CHARITÉ

Comprehensive Cancer Center
Universitätstumorzentrum

Studientitel	**CP-MGD006-01 (VOYAGE)** **A Phase 1/2, First-in-Human, Dose Escalation Study of MGD006, a CD123 x CD3 Dual Affinity Re-Targeting (DART) Bi-Specific Antibody-Based Molecule, in Patients with Relapsed or Refractory Acute Myeloid Leukemia or Intermediate-2/High Risk Myelodysplastic Syndrome**	
EudraCT-Nummer	**2015-003813-11**	
ClinicalTrials.gov Identifier	**NCT02152956**	
Sponsor	MacroGenics	
Ansprechpartner*in	Prof. Dr. med. Lars Bullinger	
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Wichtigste Einschlusskriterien	• Confirmed diagnosis of primary or secondary AML [any subtype except acute promyelocytic leukemia (APL)] according to World Health Organization (WHO) classification • Patients with AML must meet one of the following criteria, a or b: 1. Primary Induction Failure (PIF) AML, defined as disease refractory to either, i or ii: ▪ i. An intensive induction attempt, per institution. Induction attempts include high-dose and/or standard-dose cytarabine ± an anthracyclines/anthracenedione ± an anti-metabolite, with or without growth factor or targeted therapy containing regimens. Examples include but are not limited to: 1 cycle of high dose cytarabine (HiDAC) containing regimen, 1 cycle of liposomal cytarabine and daunorubicin, 2 cycles of standard dose cytarabine containing regimen	

	▪ ii. For adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy; PIF is defined as AML refractory to one of the following less intensive regimens: i ≥ 2 but ≤ 4 cycles of Bcl-2 inhibitors in combination with azacitidine, decitabine, or low dose cytarabine, or ii ≥ 2 but ≤ 4 cycles of gemtuzumab ozogamicin monotherapy 2. Early relapse (ER) AML, defined as AML in first relapse with initial CR1 duration < 6 months • Limit of 3 prior lines of therapy (excluding focal radiation therapy for palliative purposes): up to 2 induction (induction, re-induction) or 1 induction plus/minus 1 consolidation attempt, followed by a maximum of 1 salvage/re-induction attempt. • Eastern Cooperative Oncology Group (ECOG) performance status ≤2 • Life expectancy of at least 4 weeks • Peripheral blast count </= 20,000/mm3 at the time of first dose • Acceptable laboratory parameters and adequate organ reserve