Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL

ZUMA 3

Öffentlicher Titel	Überprüfung der Wirksamkeit von CAR-T Zellen bei erwachsen Patienten mit einem Rezidiv einer akuten lymphoblastischen Leukämie
Wissenschaftl. Titel	Eine multizentrische Studie der Phase 1/2 zur Beurteilung der Sicherheit und Wirksamkeit von KTE-X19 bei erwachsenen Patientenmit rezidivierter/refraktärer B Vorläufer akuter lymphoblastischer Leukämie (r/r ALL) (ZUMA-3)
Kurztitel	ZUMA 3
Studiennummer KN/ELN	LN_NN_2019_643
Studiengruppe	NN
Studienart	multizentrisch, einarmig, prospektiv, offen
Studienphase	Phase I/II
Erkrankung	Akute lymphatische Leukämie (ALL) - Ph/BCR ABL + Akute lymphatische Leukämie (ALL) - B-Vorläufer ALL
Leukämiestadium	rezidiviert/refraktär
Einschlusskriterien	- 1. Relapsed or refractory B-precursor ALL defined as one of the following: o Primary refractory disease o First relapse if first remission 12 months o Relapsed or refractory disease after 2 or more lines of systemic therapy o Relapsed or refractory disease after allogeneic transplant provided individuals is at least 100 days from stem cell transplant at the time of enrollment - 2. Morphological disease in the bone marrow (5% blasts) - 3. Individuals with Ph+ disease are eligible if they are intolerant to tyrosine kinase inhibitor (TKI) therapy, or if they have relapsed/refractory disease despite treatment with at least 2 different TKIs - 4. Age 18 or older - 5. Eastern cooperative oncology group (ECOG) performance status of 0 or 1 - 6. Adequate renal, hepatic, pulmonary and cardiac function defined as: o Creatinine clearance (as estimated by Cockcroft Gault) 60 cc/min o Serum alanine aminotransferase (ALT)/aspartate aminotransferase (AST) 2.5 x upper limit of normal (ULN) o Total bilirubin 1.5 mg/dl, except in individuals with Gilbert's syndrome. o Cardiac ejection fraction 50%, no evidence of pericardial effusion, and no clinically significant arrhythmias o Baseline oxygen saturation > 92% on room air - 7. In individuals previously treated with blinatumomab, CD19 tumor expression in bone marrow or peripheral blood
Ausschlusskriterien	- 1. Diagnosis of Burkitt's leukemia/lymphoma according to World Health Organization (WHO) classification or chronic myelogenous leukemia lymphoid blast crisis - 2. History of malignancy other than non-melanoma skin cancer or carcinoma in situ (e.g. cervix, bladder, breast) unless disease free for at least 3 years - 3. Isolated extramedullary disease - 4. Central nervous system (CNS) abnormalities o Presence of CNS-3 disease or CNS-2 disease with neurological changes o History or presence of any CNS disorder such as a seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or any autoimmune disease with CNS involvement - 5. History of concomitant genetic syndrome such as Fanconi anemia, Kostmann syndrome, Shwachman-Diamond syndrome or any other known bone marrow failure syndrome - 6. History of myocardial infarction, cardiac angioplasty or stenting, unstable angina, or other clinically significant cardiac disease within 12 months of enrollment - 7. History of symptomatic deep vein thrombosis or pulmonary embolism within 6 months of enrollment. - 8. Primary immunodeficiency

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- 9. Known infection with HIV, hepatitis B (HBsAg positive) or hepatitis C virus (anti-HCV positive).
- 10. Presence of fungal, bacterial, viral, or other infection that is uncontrolled or requiring IV antimicrobials for management.
- 11. Prior medication: o Salvage chemotherapy including TKIs for Ph+ ALL within 1 week prior to enrollment o Prior CD19 directed therapy other than blinatumomab o Treatment with alemtuzumab within 6 months prior to leukapheresis, or treatment with clofarabine or cladribine within 3 months prior to leukapheresis o Donor lymphocyte infusion (DLI) within 28 days prior to enrollment o Any drug used for graft-versus-host disease (GVHD) within 4 weeks prior to enrollment o At least 3 half-lives must have elapsed from any prior systemic inhibitory/stimulatory immune checkpoint molecule therapy prior to enrollment o Corticosteroid therapy for 7 days prior to enrollment
- 12. Presence of any indwelling line or drain (e.g., percutaneous nephrostomy tube, indwelling Foley catheter, biliary drain, or pleural/peritoneal/pericardial catheter). Ommaya reservoirs and dedicated central venous access catheters such as a Port-a-Cath or Hickman catheter are permitted

Alter	>= 18 Jahre
Status	Aktiv
Beginn der Rekrutierung	10.01.2019
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Registrierung in anderen Studienregistern	European Clinical Trials Database - EUDRACT2015-005009-35