KURZPROTOKOLL
20140286

Öffentlicher Titel	Phase I Studie zu Blinatumomab bei rezidierten/refraktären niedrigmalignen Non-Hodgkin-Lymphomen
Wissenschaftl. Titel	A Phase 1b Open-label Study Investigating the Safety and Pharmacokinetics of Administration of Subcutaneous Blinatumomab for the Treatment of Relapsed/Refractory Indolent Non-Hodgkin's Lymphoma
Kurztitel	20140286
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase I
Erkrankung	Blut: Non-Hodgkin-Lymphome (NHL), niedrig-maligne: andere NHL - rezidiviert/refraktär

Einschlusskriterien

- Subject has provided informed consent
- Age >=18 years old at the time of informed consent
- Subjects must have a histologically determined B cell NHL subtype as defined in the bullets below. In addition, they must have disease that is primary refractory after initial therapy or have relapsed disease. -Follicular Lymphoma I, II, IIIA; -Marginal zone lymphoma (extranodal, nodal, or splenic). Subjects with gastric mucosa-associated lymphoid tissue must have progressed after Helicobacter pylori therapy and radiation. Subjects with splenic marginal zone lymphoma must have prior splenectomy; -Lymphoplasmocytic lymphoma; -Mantle cell lymphoma ([MCL] with the exception of aggressive MCL, defined as Ki67 > 30%, or blastoid histology); -Small lymphocytic lymphoma
- Subjects without standard therapy alternatives, or contraindicated for standard therapy by investigator, or subjects unwilling to receive standard therapy. The disease status must be 1 of the following: -primary refractory (at least 1 prior line of therapy); -relapsed within 1 year of first response; -responded to initial therapy for >=1 year and relapsed after 2 or more lines of therapy, including an anti-CD20 monoclonal antibody
- Measurable disease that has not been previously irradiated on positron emission tomography–computed tomography (PET-CT), or computed tomography (CT), of at least 1.5 cm within the last 21 days before the start of IP treatment.
- Eastern Cooperative Oncology Group (ECOG) performance status <=2
- Life expectancy >=3 months as determined by the treating physician
- Subjects must have adequate organ and bone marrow function at screening

Ausschlusskriterien

- Currently receiving treatment in another investigational device or drug study, or less than 30 days between ending treatment on another investigational device or drug study(ies) and start of IP treatment. Other investigational procedures while participating in this study are excluded
- Known hypersensitivity to immunoglobulins or any other component of the study drug.
- Subject likely to not be available to complete all protocol required study visits or procedures to the best of the subject and investigator's knowledge.
- History or evidence of any other clinically significant disorder, condition or disease (with the exception of those outlined above) that, in the opinion of the investigator or Amgen physician, if consulted, would pose a risk to subject safety or interfere with the study evaluation, procedures or completion.
- Subjects who have had treatments with anti-cancer agents including rituximab or obinutuzumab and/or other monoclonal antibody or radioimmunotherapy within 6 weeks prior to starting IP treatment.
- Autologous stem cell transplantation within 12 weeks prior to starting IP treatment or past history of allogeneic stem cell transplantation.
- Subjects who have received anti-CD 19 targeted therapies, chimeric antigen receptor T-cell or other cellular therapies for the treatment of their lymphoma.

- Subjects with suspected or known brain metastases should be excluded from this clinical study because of their poor prognosis and because they often develop progressive neurologic dysfunction that would confound the evaluation of neurologic and other adverse events.
- Infection with human immunodeficiency virus (HIV) or chronic infection with hepatitis B virus or hepatitis C virus.
- History of or clinically relevant central nervous system (CNS) pathology such as epilepsy, recurrent seizures, paresis, aphasia, apoplexia, severe brain injuries, cerebellar disease, organic brain syndrome, or psychosis.
- History of malignancy other than their lymphoma with the exception of: -Malignancy treated with curative intent and with no known active disease present for >= 3 years before enrollment and felt to be at low risk for recurrence by the treating physician; -Adequately treated non-melanoma skin cancer or lentigo maligna without evidence of disease; -Adequately treated cervical carcinoma in situ without evidence of disease; -Adequately treated breast ductal carcinoma in situ without evidence of disease; -Prostatic intraepithelial neoplasia without evidence of prostate cancer; -Adequately treated urothelial papillary noninvasive carcinoma or carcinoma in situ.
- Uncontrolled intercurrent illness including, but not limited to, ongoing or uncontrolled systemic fungal, bacterial, viral, or other infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.
- A female who is pregnant or breastfeeding or planning to become pregnant or breastfeed during treatment and for an additional 48 hours (Period 1) or 72 hours (Period 2), respectively, after the last dose of blinatumomab (Female subjects of childbearing potential should only be included in the study after a confirmed menstrual period and a negative highly sensitive urine or serum pregnancy test).
- A female of childbearing potential unwilling to use a highly effective method of contraception during treatment and for an additional 48 hours (Period 1) or 72 hours (Period 2), respectively, after the last dose of blinatumomab. Refer to Section 6.9 for additional contraceptive requirement information.

Alter	18 Jahre und älter
Sponsor	AMGEN GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02961881 EudraCT 2016-002034-76