vaccentis
PERSONALIZED MEDICINE

VCC-001 CLINICAL/REGULATORY ROADMAP 2023

	MANUFACTURING/QC	PRECLINICAL	PHASE I	PHASE II	PHASE III	ADDITIONAL DATA	GOAL I	GOAL II
VCC-001 EXISTING DATA	Initial Quality Control method development Manufacturing Process development	Initial exploration of Mode of Action and exploratory antigen mapping Data on file: Including data on repeated dose, toxicology, histopathology Doehn et al, 2009 (RENCA Vaccine mouse model, MoA) Wittke et al., 2016 – Initial data on Ag mapping of RCC		Pilot Study Repmann et al, 1997 Pilot Study in 116 Patients. Adjuvant Therapy in Renal Cell Carcinoma with Active-Specific Immunotherapy (ASI) using Autologous Tumour Vaccine Pilot Study Repmann et al., 2003 5 Year Follow up of Pilot Study in 116 Patients. Adjuvant Therapy of Renal Cell Carcinoma Patients with an autologous Tumour Cell Lysat Vaccine: A 5-Years Follow-up Analysis	Phase III trial: Jocham et al., 2004, Lancet Doehn et al., 2006, abstract, supplements, JUrol. 2nd Analysis of Phase III. An adjuvant vaccination with VCC-001 prolongs survival in patients with renal cell carcinoma following radical nephrectomy: secondary analysis of a multicente Phase III trial. May et al., 2009 n 1267 patients who received treatment with VCC-001. Ten-year survival analysis for renal cell carcinoma patients treated with autologous tumour lysate vaccine in an adjuvant setting			
VCC-001 NEW DEVELOPMENT	Consolidate existing manufacturing process and develop Good Manufacturing Practice prerequisites of CMO Development of additional Quality Control tests Update/preparation of relevant Regulatory documents Further build manufacturing capacity for development program of VCC-001 Develop scale up opportunities for production in key markets	Further build pre-clinical programme including all EMA/FDA feedback Further charactarize Mode of Action Continue antigen-mapping of RCC		Define regulatory strategy of necessity of dose finding. – minimal required data set Small and well defined dose finding study – dose and frequency of administration – define plateau of response – maximal clinical response reached Include small pilot on exploratory endpoint for biomarker for response/monitoring of clinical efficacy	Concept for Phase III Efficacy and Safety – fulfilling all requirements for successful filling with EMA and FDA Include Biomarker as Exploratory Endpoints Input of Regulatory Advice Company and external preclinical and clinical Experts Perform Scientific Advice with EMA and FDA	Orphan Drug Designation – guaranteeing market exclusivity when marketing authorization is granted SME – Small- and Medium-sized enterprise Designation	EMA SCIENTIFIC ADVICE MEETING Q4/23	FDA SCIENTIFIC ADVICE MEETING Q1/24