VAXIMM

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VAXIMM reports positive topline data from first oral cancer vaccine trial

- Study meets endpoints and demonstrates safety and tolerability of VXM01 -

Basel (Switzerland), Mannheim (Germany), February 7th, 2013 – VAXIMM AG, a Swiss-German biotech company focusing on oral cancer vaccines, announced today topline data from the first clinical trial of its investigational oral cancer vaccine VXM01. The randomized, placebo-controlled, double-blind Phase I/II dose escalation study met all key endpoints and demonstrated safety and tolerability.

The study code-named VXM01-01-DE enrolled 45 patients with inoperable pancreatic cancer at the Heidelberg University Hospital (Heidelberg, Germany). In addition to standard-of-care treatment, the patients received several doses of VXM01, a therapeutic vaccine targeting the tumor vasculature, or placebo.

The results of the study indicate that the vaccine was safe and well tolerated. No dose-limiting toxicities were observed. Besides this primary endpoint, several important secondary endpoints, including specific T-cell response and changes in tumor perfusion, were met. After vaccination with VXM01, a quarter of the patients showed a strongly increased T-cell mediated immune response against the target (VEGFR-2). This effect was distinct from fluctuations observed in the placebo-treated patients. Immunologically responding patients occurred already in the lowest dose group. A third of the VXM01-treated patients had a strong drop in tumor perfusion following the treatment, accompanied by corresponding changes in tumor-specific and angiogenesis-related biomarkers. Tumor perfusion changes in the treatment group were correlated with the VEGFR-2 specific effector and regulatory T-cell responses. More detailed results from the trial will be submitted for presentation at upcoming scientific meetings and for publication in a peer-reviewed journal.

“We are delighted to see that VXM01 was safe and well tolerated in the patients we treated,” said PD Dr. Hubertus Schmitz-Winnenthal, principal investigator of the study. “We are especially excited about the encouraging data observed in the two key secondary endpoints. The vaccine seems to be able to induce and enhance the VEGFR-2 specific T-cell response and to impact tumor perfusion in a good proportion of treated patients.”

“We are very encouraged by these data,” added Dr. Heinz Lubenau, General Manager of VAXIMM GmbH, a fully owned subsidiary of VAXIMM AG in Germany. “It provides a strong basis for continuing the development of VXM01 for the treatment of solid tumor diseases. Following regulatory approval, we plan to re-open the study VXM01-01-DE for further recruitment of pancreatic cancer patients.”

Dr. Klaus Breiner, Executive Chairman of VAXIMM AG commented: “We are very pleased with this outcome. This first-in-man study was already designed as a placebo-controlled trial, providing us with a high level of confidence in the validity of the results.”

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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 impressive 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 in 2008 as a joint venture of BB Biotech Ventures and Merck KGaA. Merck Serono Ventures, Sunstone Capital and BioMedPartners joined as investors in 2010. 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 very impressive 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 45 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 five dose groups consisted of six patients receiving VXM01 and three patients receiving placebo, in addition to gemcitabine as standard of care. Patients were treated with four vaccinations, which were administered during the first seven days. The detailed protocol has been published in BMC Cancer (open access at http://www.biomedcentral.com/content/pdf/1471-2407-12-361.pdf).

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