Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL

SAMBA

Öffentlicher Titel	JNJ-56022473 bei MDS und AML nach Versagen einer Therapie basierend auf hypomethylierenden Substanzen
Wissenschaftl. Titel	Single agent JNJ-56022473 in MDS and AML patients failing hypomethylating agentbased therapy
Kurztitel	SAMBA
Studiennummer KN/ELN	LN_DEUTSC_2016_604
Studiengruppe	Deutsche MDS
Studienart	multizentrisch, einarmig, offen
Studienphase	Phase II
Erkrankung	Myelodysplastisches Syndrom (MDS) - Niedrigrisko und Intermediär I Myelodysplastisches Syndrom (MDS) - Intermediär II und Hochrisiko Myelodysplastisches Syndrom (MDS) - RAEB I Myelodysplastisches Syndrom (MDS) - RAEB II
Leukämiestadium	.
Haupt- und Nebenzielkriterien	- To assess the efficacy of JNJ-56022473 for the treatment of MDS and AML patients who have relapsed after or are refractory to treatment with HMAs To assess the efficacy of JNJ-56022473 for the treatment of MDS and AML patients who have relapsed after or are refractory to treatment with HMAs (Hauptzielkriterium)
Einschlusskriterien	- >=18 years of age - Diagnosis of AML or MDS - At least >= 5% BM blasts at the time of screening (done by central morphology) - At least one cytopenia (ANC < 1800/L or platelet count < 100,000/L or hemoglobin < 10 g/dL) - Failure to achieve complete or partial response or hematological improvement after at least six (azacitidine) or four (decitabine) 4-week treatment cycles administered during the past two years OR - Relapse after initial complete or partial response or hematological improvement observed after at least six (azacitidine) or four (decitabine) 4-week treatment cycles administered during the past two years OR - Intolerance to treatment with HMA (hypomethylating agents) defined by drug-related >= Grade 3 liver or renal toxicity leading to treatment discontinuation during the past two years - Failed to respond to, relapsed following, not eligible, or opted not to participate in bone marrow transplantation - Off all other treatments for AML/MDS for at least four weeks; Filgrastim (G-CSF) and erythropoietin are allowed before and during the study as clinically indicated - No medical need for or patient opted not to receive induction chemotherapy - ECOG performance status of 0-2 - Willing to adhere to the prohibitions and restrictions specified in the protocol - Signed informed consent
Ausschlusskriterien	- Previous treatment with a CD123 agent or T- or NK cell redirecting therapy - Patients having received intensive chemotherapy to treat HMA failure - Diagnosis of acute promyelocytic leukemia (APL) - WBC > 15 GPT/L - Any active malignancy within the past year, except basal cell or squamous cell skin cancer or carcinoma in situ of the cervix or breast

- Uncontrolled intercurrent illness including, but not limited to, symptomatic congestive heart failure, unstable angina pectoris, or cardiac arrhythmia
- Active infection not adequately responding to appropriate therapy
- Total bilirubin > 1.5 mg/dL not related to hemolysis or Gilbert's disease
- ALT/AST > 2.5 x upper limit of normal
- Serum creatinine > 2.0 mg/dL
- Patients who are unwilling to follow strict contraception requirements (including condom use for males with sexual partners, and for females: prescription oral contraceptives, contraceptive injections, intrauterine device, double-barrier method, contraceptive patch, or surgical sterilization) before entry, throughout the study and within 3 months after last study drug administration Female patients with reproductive potential who do not have a negative urine ß-HCG pregnancy test at screening and prior to the first study drug administration
- Female patients with reproductive potential who do not have a negative urine beta-HCG pregnancy test at screening and prior to the first study drug administration
- Female patients who are lactating

Alter	>= 18 Jahre
Status	Aktiv
Beginn der Rekrutierung	01.09.2016
Fallzahl	43
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Sponsoren	GWT-TUD GmbH
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Registrierung in anderen Studienregistern	European Clinical Trials Database - EUDRACT2016-000327-10