# Studienregister UKB

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| Kürzel | IMA202-101 |
| Studie | IMA202 - 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 Kopf-Hals-Karzinom |
| Einschluss | Inclusion Criteria:<br>• Patients must have pathologically confirmed advanced/metastatic solid tumors including but not limited to one of the following indications. For patients with other solid tumors, there should be evidence of sufficient high likelihood of target expression e.g. as the prevalence in the given indication is high or as there is evidence for the individual patient from previous assessments that the tumor is target positive. These patients should have relapsed and/or refractory solid cancers with no established treatment available and they are terminally ill:<br>• Pathologically confirmed diagnosis of stage IIIB/IV recurrent NSCLC OR Pathologically or radiologically (fulfilling non-invasive criteria) confirmed diagnosis of HCC not amenable to resection (partial hepatectomy or liver transplantation) or local therapy with curative intent (e.g. radiofrequency ablation)<br>• Eastern Cooperative Oncology Group (ECOG) performance status 0-1<br>• Signed written informed consent form<br>• Women of childbearing potential must use adequate contraception<br>MAIN SCREENING:<br>• HLA phenotype positive. Note: Patients who were previously HLA-typed for participation in other Immatics' sponsored clinical trials and were HLA phenotype positive may enter IMA202-101 main screening<br>• Patient's tumor must express specified biomarkers. Note: Patients who were previously screened for participation in other Immatics' sponsored clinical trials and whose biomarkers are positive for IMA202-101 based on IMA_Detect may enter IMA202-101 screening<br>• Adequate organ and marrow function, defined per protocol<br>• Measurable disease<br>• At least one lesion (metastasis or primary tumor) being considered accessible for a biopsy |

- Adequate hepatic function for squamous cell NSCLC patients, as defined per protocol. For HCC patients: Child-Pugh score ≤6 and Model for End-Stage Liver Disease (MELD) score≤15
- Serum creatinine within 1.5 x normal range for age OR creatinine clearance with a recommended eGFR ≥ 50 mL/min/1.73m^2
- Adequate pulmonary function
- Acceptable coagulation status
- Availability of production capacities for the patient's IMA202 product prior to the leukapheresis

TREATMENT SCREENING:

These patients should have relapsed and/or refractory solid cancers with no established treatment available and they are terminally ill:

- Available IMA202 product passed all required release tests
- Adequate hepatic function for squamous cell NSCLC patients, as defined per protocol. For HCC patients: Child-Pugh score ≤6 and Model for End-Stage Liver Disease (MELD) score≤15
- Serum creatinine within 1.5 x normal range for age OR creatinine clearance with a recommended eGFR ≥ 50 mL/min/1.73m^2
- Measurable disease
- Male patients must agree to use effective contraception or be abstinent while on study and for 90 days after the infusion of IMA202 product

Ausschluss

Exclusion Criteria:

- Pregnant or breastfeeding
- Serious autoimmune disease

HLA SCREENING:

• History of other malignancies (except for adequately treated basal or squamous cell carcinoma or carcinoma in situ) within the last 3 years

MAIN SCREENING:

- Any condition contraindicating leukapheresis
- Brain metastases. Note: Patients with a history of brain metastases may be eligible, if an imaging scan with contrast enhancement not older than 4 weeks is able to exclude the existence of currently active brain metastasis
- HIV infection, active hepatitis B or C infection. History of treated hepatitis B or C is permitted if the viral load is undetectable. HCC patients with controlled or chronic stable HBV infection will be eligible for screening. HCC patients with HBV infections who are not on anti-HBV treatment will be excluded from the study. HCC subjects with HCV infections will be allowed for screening; however, subjects with both HBV and HCV infections will be excluded for screening
- Patient has received any chemotherapy, surgery, radiotherapy (for therapeutic purposes), tyrosine kinase inhibitors, investigational drugs, chronic use of systemic corticosteroids or statin therapy within 2 weeks prior to the leukapheresis
- Concomitant therapy indicated with any of the following: interferons or other non-study immunotherapy regimens; immunosuppressive agents; other investigational therapies; or chronic use of systemic corticosteroids
- Severe immune-related toxicity related to checkpoint inhibitors defined as any Grade 4 toxicity or Grade 3 toxicity

- Cardiac conditions per protocol
- Prior stem cell transplantation or solid organ transplantation
- Concurrent severe and/or uncontrolled medical disease that could compromise participation in the study
- Active diverticulitis, intra-abdominal abscess or gastrointestinal (GI) obstruction
- History of hypersensitivity to cyclophosphamide, fludarabine or IL-2
- History of or current immunodeficiency disease or prior treatment compromising immune function
- Patients with active pneumonitis

TREATMENT SCREENING:

- Patient received chemotherapy, surgery, or radiotherapy (for therapeutic purposes) within 3 weeks, monoclonal antibodies or investigational drugs within 4 weeks or tyrosine kinase inhibitor within 1 week, or the patient has not recovered prior to lymphodepletion regimen. Note: Patient may be still eligible if the patient has not fully recovered from grade ≥2 toxicities if accumulated toxicities with the lymphodepletion therapy are not expected
- Active pneumonitis
- Patient unable to tolerate lymphodepletion, low-dose IL-2 and/or IMA202 product
- Severe immune-related toxicity related to checkpoint inhibitors defined as any Grade 4 toxicity or Grade 3 toxicity

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| Ziel | Number of subjects with dose-limiting toxicity (DLT) and adverse events (AE) |
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