KURZPROTOKOLL
MOR208C203

Öffentlicher Titel	Phase II Studie zu Lenalidomid mit MOR00208 bei Patienten mit rezidiviert/refraktärem diffusen großzelligen B-Zell-Lymphom
Wissenschaftl. Titel	A Phase II, Single Arm, Open-label, Multicentre Study to Evaluate the Safety and Efficacy of Lenalidomide Combined with MOR00208 in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R-R DLBCL)
Kurztitel	MOR208C203
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig
Studienphase	Phase II
Erkrankung	Blut: Non-Hodgkin-Lymphome (NHL), hoch-maligne: Rezidiviert/refraktär
Ziele	- Objective response rate (ORR = complete response [CR] + partial response [PR]) - Disease control rate (DCR) DCR = CR + PR + SD - Duration of response (DoR) - Progression-free survival (PFS) - Overall survival (OS) - Time to progression (TTP) - Time to next treatment (TTNT) TTNT is defined as the time from study entry (= first dosing) to the institution of next therapy for any reason including disease progression, treatment toxicity and patient preference. TTNT will be descriptively analysed. - Safety of LEN combined with MOR00208 according to the frequency and severity of adverse events (AEs) Safety profile is assessed according to the frequency and severity of adverse events (AEs) - Potential immunogenicity of MOR00208 The absolute number and percentage of patients, who develop anti-MOR00208 antibodies, and the results of semi-quantitative anti-MOR00208 antibody titre determinations of confirmed positive sample assessments will be tabulated - Pharmacokinetics (PK) of MOR00208 maximum serum concentration [Cmax] - Pharmacokinetics (PK) of MOR00208 time to maximum serum concentration [tmax] - Pharmacokinetics (PK) of MOR00208 apparent trough serum concentration before dosing [Cpd] - Pharmacokinetics (PK) of MOR00208 area under the serum concentration versus time curve from time 0 to the time t of the last quantifiable concentration [AUC0-t]
Einschlusskriterien	- Age 18-80 years old - Histologically confirmed diagnosis of DLBCL - Fresh tumour tissue for central pathology review and correlative studies must be provided. The only exception is the availability of tumour tissue acquired 3 years prior to screening for this protocol - Patients must have: relapsed and/or refractory disease at least one bidimensionally measurable disease site (transverse diameter of 1.5 cm and perpendicular diameter of 1.0 cm at baseline) received at least one, but no more than two previous systemic regimens for the treatment of DLBCL and one therapy line must have included a CD20-targeted therapy Eastern Cooperative Oncology Group 0 to 2 - Patients not considered in the opinion of the investigator eligible, or patients unwilling to undergo intensive salvage therapy including ASCT - Patients must meet the following laboratory criteria at screening: absolute neutrophil count 1.5 × 109/L platelet count 90 × 109/L total serum bilirubin 2.5 × ULN or 3 × ULN in cases of liver involvement alanine transaminase, aspartate aminotransferase and alkaline phosphatase 3 × ULN or <5 × ULN in cases of liver involvement serum creatinine clearance 60 mL/minute

	- Females of childbearing potential (FCBP) must: not be pregnant refrain from breastfeeding and donating blood or oocytes agree to ongoing pregnancy testing commit to continued abstinence from heterosexual intercourse, or agree to use and be able to comply with the use of double-barrier contraception - Males (if sexually active with a FCBP) must use an effective barrier method of contraception refrain from donating blood or sperm - In the opinion of the investigator the patients must: be able and willing to receive adequate prophylaxis and/or therapy for thromboembolic events be able to understand the reason for complying with the special conditions of the pregnancy prevention risk management plan and give written acknowledgement of this.
Ausschlusskriterien	- Patients who have: other histological type of lymphoma primary refractory DLBCL or relapsed within period 3 months of prior CD20-targeted therapy a history of "double/triple hit" DLBCL - Patients who have, within 14 days prior to Day 1 dosing: not discontinued CD20-targeted therapy, chemotherapy, radiotherapy, investigational anticancer therapy or other lymphoma specific therapy undergone major surgery or suffered from significant traumatic injury received live vaccines. required parenteral antimicrobial therapy for active, intercurrent infections - Patients who: were previously treated with CD19-targeted therapy or IMiDs® (e.g. thalidomide, LEN) have undergone ASCT within the period 3 months prior to signing the informed consent form. have undergone previous allogenic stem cell transplantation have a history of deep venous thrombosis/embolism and who are not willing/able to take venous thromboembolic event prophylaxis during the entire treatment period concurrently use other anticancer or experimental treatments - Prior history of malignancies other than DLBCL, unless the patient has been free of the disease for 5 years prior to screening. - Patients with: positive hepatitis B and/or C serology. known seropositivity for or history of active viral infection with human immunodeficiency virus (HIV) CNS lymphoma involvement history or evidence of clinically significant cardiovascular, CNS and/or other systemic disease that would in the investigator's opinion preclude participation in the study or compromise the patient's ability to give informed consent.
Alter	18 - 80 Jahre
Fallzahl	80
Sponsor	MorphoSys AG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02399085 EudraCT 2014-004688-19