KURZPROTOKOLL
ARMY-1

Öffentlicher Titel	CD157 Antikörper bei rezidivierte/refraktärer akuter myeloischer Leukämie
Wissenschaftl. Titel	First in man study with MEN1112, a CD157 targeted monoclonal antibody, in relapsed or refractory Acute Myeloid Leukemia
Kurztitel	ARMY-1
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase I
Erkrankung	Blut: Akute myeloische Leukämie (AML): Rezidiviert/refraktär

Einschlusskriterien

- Male or female patients aged >= 18 years.
- Documented definitive diagnosis of AML (according to WHO criteria, 2008) that is relapsed/refractory to standard treatment, for which no standard therapy is available or the patient refuses standard therapy. For the purpose of this study, refractory AML is defined as following: Failure to achieve Complete Remission/Complete Remission with incomplete blood count recovery (CR/CRi) (InternationalWorking Group (IWG criteria, 2003) following at least 1 cycle of cytotoxic chemotherapy (or hypomethylating agents if unsuitable for cytotoxic chemotherapy) and unlikely, as per Investigator’s judgement, to achieve CR/CRi with further cytotoxic chemotherapy (or hypomethylating agents if unsuitable for cytotoxic chemotherapy).
- White Blood Cells (WBC) count <= 10 x 10^9/L at Visit 1 (Day 1); hydroyxurea is allowed to lower WBC count
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 at Visit 1 (Day 1).
- Life expectancy of at least 2 months.
- Adequate renal and hepatic laboratory assessments: a) Aspartate aminotransferase (AST), alanine aminotransferase (ALT) and alkaline phosphatase (ALP) <=3.0 × Upper Limit of Normal (ULN), unless considered due to leukemic organ involvement; b) Total Bilirubin <=2.0 × ULN; c) Serum creatinine <=2.0 × ULN.
- A female of childbearing potential may be enrolled providing she: a) has a negative pregnancy test during screening period and; b) is routinely using an effective method of birth control that both results in a Pearl index < 1 and is considered highly effective as defined by the Clinical Trial Facilitation Group (e.g. combined estrogen and progestogen containing hormonal contraception, associated with inhibition of ovulation, intrauterine device, total sexual abstinence or bilateral tubal occlusion) until 6 months from the last study drug administration; c) undergoes a monthly pregnancy test until 6 months from the last study drug administration
- Able to give written informed consent before any study related procedure.
- NOTE: Inclusion criteria will be evaluated during the Screening Period, with the exception of inclusion criteria 3 and 4, which will be evaluated at Visit 1; inclusion criteria 5 and 6 will be re-evaluated prior to the first study drug administration (Visit 1).

Ausschlusskriterien

- Acute promyelocytic leukaemia (French-American-British (FAB) M3 classification).
- Active central nervous system involvement.
- Haematopoietic stem cell transplantation (HSCT) performed within 3 months prior to Screening Period. Patients with prior allogeneic HSCT performed more than 3 months prior to Screening Period are eligible with Medical Monitor approval.
- Active infection requiring intravenous antibiotics.
- Life-threatening illnesses other than AML, uncontrolled medical conditions or organ system dysfunction which, in the investigator's opinion, could compromise the patient's safety or interfere with the patient’s ability to comply with the study activities.
- Anti-tumour therapy within 14 days of study Visit 1 (Day 1, excluding hydroxyurea).
- Prior participation in an investigational study (procedure or device) within 21 days of study Visit 1 (Day 1).

	- Major surgery within 28 days of study Visit 1 (Day 1). - Radiotherapy within 28 days prior to study Visit 1 (Day 1) or scheduled along the study conduct. - Known history of human immunodeficiency virus (HIV) or active infection with hepatitis C virus (HCV) or hepatitis B virus (HBV). - Known hypersensitivity to MEN1112 excipients. - Other active malignancies. History of malignancy in the last 12 months (except basal cell or squamous cell skin cancer or carcinoma in situ of the cervix or breast or non-melanoma skin cancer). - Pregnant or breast-feeding women. - NOTE: Exclusion criteria will be evaluated during the Screening Period, with the exception of exclusion criteria 6, 7, 8 and 9, which will be evaluated at Visit 1; exclusion criteria 4 and 5 will be reevaluated prior to the first study drug administration (Visit 1)
Alter	18 Jahre und älter
Molekularer Marker	CD157
Prüfzentren	**Innere Medizin 2** (Geschlossen) Hämatologie / Medizinische Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Allg. Ansprechpartner der Abteilung Häma/Onko **Universitätsklinikum Frankfurt** (Geschlossen) Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Allg. Ansprechpartner der Abteilung Häma/Onko
Sponsor	Menarini Ricerche S.p.A.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02353143 EudraCT 2014-002433-59