

<b>Öffentlicher Titel</b>	JNJ-56022473 bei MDS und AML nach Versagen einer Therapie basierend auf hypomethylierenden Substanzen
<b>Wissenschaftl. Titel</b>	Single agent JNJ-56022473 in MDS and AML patients failing hypomethylating agentbased therapy
<b>Kurztitel</b>	SAMBA
<b>Studiennummer KN/ELN</b>	LN_DEUTSC_2016_604
<b>Studiengruppe</b>	Deutsche MDS
<b>Studienart</b>	multizentrisch, einarmig, offen
<b>Studienphase</b>	Phase II
<b>Erkrankung</b>	Myelodysplastisches Syndrom (MDS) - Niedrigrisiko und Intermediär I Myelodysplastisches Syndrom (MDS) - Intermediär II und Hochrisiko Myelodysplastisches Syndrom (MDS) - RAEB I Myelodysplastisches Syndrom (MDS) - RAEB II
<b>Leukämienstadium</b>	.
<b>Haupt- und Nebenzielkriterien</b>	- 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)
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"> <li>- <math>\geq 18</math> years of age</li> <li>- Diagnosis of AML or MDS</li> <li>- At least <math>\geq 5\%</math> BM blasts at the time of screening (done by central morphology)</li> <li>- At least one cytopenia (ANC <math>&lt; 1800/L</math> or platelet count <math>&lt; 100,000/L</math> or hemoglobin <math>&lt; 10</math> g/dL)</li> <li>- 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</li> <li>- 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</li> <li>- Intolerance to treatment with HMA (hypomethylating agents) defined by drug-related <math>\geq</math> Grade 3 liver or renal toxicity leading to treatment discontinuation during the past two years</li> <li>- Failed to respond to, relapsed following, not eligible, or opted not to participate in bone marrow transplantation</li> <li>- 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</li> <li>- No medical need for or patient opted not to receive induction chemotherapy</li> <li>- ECOG performance status of 0-2</li> <li>- Willing to adhere to the prohibitions and restrictions specified in the protocol</li> <li>- Signed informed consent</li> </ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"> <li>- Previous treatment with a CD123 agent or T- or NK cell redirecting therapy</li> <li>- Patients having received intensive chemotherapy to treat HMA failure</li> <li>- Diagnosis of acute promyelocytic leukemia (APL)</li> <li>- WBC <math>&gt; 15</math> GPT/L</li> <li>- Any active malignancy within the past year, except basal cell or squamous cell skin cancer or carcinoma in situ of the cervix or breast</li> </ul>

- 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  $\beta$ -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

<b>Alter</b>	>= 18 Jahre
<b>Status</b>	Aktiv
<b>Beginn der Rekrutierung</b>	01.09.2016
<b>Fallzahl</b>	43
<b>Studienleiter/in</b>	Platzbecker, Prof. Dr. med., Uwe Universitätsklinikum Dresden Medizinische Klinik und Poliklinik Fetscherstr. 74 01307 Dresden Tel: +49 (0)351 4582583 Fax: +49 (0)351 458-5362 E-Mail: <a href="mailto:Uwe.Platzbecker@uniklinikum-dresden.de">Uwe.Platzbecker@uniklinikum-dresden.de</a>
<b>Kontaktperson f. wissenschaftl. Anfragen (WHO)</b>	Platzbecker, Prof. Dr. med., Uwe Universitätsklinikum Dresden Medizinische Klinik und Poliklinik Fetscherstr. 74 01307 Dresden Tel: +49 (0)351 4582583 Fax: +49 (0)351 458-5362 E-Mail: <a href="mailto:Uwe.Platzbecker@uniklinikum-dresden.de">Uwe.Platzbecker@uniklinikum-dresden.de</a>
<b>Ansprechpartner</b>	<b>Organisatorische Anfragen</b> Gloaguen, Silke Tel: +49 (0)351 4584722 E-Mail: <a href="mailto:silke.gloaguen@uniklinikum-dresden.de">silke.gloaguen@uniklinikum-dresden.de</a>
<b>Sponsoren</b>	GWT-TUD GmbH
<b>Förderer</b>	Janssen
<b>Registrierung in anderen Studienregistern</b>	European Clinical Trials Database - EUDRACT2016-000327-10