

Protocol SAKK 11/16: Personalized and cell-based anti-tumor immunization MVX-ONCO-1 in advanced head and neck squamous cell carcinoma. A single arm, open label, multicenter phase II trial

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MVX-ONCO-1 is a form of active specific immunotherapy, a process by which the patient's immune response to tumor cells is stimulated and/or augmented. MVX-ONCO-1 is a patient specific, cell-based, immunotherapy composed of: a. An immune-modulator (GM-CSF: granulocyte-macrophage colony stimulating factor) released from an immuno-protected, encapsulated, allogeneic, genetically modified cell line (MVX-1), and b. Irradiated, autologous tumor cells as source of antigen. The IMP (MVX-ONCO-1) is a medication without marketing authorization in Switzerland or any other market. MVX-ONCO-1 is an ex-vivo gene therapy (GMO), a transplantation product regulated by the Transplantation Act (Art. 49) in accordance to the Therapeutic Products Act (TPA), the Human Research Act (HRA) and the Clinical Trials Ordinance (ClinO); this trial is classified into clinical trial as a category C.

keywords	Hand and neck cancer; personalized immunotherapy
project partner	Dr. Veronika Nagy, Dr. Karen Nestor, Dr. Sabrina Ebinger, Prof. Dr. Markus Joerger, Frau Jessica Hollenstein, Dr. Nikolaus Wagner
type of project	clinical studies
status	scheduled
start of project	2020
end of project	2025
study design	Phase II
Swissmedic notification number	2016GT2009
responsible person	Markus Jörge