VAXIMM

VAXIMM Announces Collaboration with Merck KGaA, Darmstadt, Germany, and Pfizer to Evaluate Combination of *VXM01* with Avelumab in Glioblastoma and Colorectal Cancer in Phase I/II Clinical Studies

Basel (Switzerland) and Mannheim (Germany), May 9, 2017 – VAXIMM AG, a Swiss/German biotech company focused on developing oral T-cell immunotherapies, today announced that it has entered into a collaboration agreement with Merck KGaA, Darmstadt, Germany, a leading science and technology company which in the US and Canada operates as EMD Serono, and Pfizer Inc. (NYSE: PFE) to evaluate avelumab*, a human anti-PD-L1 antibody, in combination with VAXIMM's VXM01. VXM01 is an investigational oral T-cell immunotherapy designed to activate T-cells to attack the tumor vasculature, and, in several tumor types, attack cancer cells directly. Under the terms of the agreement, VAXIMM will be responsible for conducting two open-label Phase I/II trials – one in glioblastoma and one in metastatic colorectal cancer.

"There is a strong scientific rationale for combining VXM01 oral T-cell immunotherapy with checkpoint inhibitors, as they have complementary modes of action," said Matthias Schroff, Ph.D., Chief Executive Officer of VAXIMM. "We are excited to have the opportunity to work with Merck KGaA, Darmstadt, Germany, and Pfizer to explore the combination of VXM01 with avelumab in cancers for which there is an urgent need for more effective therapies."

"We continue to explore the role of avelumab in a variety of challenging cancers across our extensive clinical development program," said Alise Reicin, M.D., Head of Global Clinical Development at the biopharma business of Merck KGaA, Darmstadt, Germany. "We hope that this clinical investigation of avelumab as a combination therapy with VAXIMM's VXM01 will provide further insights into new ways of addressing these hard-to-treat cancers."

"A key facet of our clinical development program for avelumab includes evaluating the role of combination approaches in immuno-oncology," said Chris Boshoff, M.D., Ph.D., Senior Vice President and Head of Immuno-oncology, Early Development and Translational Oncology, Pfizer Global Product Development. "Our collaboration with VAXIMM will help advance our understanding of how the combined approach of an oral T-cell immunotherapy combined with avelumab could potentially help patients with glioblastoma and metastatic colorectal cancer."

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* *Avelumab is under clinical investigation for treatment of glioblastoma and metastatic colorectal cancer and has not been demonstrated to be safe and effective for these indications. There is no guarantee that avelumab will be approved for glioblastoma and metastatic colorectal cancer by any health authority worldwide.*

About glioblastoma:

Glioblastoma is a deadly form of brain cancer. The disease can be difficult to treat because the tumors contain many different types of cells. According to recent statistics, in Europe (EU-27) there were estimated to be more than 42,000 cases of brain and nervous system tumors and over 32,000 deaths[i]. In the US, there were over 21,000 cases and over 15,000 deaths.[ii] Radiation and chemotherapy may be used to slow the growth of glioblastomas that cannot be removed with surgery.[iii] However, according to the American Association of Neurological Surgeons, patients typically die in the first 15 months after diagnosis.[iv] Thus, there is an urgent need to find more effective treatment options.

About colorectal cancer:

Colorectal cancer is the third most common cancer in men and the second most common cancer in women. According to recent statistics, in Europe (EU-28) there were an estimated 345,000 cases of colorectal cancer and 152,000 deaths from this disease. In the US, there were 134,000 cases and 52,000 deaths.[v] Treatment includes surgery for cancer that has not spread; chemotherapy alone or in combination with radiation therapy is used for cancer that has spread to the lymph nodes. Chemotherapy or targeted therapy is used to treat metastatic disease. According to the American Cancer Society, the 5-year survival rate is 65%; however, for patients whose cancer has spread, the rate is only 14%.[vi] Thus, there remains a major need for new treatments for metastatic colorectal cancer.

About Avelumab:

Avelumab is a human antibody specific for a protein called PD-L1, or programmed death ligand-1. Avelumab is designed to potentially engage both the adaptive and innate immune systems. By binding to PD-L1, avelumab is thought to prevent tumor cells from using PD-L1 for protection against white blood cells, such as T-cells, exposing them to anti-tumor responses. Avelumab has been shown to induce antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro. Common adverse reactions in patients treated with avelumab include fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, peripheral edema, decreased appetite, and rash. Immune-mediated adverse reactions have also been reported and can include pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction. In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

On March 23, 2017, the US Food and Drug Administration granted accelerated approval for avelumab (BAVENCIO®) for the treatment of metastatic Merkel cell carcinoma in adults and pediatric patients 12 years and older. Continued approval for this indication in the US may be contingent upon verification and description of clinical benefit in confirmatory trials. Avelumab has not yet been approved for metastatic Merkel cell carcinoma outside of the US.

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 studies in colorectal cancer and glioblastoma are ongoing.

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 clinical operations. For more information, please see www.vaximm.com.

Alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US:

Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US, enables the companies to benefit from each other's strengths and capabilities and further explore the therapeutic potential of avelumab, an anti-PD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance will jointly develop and commercialize avelumab and advance Pfizer's PD-1 antibody. The alliance is focused on developing high-priority international clinical programs to investigate avelumab as a monotherapy, as well as in combination regimens, and is striving to find new ways to treat cancer.

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[i] Source: EUCAN cancer fact sheets, http://eco.iarc.fr/eucan
[ii] Source: World Health Organization, IARC, Cancer Today, http://gco.iarc.fr/today
[iii] Source: American Brain Tumor Assn, abta.org
[iv] Source: American Association of Neurological Surgeons (AANS), www.aans.org
[v] Source: World Health Organization, IARC. Globocan 2012, http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx
[vi] Source: American Cancer Society, Cancer Facts and Figures 2017, www.cancer.org