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VAXIMM Announces First Results from Phase I/II Trial in Progressive Glioblastoma with Oral T-cell Immunotherapy VXM01 in Combination with PD-L1 Inhibitor Avelumab to be Presented at ASCO20 Virtual

- Results from first nine patients include three objective responses
- Two of these patients are progression-free >6 months
- VXM01 in combination with avelumab was safe and produced specific immune responses
- Results accepted for an oral presentation at conference

Basel (Switzerland) and Mannheim (Germany), May 14, 2020 – VAXIMM AG, a Swiss/German biotech company focused on developing oral T-cell immunotherapies, today announced that the safety run-in results from a Phase I/II study in progressive glioblastoma with its lead product candidate, oral VXM01, in combination with the PD-L1 inhibitor avelumab are being presented as an oral presentation at the 2020 American Society of Clinical Oncology (ASCO) Virtual Meeting being held May 29-31, 2020. The trial is part of a collaboration with Merck KGaA, Darmstadt, Germany and Pfizer Inc.

The presentation, entitled, "Oral DNA vaccination targeting VEGFR2 combined with anti-PD-L1 avelumab in patients with progressive glioblastoma: Safety run-in results—NCT03750071," will be given as part of the Developmental Therapeutics – Immunotherapy Oral Session. The abstract (#3001) is available on the ASCO website here, and the presentation will be available on demand beginning Friday, May 29th at 8:00 AM ET/2:00 PM CET.

The multicenter, open-label Phase I/II trial (EudraCT #: 2017-003076-31) is designed to evaluate the safety and tolerability of VXM01 in combination with the PD-L1 inhibitor avelumab in 30 patients with recurrent glioblastoma at multiple clinical sites in Europe. Secondary endpoints include objective response rate (ORR), clinical response using immune-response assessment in neuro-oncology (iRANO) criteria and immunological assays. Nine patients treated with VXM01 and avelumab in 2 dose groups had completed the safety run-in phase.

No treatment-related toxicities were observed in the 9 patients treated. Three partial responses according to iRANO criteria with tumor reductions of 58, 81 and 95% to baseline were reported. Two of these patients have been progression free for more than 6 months. Furthermore, significant VEGFR2-specific T-cell responses were measured in several patients, and pre-existing intra-tumoral T-cells were positively associated with the effectiveness of the immunotherapy combination.

Prof. Wolfgang Wick, MD, Chairman, Department of Neurology, Heidelberg University Hospital, Heidelberg, Germany, and principal investigator of the study, commented: "We are excited to see these highly encouraging initial results, including three partial responses, from this combination trial. The data seen so far support the scientific rationale that PD-L1 checkpoint inhibition may enhance the activity of the VXM01 vaccine. There is an urgent need for effective treatments for this deadly form of brain cancer."

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 activity in terms of objective responses and survival has been observed in recurrent glioblastoma.

Avelumab Approved Indications

Avelumab (BAVENCIO®) in combination with axitinib is approved in the US, EU, Japan and other countries for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

The US Food and Drug Administration (FDA) granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (mMCC) and (ii) patients with locally advanced or metastatic urothelial carcinoma (mUC) who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. These indications are approved under accelerated approval based on tumor response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Avelumab is also currently approved for patients with mMCC in 50 countries globally, with the majority of these approvals in a broad indication that is not limited to a specific line of treatment.

Avelumab Important Safety Information from the US FDA-Approved Label

The warnings and precautions for avelumab (BAVENCIO®) include immune-mediated adverse reactions (such as pneumonitis and hepatitis [including fatal cases], colitis, endocrinopathies, nephritis and renal dysfunction and other adverse reactions [which can be severe and have included fatal cases]), infusion-related reactions, hepatotoxicity, major adverse cardiovascular events (MACE) [which can be severe and have included fatal cases], and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with BAVENCIO® monotherapy include fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, peripheral edema, decreased appetite/hypophagia, urinary tract infection

and rash. Common adverse reactions (reported in at least 20% of patients) in patients receiving BAVENCIO® in combination with axitinib include diarrhea, fatigue, hypertension, musculoskeletal pain, nausea, mucositis, palmar-plantar erythrodysesthesia, dysphonia, decreased appetite, hypothyroidism, rash, hepatotoxicity, cough, dyspnea, abdominal pain and headache. Grade 3-4 clinical chemistry and hematology laboratory value abnormalities reported in at least 10% of patients treated with BAVENCIO® monotherapy include hyponatremia, lymphopenia, GGT increased; in patients receiving BAVENCIO® in combination with axitinib, grade 3-4 clinical chemistry and hematology laboratory value abnormalities included blood triglyceride increased and lipase increased.

For full Prescribing Information and Medication Guide for BAVENCIO®, please see www.BAVENCIO.com.

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. The Company has a pipeline of complementary development candidates targeting different tumor structures. 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 brain cancer. As part of a scientific collaboration with Merck KGaA, Darmstadt, Germany, and Pfizer Inc., VAXIMM has an ongoing clinical trial evaluating VXM01 in combination with the human anti-PD-L1 antibody, avelumab.

VAXIMM also has a neoantigen program currently in preclinical development; the Company's platform allows for fast generation and delivery of personalized T-cell cancer vaccines and may overcome key issues faced by other neoantigen approaches. VAXIMM has a strategic clinical trial collaboration with NEC Corporation for the development of personalized neoantigen cancer vaccines. VAXIMM also has a collaboration agreement with China Medical System Holdings (CMS), granting CMS full rights in China and other Asian countries (excluding Japan) to VAXIMM's existing programs. VAXIMM's investors include: BB Biotech Ventures, BCM Europe, BioMed Partners, CMS, M Ventures, NEC and Sunstone Capital. VAXIMM AG is headquartered in Basel, Switzerland. Its wholly owned subsidiary, VAXIMM GmbH, located in Mannheim, Germany, is responsible for the Company's development activities. For more information, please see www.vaximm.com.

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