# Kompetenznetz "Akute und chronische Leukämien"

***KURZPROTOKOLL***

***CD19 CAR-T***

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| **Öffentlicher Titel** | Phase-I/II-Studie mit MB-CART19.1 zur Beurteilung der Sicherheit und Machbarkeit sowie zur Dosisfindung bei Patienten mit wiederkehrenden oder therapie-unempfindlichen CD19 positiven B-Zell Erkrankungen |
| **Wissenschaftl. Titel** | A phase I/II safety, dose finding and feasibility trial of MB-CART19.1 in patients with relapsed or refractory CD19 positive B cell malignancies. |
| **Kurztitel** | CD19 CAR-T |
| **Studiennummer KN/ELN** | LN_NN_2018_644 |
| **Studiengruppe** | NN |
| **Studienart** | multizentrisch, offen |
| **Studienphase** | Phase I/II |
| **Erkrankung** | Akute lymphatische Leukämie (ALL) - Ph/BCR ABL +<br>Akute lymphatische Leukämie (ALL) - B-Vorläufer ALL |
| **Leukämiestadium** | rezidiviert/refraktär |
| **Einschlusskriterien** | - Male or female patients must have r/r CD19-expressing ALL or NHL and meet the following disease-specific criteria:<br>- patients with >5% blasts in BM (M2 or M3) after at least one standard chemotherapy and one salvage regimen who are ineligible for allogeneic stem cell transplant (alloSCT) or have refractory disease activity precluding alloSCT at this time, or<br>- patients who have relapsed post alloSCT at least 100 days post-transplant, with no evidence of active GVHD, and no longer taking immunosuppressive agents for at least 30 days prior to enrollment.<br>- patients with Ph+ ALL if they are intolerant to tyrosine kinase inhibitor (TKI) therapy, or if they have r/r disease after treatment with at least 2 different TKIs.<br>- ALL patients with combined bone marrow and CNS and/or testicular relapse are eligible only if the extramedullary disease has been successfully cleared by conventional therapy at the time of inclusion (e.g. intrathecal chemotherapy, orchiectomy). |
| **Ausschlusskriterien** | - Isolated CNS or testicular relapse in ALL;<br>- Isolated CNS lymphomas;<br>- Active solid brain metastases or history of solid brain metastases<br>- Current autoimmune disease, or history of autoimmune disease with potential CNS involvement;<br>- Active clinically significant CNS dysfunction (including but not limited to uncontrolled seizure disorders, cerebrovascular ischemia or hemorrhage, dementia, paralysis);<br>- History of an additional malignancy other than non-melanoma skin cancer or carcinoma in situ unless disease free for 3 years;<br>- Pulmonary function: Patients with pre-existing severe lung disease or an oxygen requirement of >28% O2 supplementation or active pulmonary infiltrates on chest X-ray;<br>- Cardiac function: Fractional shortening <28% or left ventricular ejection fraction <50% by echocardiography;<br>- Renal function: Creatinine clearance <50 mL/min/1.73 m2, by Cockcroft-Gault formula for patients 18 yrs, and Schwartz formula for patients <18 yrs of age;<br>- Liver function: Patients with a serum bilirubin >3 times upper limit of normal or an AST or ALT > 5 times upper limit of normal, unless due to leukemic liver infiltration in the estimation of the investigator;<br>- Rapidly progressive disease that in the estimation of the investigator would compromise ability to complete study therapy;<br>- Pregnant or breast-feeding females; |

- Medications: a Systemic chemotherapies, corticosteroids with the exception of physiologic replacement dosing, tyrosine kinase inhibitors (TKI) within 7 days prior to leukapheresis, b Fludarabine/clofarabine or immunosuppressive drugs and antibodies (e.g. rituximab, calcineurin inhibitors, blinatumomab) or investigational drugs or donor lymphocyte transfusions or radiation therapy within 30 days prior to apheresis, c Alemtuzumab within 3 months prior to leukapheresis, d Exception: Intrathecal chemotherapy is allowed at any time prior to treatment, but should be discontinued in ALL and BL 10 days prior to MB-CART19.1 infusion to limit risk of neurotoxicities;
- Hypersensitivity against any drug or its ingredients/impurities that is scheduled or likely to be given during trial participation, e.g. as part of the mandatory lymphodepletion protocol, pre-medication for infusion, rescue medication/salvage therapies for treatment related toxicities;
- Intake of concomitant medication contraindicated for other reasons than hypersensitivity, e.g. live vaccines and fludarabine;
- Contraindication of trial related procedures as judged by the investigator, e.g. lumbar punctures for CSF sampling;
- Female patients of child-bearing potential not willing to practice a highly effective form of birth control from the time of enrollment and for 12 months after dosing the IMP;
- Male patients of fathering potential not willing to practice a highly effective form of birth control from the time of enrollment and for 12 months after dosing the IMP;
- Concurrent participation in another interventional trial that could interact with this trial, e.g. CAR T trials;
- Other investigational treatment within 4 weeks before IMP infusion;
- Cerebral dysfunction, legal incapacity of adult patients;
- Committal to an institution on judicial or official order.

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| **Alter** | >= 18 Jahre |
| **Status** | Aktiv |
| **Beginn der Rekrutierung** | 15.05.2018 |
| **Studienleiter/in** | Rössig, Prof. Dr. med., Claudia<br>UK Münster<br>E-Mail: rossig@ukmuenster.de |
| **Sponsoren** | Miltenyi Biotec GmbH |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.govNCT03853616<br>European Clinical Trials Database - EUDRACT2017-002848-32 |