular endothelium growth factor receptor-2 (VEGFR-2) as target gene. An analog vaccine has shown anti-tumor activity in different tumor types in numerous animal studies. This activity was linked to a VEGFR-2 specific T-cell response and correlated with the destruction of the tumor vasculature. In animals, the vaccine appeared to be safe and well tolerated. The original work that led to VXM01 was conducted at The Scripps Research Institute. VXM01 is currently in clinical phase I/II development as a treatment for solid cancer types. The profile of VXM01 makes it an ideal combination partner for various established cancer treatments.

About Study VXM01-01-DE

The first clinical study of VXM01 enrolled 72 patients with inoperable pancreatic cancer and primarily tested the safety and tolerability of the oral, VEGFR-2 directed T-cell vaccine. Secondary endpoints of the trial included immunological response, effects on tumor perfusion and other angiogenesis-related biomarkers, clinical responses (RECIST) and overall survival. VXM01-01-DE was designed as a randomized, double-blind, placebo-controlled dose escalation study. Each of the tested dose groups consisted of six patients receiving VXM01 and three patients receiving placebo, in addition to gemcitabine as standard of care. In the first study part (N=45), patients were treated with four vaccinations, which were administered during the first seven days. In the second part of the study (N=27), patients in the treatment arm received in addition monthly follow-on vaccinations for up to six months.

Contact:

Dr. Heinz Lubenau

Tel.: +49 621 8359 687 0

Email: info@vaximm.com