Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL

DCOne-002

Öffentlicher Titel	Phase II Studie zur DCP-001 Immuntherapie bei akuter myeloischer Leukämie mit persistierender MRD
Wissenschaftl. Titel	An International, Multicentre, Open-label Study To Evaluate The Efficacy and Safety of Two Different Vaccination Regimens of Immunotherapy With Allogeneic Dendritic Cells, DCP-001, in Patients With Acute Myeloid Leukaemia That Are In Remission With Persistent MRD
Kurztitel	DCOne-002
Studiennummer KN/ELN	LN_NN_2019_699
Studiengruppe	NN
Studienart	multizentrisch, offen
Studienphase	Phase II
Erkrankung	Akute myeloische Leukämie (AML) - AML alle außer FAB M3
Leukämiestadium	rezidiviert/refraktär

Einschlusskriterien

- Confirmed diagnosis of AML according to WHO2016 criteria, including cytological, molecular and cytogenetic criteria (except acute pro-myelocytic leukemia/APL)
- In CR1 (first complete remission) or CRi (incomplete blood count recovery) documented by bone marrow examination up to one month before vaccination; CR defined as less than 5% blasts in normo-cellular bone marrow, ANC >1*E9/L, platelet count 100*E9/L, no evidence of extra-medullary disease. Patients in CRi (patients in CR1 but with incomplete blood count recovery) should have platelets >50 E9/L
- MRD as defined by multicolor flow cytometry (MFC) at a value of > 0.1%
- Patients that are in CR1 or Cri. Patients not having undergone consolidation therapy must have been in CR1 or CRi for at least 1 month prior to enrolment. Patients treated with hypomethylating agents must have been given at least two cycles and up to a maximum of nine cycles of hypomethylating agents
- Expected and willing to undergo all study procedures, including outpatient evaluations for clinical and immunological monitoring
- Male or female of > 18 years of age
- Women of childbearing potential must be on anti-conceptive therapy or use two (2) barrier contraceptive methods (one by each partner and at least one of the barrier methods must include spermicide (unless spermicide is not approved in the country or region) , or underwent tubal ligation, or the partner was vasectomized, or is sexually abstinent
- ECOG (WHO) performance status 0-2
- Willing and able to provide written informed consent for participation in the study and for tissue sample biobanking

Ausschlusskriterien

- Acute Promyelocytic (APL; M3) type of AML
- Patients who have undergone or are scheduled/eligible for allogeneic stem cell transplantation
- History of previous allogeneic bone marrow or solid organ transplantation
- Uncontrolled or serious infections
- Ongoing immunosuppressive therapy, other than short use of low dose steroids, i.e. equivalent to an average dose of 10mg of prednisone
- Chemotherapy and antineoplastic therapy within 28 days prior to the screening visits, with the exception of hypomethylating agents such as azacitidine and decitabine, or midostaurin for FLT3 mutations, or patients treated with IDH1/2 inhibitors in mIDH1/2
- Current or past medical history of autoimmune disease
- Inadequate liver function (AST and ALT > 3 x ULN, serum bilirubin >3 x ULN)

- Other active Malignancies within the last 5 years, except for adequately treated carcinoma in situ of the cervix or squamous carcinoma of the skin or adequately controlled limited basal cell skin cancer
- Pregnant or lactating females
- Major surgical procedure (including open biopsy) within 28 days prior to the first study treatment, or anticipation of the need for major surgery during the course of the study treatment
- Uncontrolled hypertension (systolic > 150 mm Hg and/or diastolic > 100 mm Hg) or clinically significant (i.e. active) cardiovascular disease
- Evidence of any other medical conditions (such as psychiatric illness, physical examination or laboratory findings) that may interfere with the planned treatment, affect patient compliance or place the patient at high risk from treatment-related complications
- Known HIV, Hepatitis B or C infections
- History of hypersensitivity to the investigational medicinal product or to any excipient present in the pharmaceutical form of the investigational medicinal product

Alter	>= 18 Jahre
Status	Aktiv
Beginn der Rekrutierung	10.07.2019
Sponsoren	DCPrime
Registrierung in anderen Studienregistern	European Clinical Trials Database - EUDRACT2017-003426-32