Studienregister UKB

Kürzel	IMA203-101
Studie	IMA203 - Behandlung von Patienten mit soliden Tumoren mit genetisch veränderten, patienteneigenen T-Zellen, die einen tumor-spezifischen T-Zellrezeptor tragen (Phase I Prüfung)
Indikation	Solide Tumoren Nicht-Kleinzelliges Bronchialkarzinom (NSCLC) Kleinzelliges Bronchialkarzinom (SCLC) Malignes Melanom Ovarialkarzinome (Eierstockkrebs) Kopf-Hals-Karzinom
Einschluss	Main inclusion criteria:

- Pathologically confirmed advanced and/or metastatic solid tumor
- Patients may enter screening procedure before, during, or after the last available indicated standard of care treatment. There is no limitation for prior anti cancer treatments.
- Eastern Cooperative Oncology Group (ECOG) performance status 0-1
- HLA phenotype positive
- Measurable disease and accessible to biopsy
- Adequate pulmonary function per protocol
- Acceptable organ and bone marrow function per protocol
- Acceptable coagulation status per protocol
- Adequate hepatic function per protocol
- Serum creatinine within normal range for age OR creatinine clearance with a recommended estimated glomerular filtration rate ≥ 50 mL/min/1.73 m2
- Patient's tumor must express tumor antigen by qPCR using a fresh tumor biopsy specimen
- Life expectancy more than 3 months
- Confirmed availability of production capacities for IMA203 product
- Patients must have recurrent/progressing and/or refractory solid tumors and must have received or not be eligible for all available indicated standard of care treatment.

Ausschluss	Main exclusion criteria:

- History of other malignancies (except for adequately treated basal or squamous cell carcinoma or carcinoma in situ) within the last 3 years
- Solid tumors with low likelihood of tumor biomarker expression per protocol
- Pregnant or breastfeeding
- Serious autoimmune disease Note: At the discretion of the investigator, these patients may be included if their disease is well controlled without the use of immunosuppressive agents.
- History of cardiac conditions as per protocol
- Prior stem cell transplantation or solid organ transplantation

Ziel	The study purpose is to establish the safety and tolerability of IMA203 product in patients with solid tumors that express preferentially expressed antigen in melanoma (PRAME).
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