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Trial record **1 of 1** for: MOR202C101

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A Phase I/IIa Study of Human Anti-CD38 Antibody MOR03087 in Relapsed/Refractory Multiple Myeloma

This study is currently recruiting participants.

Verified June 2013 by MorphoSys AG

Sponsor:
MorphoSys AG

Information provided by (Responsible Party):
MorphoSys AG

ClinicalTrials.gov Identifier:
NCT01421186

First received: July 29, 2011
Last updated: June 27, 2013
Last verified: June 2013
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

This is an open-label, multicentre, dose escalation study to characterize the safety and preliminary efficacy of the human anti CD38 antibody MOR03087 in adult subjects with relapsed/refractory multiple myeloma as monotherapy and in adult subjects with relapsed/refractory multiple myeloma as combination with standard therapy.

Condition	Intervention	Phase
Multiple Myeloma	Drug: MOR03087 Drug: MOR03087, Bortezomib, Dexamethasone Drug: MOR03087, Lenalidomide, Dexamethasone	Phase 1 Phase 2

Study Type: Interventional

Study Design: Allocation: Non-Randomized
Endpoint Classification: Safety Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase I/IIa, Open-Label, Multicentre, Dose-Escalation Study to Evaluate the Safety and Preliminary Efficacy of the Human Anti-CD38 Antibody MOR03087 as Monotherapy and in Combination With Standard Therapy in Subjects With Relapsed/Refractory Multiple Myeloma

Resource links provided by NLM:

MedlinePlus related topics: Multiple Myeloma

Drug Information available for: Dexamethasone Dexamethasone acetate Dexamethasone sodium phosphate Bortezomib Lenalidomide

U.S. FDA Resources

Further study details as provided by MorphoSys AG:

Primary Outcome Measures:

- 1. Determination of maximum tolerated dose and / or recommended dose [Time Frame: after all patients have completed the first 2 cycles of treatment (up to 20 weeks)] [Designated as safety issue: Yes]
- 2. Safety will be evaluated by assessing adverse events, clinical lab data and vital signs [Time Frame: every 2 to 4 weeks] [Designated as safety issue: Yes]
- 3. Number of participants who develop anti-MOR03087 antibodies as a measure of immunogenicity [Time Frame: 10 weeks] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- 1. Pharmacokinetics of MOR03087 (Pharmacokinetic assessment comprises: C max, t max, t 1/2, CL, AVC) [Time Frame: 10 weeks] [Designated as safety issue: No]
- 2. Overall response rate based on standard response criteria, change from baseline in serum M protein levels [Time Frame: monthly (approximately 1 year)] [Designated as safety issue: No]

Estimated Enrollment:	82
Study Start Date:	July 2011
Estimated Study Completion Date:	June 2015
Estimated Primary Completion Date:	April 2015 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Phase I Dose escalation	Drug: MOR03087 Intravenous infusion of MOR03087 for up to 2 cycles
Experimental: Phase IIa Monotherapy extension	Drug: MOR03087 Intravenous infusion of MOR03087 for up to 4 cycles
Experimental: Phase Ib MOR03087 combined with bortezomib	Drug: MOR03087, Bortezomib, Dexamethasone Intravenous infusion of MOR03087 in combination with intravenous injection of bortezomib (and if applicable, addition of dexamethasone)
Experimental: Phase Ib MOR03087 combined with lenalidomide	Drug: MOR03087, Lenalidomide, Dexamethasone Intravenous infusion of MOR03087 in combination with oral lenalidomide and dexamethasone

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 subjects 18 years and older
2. Relapsed or refractory multiple myeloma defined as failure of at least 2 previous therapies
3. Presence of serum M-protein ≥ 0.5 g per 100 mL (≥ 5 g/L) and / or urine M-protein ≥ 200 mg/24-h period and / or serum FLCs ≥ 10 mg/100 mL (≥ 100 mg/L) combined with an abnormal ratio of lambda and kappa chains
4. ANC ≥ 1.0 (1,000 / mm3) and platelets ≥ 80x10E9/L
5. Haemoglobin ≥ 8 g/dL
6. Ability to comply with all study related procedures, medication use and evaluations

Exclusion Criteria:

1. Primary refractory multiple myeloma
2. History of significant cerebrovascular disease or sensory or motor neuropathy of toxicity grade 3 or higher
3. Treatment with systemic investigational agent within 28 days prior screening visit
4. Solitary plasmocytoma or plasma cell leukaemia

5. Previous allogenic SCT
6. Prior therapy with other monoclonal antibodies targeting the CD38 antigen and prior therapy with other IgG monoclonal antibodies within 3 months prior to screening and IgM monoclonal antibodies within 1 month prior to screening visit
7. Active systemic infection
8. Systemic disease preventing study treatment
9. Multiple myeloma with CNS involvement
10. Active treatment / chemotherapy for other primary malignancy within past 3 years
11. Significant uncontrolled cardiovascular disease or cardiac insufficiency

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01421186

Contacts

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Locations

Austria

Universitätsklinikum Graz, Auenbruggerplatz 38 **Recruiting**
Graz, Austria, 8036

Allgemeines Krankenhaus Wien, Währinger Gürtel 18-20 **Recruiting**
Wien, Austria, 1090

Germany

Universitäsklinikum Heidelberg, Klin.-Pharmakologisches Studienzentrum, Im Neuenheimer Feld 410 **Recruiting**
Heidelberg, Germany, 69120

Klinikum rechts der Isar/ Studien / III. Med. Klinik/ Ismaninger Str. 22 **Recruiting**
Munich, Germany, 81675

Universitätsklinikum Würzburg, Medizinische Klinik und Poliklinik II, Studienambulanz für Hämatologie/Onkologie und Infektiologie, Oberdürrbacher Straße 6 **Recruiting**
Würzburg, Germany, 97080

Sponsors and Collaborators

MorphoSys AG

More Information

No publications provided

Responsible Party:	MorphoSys AG
ClinicalTrials.gov Identifier:	NCT01421186 History of Changes
Other Study ID Numbers:	**MOR202C101**, DRKS00003145
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Health Authority:	Germany: Paul-Ehrlich-Institut Austria: Bundesamt für Sicherheit im Gesundheitswesen

Keywords provided by MorphoSys AG:
Multiple Myeloma
MOR03087
Lenalidomide
Bortezomib
CD38

Additional relevant MeSH terms:

Multiple Myeloma	Dexamethasone
Neoplasms, Plasma Cell	Dexamethasone 21-phosphate
Neoplasms by Histologic Type	Bortezomib
Neoplasms	Lenalidomide
Hemostatic Disorders	Thalidomide
Vascular Diseases	BB 1101
Cardiovascular Diseases	Anti-Inflammatory Agents
Paraproteinemias	Therapeutic Uses
Blood Protein Disorders	Pharmacologic Actions
Hematologic Diseases	Antiemetics
Hemorrhagic Disorders	Autonomic Agents
Lymphoproliferative Disorders	Peripheral Nervous System Agents
Immunoproliferative Disorders	Physiological Effects of Drugs
Immune System Diseases	Central Nervous System Agents
Dexamethasone acetate	Gastrointestinal Agents

ClinicalTrials.gov processed this record on December 08, 2013