

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 expansion 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	<ul style="list-style-type: none">- 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	<ul style="list-style-type: none">- 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.

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- 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
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Registrierung in anderen Studienregistern ClinicalTrials.gov NCT03871348
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