This study is currently recruiting participants.

Verified December 2013 by MorphoSys AG

Sponsor:
MorphoSys AG

Information provided by (Responsible Party):
MorphoSys AG

ClinicalTrials.gov Identifier:
NCT01685008

First received: September 3, 2012
Last updated: December 17, 2013
Last verified: December 2013

Purpose

This is an open-label, multicentre study to characterize the safety and preliminary efficacy of the human anti CD19 antibody MOR00208 in adult subjects with relapsed/refractory non-Hodgkin’s lymphoma (NHL) who have received at least 1 prior therapy containing rituximab (at least once).

**Condition**

Non-Hodgkin Lymphoma

**Intervention**

Drug: MOR00208 (formerly Xmab 5574)

**Phase**

Phase 2

Study Type: Interventional

Study Design: Endpoint Classification: Efficacy Study

Intervention Model: Single Group Assignment

Masking: Open Label

Primary Purpose: Treatment

Official Title: A Phase IIa, Open-label, Multicenter Study of Single-Agent MOR00208, an Fc-optimized Anti-CD19 Antibody in Patients With Relapsed or Refractory Non-Hodgkin’s Lymphoma (NHL)

Resource links provided by NLM:

MedlinePlus related topics: Lymphoma

Genetic and Rare Diseases Information Center resources: Lymphoma, Small Cleaved-cell, Diffuse B-cell Lymphomas

U.S. FDA Resources

Further study details as provided by MorphoSys AG:

Primary Outcome Measures:

- Overall response rate (ORR) [ Time Frame: 4 years ] [ Designated as safety issue: No ]
  - ORR=CR (Complete Remission) + PR(Partial Remission) Antitumor activity of MOR00208

Secondary Outcome Measures:

- 1. Patients response duration evaluation by hematology, bone marrow aspirated or biopsy, CT [ Time Frame: bi monthly, up to 48 months ] [ Designated as safety issue: No ]
  - 2. Survival will be evaluated by assessing adverse events, clinical lab data and vital signs, ECG, physical exam [ Time Frame: weekly, up to 4 years ] [ Designated as safety issue: Yes ]
  - 3. Pharmacokinetics of MOR00208 (Pharmacokinetic assessment comprises: Cmax, tmax, t1/2, CL [ Time Frame: weekly, up to 12 weeks; 0, 1, 4, 24 hours post dose ] [ Designated as safety issue: No ]
  - 4. Number of patients who develop anti-MOR00208 antibodies as a measure of immunogenicity [ Time Frame: monthly up to 4 years ] [ Designated as safety issue: No ]

Estimated Enrollment: 120

Study Start Date: May 2013

Estimated Study Completion Date: February 2017

Estimated Primary Completion Date: November 2016 (Final data collection date for primary outcome measure)
Arms

Experimental: MOR00208 (formerly Xmab5574)
intravenous Infusion of MOR00208, Fc-Optimized Anti-CD19 Antibody

Assigned Interventions

Drug: MOR00208 (formerly Xmab 5574)
Other Name: MOR208

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
1. male or female patients ≥ 18 years of age.
2. histologically-confirmed diagnosis according to REAL/WHO classification, of the following B-cell lymphomas :
   a. FL
   b. MCL
   c. DLBCL
   d. Other indolent NHL (eg, MZL/MALT)
3. Patients’ NHL must have progressed after at least 1 prior rituximab containing regimen.
4. one site of measurable disease by magnetic resonance imaging (MRI) or computed tomography (CT) scan defined as at least one lesion that measures at least 1.5 × 1.5 cm, Exception: For patients with MCL only, patients with nonmeasurable disease but evaluable sites (bone marrow, spleen, peripheral blood, gastrointestinal tract) can be enrolled.
5. Patients who have previously received an autologous stem cell transplantation must be at least 4 weeks post-transplant before study drug administration and must have exhibited a full haematological recovery
6. discontinued previous monoclonal antibody therapy (except rituximab) or radioimmunotherapy administration for at least 60 days before study drug administration.
7. off rituximab for at least 14 days before the screening visit and be confirmed to have either no response or have disease progression after rituximab treatment.
8. Patients with DLBCL had a positive [18F]fluorodeoxy glucose-positron emission tomography (FDG-PET) scan at baseline (Cheson response criteria)
9. Life expectancy of > 3 months.
10. ECOG performance status of < 3.
11. laboratory criteria at screening:
   a. Absolute neutrophil count (ANC) ≥ 1.0 (1000/mm3)
   b. Platelet count ≥ 75 × 10^9/L without previous transfusion within 10 days of first study drug administration
   c. Haemoglobin ≥ 8.0 g/dL (may have been transfused)
   d. Serum creatinine < 2.0 x upper limit of normal (ULN)
   e. Total bilirubin ≤ 2.0 × ULN
   f. Alanine transaminase (ALT) and aspartate aminotransferase (AST) ≤ 2.5 × ULN.
12. If a female of childbearing potential, a negative pregnancy test must be confirmed before enrolment and use of double-barrier contraception, oral contraceptive plus barrier contraceptive, or confirmation of having undergone clinically documented total hysterectomy and/or oophorectomy, tubal ligation.
13. If a male, an effective barrier method of contraception must be used during the study and for 3 months after the last dose if the patient is sexually active with a female of childbearing potential.
14. able to comply with all study-related procedures, medication use, and evaluations.
15. able understand and give written informed consent and comply with the study protocol.

Exclusion Criteria:
1. Previous treatment with cytotoxic chemotherapy, immunotherapy, radiotherapy or other lymphoma specific therapy within 14 days before the screening visit or patient has not recovered from side effects of previous lymphoma-specific therapy.
2. Treatment with a systemic investigational agent within 28 days before the screening visit.
3. Previous treatment with an anti-CD19 antibody or fragments
4. Previous allogenic stem cell transplantation.
5. Known or suspected hypersensitivity to the excipients contained in the study drug formulation.
6. Clinically significant cardiovascular disease or cardiac insufficiency,cardiomyopathy, preexisting clinically significant arrhythmia, acute myocardial infarction within 3 months of enrolment, angina pectoris within 3 months of enrolment.
7. Clinical or laboratory evidence of active hepatitis B or hepatitis C.8. History of HIV infection.
9. Any active systemic infection (viral, fungal, or bacterial) requiring active parenteral antibiotic therapy within 4 weeks of study drug administration.
10. Current treatment with immunosuppressive agents other than prescribed corticosteroids (not more than 10-mg prednisone equivalent).
11. Major surgery or radiation therapy within 4 weeks before first study drug administration.
12. Systemic diseases (cardiovascular, renal, hepatic, etc) that would prevent study treatment in the investigator's opinion.

13. History or clinical evidence of central nervous system (CNS), meningeal, or epidural disease, including brain metastasis.

14. Active treatment/chemotherapy for another primary malignancy within the past 5 years. Pregnancy or breastfeeding in women and women of childbearing potential not using an acceptable method of birth control.

16. History of noncompliance to medical regimens or patients who are considered potentially unreliable or not cooperative.

**Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT01685008

**Contacts**

Contact: Harald Haeske +49 89 89927 ext 0 info@morphosys.com

**Locations**

**United States, Connecticut**

MorphoSys Research Site  
Norwalk, Connecticut, United States, 06856  
Contact: Jennifer Long  203-852-2996 jennifer.long@norwalkhealth.org  
Principal Investigator: Richard Frank, MD

**United States, New Jersey**

MorphoSys Research Site  
Hackensack, New Jersey, United States, 07601  
Contact: Andre Goy, MD  201-336-8772 agoy@humed.com  
Contact: Kara Yannotti  201-495-0605 kyannotti@hackensackumc.org  
Principal Investigator: Andre Goy, MD

**United States, Ohio**

Morphosys Research Site  
Columbus, Ohio, United States, 43201

**United States, Texas**

Morphosys Research Site  
Lubbock, Texas, United States, 79410  
Contact: Donald Quick, MD  806-725-8000  
Contact: Erin Cotton  806.725.8001 cottone1@covhs.org  
Principal Investigator: Donald Quick, MD

**Belgium**

MorphoSys Research Site  
Brussels #1, Belgium

MorphoSys Research Site  
Brussels #2, Belgium

MorphoSys Research Site  
Edegem, Belgium

**Germany**

MorphoSys Research Site  
Berlin, Germany

MorphoSys Research Site  
Mainz, Germany

Morphosys Research Site  
Ulm, Germany

**Hungary**

Morphosys Research Site  
Budapest #1, Hungary

MorphoSys Research Site  
Budapest #2, Hungary

Morphosys Research Site  
Debrecen, Hungary

**Italy**

MorphoSys Research Site  
Bologna, Italy
MorphoSys Research Site
Firenze, Italy
Morphosys Recruiting
Genova, Italy
Morphosys Research Site
Modena, Italy
Morphosys Research Site
Novara, Italy
Morphosys Recruiting
Poland
MorphoSys Research Site
Chorzów, Poland
MorphoSys Research Site
Kraków, Poland
MorphoSys Research Site
Lódz, Poland
MorphoSys Research Site
Slupsk, Poland
Morphosys Recruiting
Spain
Morphosys Research Site
Madrid #1, Spain
Morphosys Recruiting
Madrid #2, Spain
Morphosys Recruiting
Madrid #3, Spain
Morphosys Research Site
Sevilla, Spain
Morphosys Recruiting
Sponsors and Collaborators
MorphoSys AG

Investigators
Principal Investigator: Kristi Blum, MD Ohio State University

More Information
No publications provided

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Other Study ID Numbers: MOR208C201, 2012-002659-41
Study First Received: September 3, 2012
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Health Authority:
United States: Food and Drug Administration
Germany: Paul-Ehrlich-Institut
Italy: The Italian Medicines Agency
Spain: Spanish Agency of Medicines
Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Hungary: National Institute of Pharmacy
Belgium: Federal Agency for Medicinal Products and Health Products

Keywords provided by MorphoSys AG:
NHL
CD19
MOR208
MOR00208
Xmab5574
B-Cell Non-Hodgkin’s Lymphoma
Fc-optimized Anti-CD19 Antibody

Additional relevant MeSH terms:
Lymphoma
Lymphoma, Non-Hodgkin
Neoplasms by Histologic Type
Neoplasms
Lymphoproliferative Disorders
Lymphatic Diseases
Immunoproliferative Disorders
Immunologic Factors
Physiological Effects of Drugs
Pharmacologic Actions

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