KURZPROTOKOLL
SanofiTED15297

Öffentlicher Titel	First-in-Human-Studie zu SAR441000 bei fortgeschrittenen soliden Tumoren
Wissenschaftl. Titel	A Phase 1 First in Human dose escalation and expansation study for the evaluation of safety, pharmacokinetics,pharmacodynamics and anti-Tumor activity of SAR441000 administered intratumorally in patients with advanced solid tumors
Kurztitel	SanofiTED15297
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase I
Erkrankung	Haut: Hautkrebs: sonstige Therapiestudien Kopf-Hals: Kopf-Hals-Tumoren: sonstige Therapiestudien
Einschlusskriterien	- At least 18 years of age - Advanced solid malignant tumor disease for which no standard alternative therapy is available (escalation phase). - Advanced melanoma (Stage IIIB-C or Stage IV, anti-PD-1/PD-L1 treated or not) or anti-PD-1/PD-L1 not treated advanced Head and Neck Squamous Cell Cancer or Advanced Cutaneous Squamous Cell Cancer where no other alternative treatment option exists (expansion phases). - Minimum 3 lesions (patient with 2 lesions is acceptable in selected cases) at enrollment. - Injectable disease (i.e., suitable for direct intratumoral injection based on the dose level volume of each cohort and cumulative lesion size; according to the investigator's judgement). - Patients with measurable disease according to the Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 criteria. - Life expectancy more than 3 months. - Willingness to provide mandatory tumor biopsy. - Male and female patients who agree to use effective contraceptive methods. - Signed informed consent.
Ausschlusskriterien	- Eastern Cooperative Oncology Group (ECOG) performance score >1. - Significant and uncontrolled concomitant illness that would adversely affect the patient's participation in the study. - Any prior organ transplantation. - History within the last 5 years of an invasive malignancy other than the one treated in this study, with the exception of resected basal or squamous-cell skin cancer or carcinoma, in situ of cervix or other local tumors considered cured by local treatment. - History of unresolved viral hepatitis; systemic immune suppression including acquired immunodeficiency syndrome (AIDS) related illnesses or human immunodeficiency virus (HIV) disease requiring antiretroviral treatment. - Prior splenectomy. - New and progressive brain lesions. - Poor bone marrow reserve resulting low blood cell count. - Poor liver and kidney functions, abnormal coagulation tests. - Ongoing or recent (within 5 years) evidence of significant autoimmune disease that required treatment with systemic immunosuppressive treatments. - Maintenance therapy with prednisolone >7.5 mg/day orally or equivalent during the study. - Non-resolution of any prior treatment related toxicity to Grade <2, except alopecia, vitiligo and thyroiditis controlled with replacement therapies. - Uveal or mucosal melanoma.

	- Moderate to severe immune related adverse event to prior immune-modulating agents within 90 days prior to the first study treatment
Alter	18 Jahre und älter
Sponsor	Sanofi Aventis GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03871348 EudraCT 2017-004766-94