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PRESS RELEASE

MaxiVAX starts Phase 2 study in Switzerland of innovative cancer vaccine in patients with Head & Neck cancer

- **Company winner of 2017 CTI Swiss Medtech Award**
- **US FDA accepted IND in 2018**

Geneva, Switzerland – 25 September, 2018 – MaxiVAX SA, a private Swiss clinical-stage biotech company developing novel anti-cancer vaccines, announced today the start of an open label Phase 2 study to evaluate its MVX-ONCO-1 product in 40-45 patients with Head & Neck cancer. The study is being conducted across different sites in Switzerland in collaboration with SAKK, the Swiss Group for Clinical Cancer Research. All enrolled patients will have a confirmed diagnosis of Head and Neck Squamous Carcinoma (HNSCC), stage III/IV in recurrent or metastatic stage and will have failed standard therapy. The primary endpoint is overall survival at 26 weeks.

The company received the 2017 CTI Swiss Medtech Award for its ground-breaking work with MVX-ONCO-1. In 2018, the US Food and Drug Administration (FDA) accepted the company's Investigational New Drug (IND) Application to conduct clinical trials.

Dr Nicolas Mach MD, Chief Scientific Officer of MaxiVAX, commented: "I am proud that we have started this really important Phase 2 clinical trial for patients who have not responded to traditional therapy for Head & Neck tumors. There is a clear medical need for these patients."

He continued: "MVX-ONCO-1 is the first personalized cell-based cancer immunotherapy using encapsulation cell technology. Crucially, it benefits those patients whose immune system is still functioning at a certain base level. Therapy is individualized and can be applied to any cancer type."

Dr Peter Brauchli, CEO of SAKK, **the Swiss Group for Cancer Research,** said: "We are delighted to be working with MaxiVAX and be involved in the clinical development of MVX-ONCO-1. With the full engagement of our network of hospital sites, we will ensure timely completion of this important study for these patients who clearly need more effective therapies."

The Phase 2 Head and Neck study has been made possible in part thanks to grants made to Dr Nicolas Mach MD, Geneva University Hospital. In addition to his function as Deputy Head of the hospital's Oncology Division, Dr Nicolas Mach is Chief Scientific Officer of MaxiVAX and founder of its novel immunotherapy technology. A grant of CHF 240,000 was made available by the Swiss Cancer League, and another grant of CHF 300,000 was awarded by SAKK/RTFCCR/Gateway Research.

The start of the Phase 2 clinical trial follows the successful completion of a Phase 1 trial in 25 patients with a range of cancer types at an advanced stage, when no serious adverse events were reported in the study drug.

About the Phase 2 study

- *Objective* — To evaluate the efficacy, safety and tolerability of MVX-ONCO-1 in advanced Head and Neck squamous cell carcinoma
- *Number patients* — 40-45
- *Trial design* — Multicenter, prospective, single-arm, open label Phase 2
- *Treatment* — 6 immunizations over 8 weeks, follow up to week 26
- *Primary endpoint* — Overall survival at 26 weeks
- *Other endpoints* — Progression-free survival, adverse and serious events

Further information about the trial can be found at www.clinicaltrials.gov and on the Swiss National Clinical Trials Portal (SNCTP) at www.kofam.ch

About MVX-ONCO-1

MVX-ONCO-1 is a biological product made up of two components. The first consists of complete tumor cells taken from each individual patient and represents the best repertoire of antigens, i.e., cancer-specific targets against which a coordinated immune response can be directed. The cancer cells are lethally irradiated before being implanted subcutaneously in the patient.

The second component consists of the adjuvant, or booster. Adding a strong adjuvant is essential for triggering an efficient immune response. The release of the potent adjuvant GM-CSF, a white blood cell growth factor, is obtained by the implantation of a biocompatible capsule that contains a cell line genetically modified to produce the strong adjuvant. The encapsulation of the GM-CSF-producing cells allows the continuous, in-situ delivery of the immune boosting agent over seven days at the site of immunization. This is a critical parameter for the successful and sustained immunization against the cancer cells.

A recently completed Phase 1 clinical trial demonstrated that MVX-ONCO-1 was safe and well tolerated, with encouraging efficacy results. MVX-ONCO-1 is the company's first compound, for which there is IP protection in both the United States and the European Union.

About SAKK www.sakk.ch

The **Swiss Group for Clinical Cancer Research (SAKK)** is a non-profit organization, which has been conducting clinical trials in oncology since 1965. Its primary objective is to research new cancer therapies, to develop existing treatments further and to improve the chances of a cure for patients with cancer. This takes place through cooperative projects within Switzerland and in collaboration with centers and study groups abroad. The SAKK is supported by a service-level agreement with the State Secretariat for Education, Research and Innovation (SERI) and also by partners such as the Swiss Cancer League and Swiss Cancer Research.

About MaxiVAX www.maxivax.ch

MaxiVAX is a private Swiss clinical-stage biotech company with a novel, patient-specific and personalized active immunotherapy treatment for cancer. The company received the 2017 CTI Swiss Medtech Award for its ground-breaking work, and its lead product MVX-ONCO-1, which is in Phase 2 development for Head & Neck cancer in Switzerland. The company successfully filed an IND with the US FDA in 2018.

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