Studienregister UKB

Kürzel	IMA201-101
Studie	IMA201-101 - 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
Einschluss	Main Inclusion Criteria:

- Patient must have pathologically confirmed advanced and/or metastatic solid tumor.
- Patient ≥ 18 years of age
- ECOG PS 0 to 1
- Patient may enter screening procedures for HLA-A*02:01 and MAGEA4/MAGEA8 assessments at any time after the diagnosis of advanced and/or metastatic disease; a study-specific tumor biopsy should only be taken from HLA-A*02:01-positive patients; for a patient to be screened for this study, there is no limitation on prior anti-tumor treatments they may have received
- HLA phenotype: HLA-A*02:01 positive
- Patient must have a lesion considered accessible for a biopsy unless adequate tissue was obtained during a medically necessary procedure

Ausschluss Main exclusion criteria:

- 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
- Concurrent severe and/or uncontrolled medical disease that could compromise participation in the study
- History of hypersensitivity to cyclophosphamide (CY), fludarabine (FLU), or IL-2, or to any of the rescue medications
- History of or current immunodeficiency disease or prior treatment compromising immune function at the discretion of the treating physician
- HIV infection, active hepatitis B virus (HBV), active hepatitis C virus (HCV) infection, ongoing active anti-HCV treatment or detectable HBV or HCV

viral load at the most recent laboratory report. Patients with both HBV and HCV infections will be excluded from screening

1. Patients with a history of HCV infection and with an undetectable viral load per the most recent laboratory report and/or completed anti-HCV treatment but are HCV antibody positive are permitted.
2. History of treated HBV infection is permitted if the viral load is undetectable per the most recent laboratory report. Note: HCC patients with controlled HBV infection, as defined by resolved (anti-hepatitis B surface antigen [HBs-Ag] antibody (Ab) negative, anti-core antigen [HBc Ag] Ab positive) or chronic stable (anti HBs-Ag Ab positive) HBV infection will be eligible for screening. Patients with active HBV infection who are not on anti-HBV treatment will be excluded.

- Any condition contraindicating leukapheresis, lymphodepletion, low-dose IL-2, and/or IMA201 treatment
- Patients with any active viral infection
- Patients with active brain metastases

Ziel	• Inzidenz von unerwünschten Ereignissen • Dosisfindung
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