PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Phase II/III Study for Remission Induction With Bortezomib (Vel), Cyclophosphamide (C) and Dexamethasone (D) in Patients <= 60 Years With Untreated Multiple Myeloma and Planned High Dose Chemotherapy: (VelCD)

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The purpose of this clinical study is to investigate induction therapy for remission with bortezomib, cyclophosphamide and dexamethasone in patients aged 60 years and younger with multiple myeloma planned for high-dose chemotherapy with stem cell transplantation.

Brief Summary in Scientific Language

Today high dose chemotherapy (HD-CT) with stem cell support is considered the standard for younger patients with multiple myeloma. The standard protocol for induction therapy before HD-CT is a combination therapy consisting of vincristine, adriamycin and dexamethasone. 40% of the patients do not respond to conventional induction therapy. With the combination of bortezomib and cyclophosphamide, a potent cytotoxic substance already in use against multiple myeloma, an increased efficacy is expected. In this prospective, open-label, single arm, multi-center study, induction therapy for remission with bortezomib, cyclophosphamide and dexamethasone in patients aged 60 years and younger with multiple myeloma planned for high-dose chemotherapy with stem cell transplantation is investigated. In the first part an evaluation of an optimal dose of cyclophosphamide if combined with a

fixed bortezomib and dexamethasone dose is done and in the second part, efficacy and tolerance of the assessed dose is evaluated. Primary outcome of the second part is response prior to high dose chemotherapy. The first part (dose definition) has already been completed.On the days patients receive bortezomib, vital signs and blood tests and, at the first day of each cycle, a physical examination will be performed. Adverse events are to be documented and reported during the study in accordance with ICH-GCP guidelines. 400 male and female patients with untreated Multiple Myeloma are to be included in this study. In the first part of the study, the number of patients was restricted to 30. Thus, approximately 370 patients were to be included in the second part. Bortezomib 1,3 mg/m2 by intravenous bolus on Day 1, 4, 8, and 11 for a maximum of 3 cycles. One cycle consists of 21 days. Cyclophosphamide 900mg as intravenous infusion on Day 1 of each cycle. Dexamethasone 40 mg on Days 1, 2, 4, 5, 8, 9, 11, and 12 of each cycle.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00003762**
- Date of Registration in DRKS: **2012/05/02**
- Date of Registration in Partner Registry or other Primary Registry: **2009/01/23**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT00833560 (ClinicalTrials.gov)**
- Sponsor-ID: **CR005242 (Janssen-Cilag G.m.b.H)**

Health condition or Problem studied

- Free text: **Multiple Myeloma**
- Free text: **Remission Induction**
- Free text: **Stem Cell Transplantation**
- ICD10: **C90.0 - Multiple myeloma**

Interventions/Observational Groups

- Arm 1: **Drug: Cyclophosphamide (Cy)**
- Arm 2: **Drug: Bortezomib (Btz)**
- Arm 3: **Drug: Dexamethasone (D)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **II-III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Efficacy (Response); time frame: efficacy of response after every one of three cycles

Secondary Outcome

- Tolerability and comparison of response rates in different cytogenetic risk groups; time frame: efficacy of response after every one of three cycles

Countries of recruitment

Locations of Recruitment

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2006/03/31**
- Target Sample Size: **401**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **60 Years**

Additional Inclusion Criteria

- Multiple Myeloma stage II/III Durie and Salmon

- Patients without preceding cytostatic treatment, however, pretreatment with dexamethasone is allowed

- Written informed consent

- Female patients have to be postmenopausal or surgically sterilized or willing to use an acceptable method of birth control (i.e.1 hormonal contraceptives, intrauterine device, diaphragm with spermicide, total abstinence or a vasectomised partner) during and 6 months after the treatment, pregnancy test has to be negative

- Male patients have to use an acceptable method of birth control during and 6 months after the treatment

- males should be offered sperm cryoconservation

- Karnofsky performance status >= 60%

- AST and ALT < 2.5 x the upper limit of normal (ULN)

- Bilirubin < 2.5 x the upper limit of normal (ULN)

- Adequate haematological parameters: leucocytes >= 3.0 x 109/l, neutrophils >= 1.5 x 109/l, platelets >= 75 x 109/l

- Creatinin < 2 x the upper limit of normal (ULN)

Exclusion criteria

- Non-secretory multiple myeloma

- known allergy or hypersensitivity to bortezomib, bor, mannitol, cyclophosphamide

- Estimated life expectancy less than 3 months

- History of cancer (except basal cell carcinoma) in the last 5 years

- Patients with history of peripheral neuropathy CTC grade >= 2

- Other severe illnesses that could potentially interfere with the completion of treatment according to this protocol: a. Insufficient liver or renal function, clinically relevant lung disease or gastrointestinal diseases, b. New York Heart Association (NYHA) > Class II heart failure, myocardial infarction within 6 months of enrollment, uncontrolled angina, severe uncontrolled ventricular arrhythmias (Lown IVB), electrocardiographic evidence of acute ischemia or active conduction system abnormalities, cardiac amyloidosis, c. Active systemic infection requiring treatment, d. Poorly controlled hypertension or vascular disease. Diabetes mellitus, or other serious endocrine or metabolic diseases

- Patients with hypotension (defined as RRsys sitting <= 100 mmHg and/or RRdia sitting <= 60 mmHg

- HIV positive patients

- Patients with active hepatitis B and/or C

- Pregnant or breast-feeding female patients

- Insufficient compliance, foreseeable follow-up problems, psychiatric diseases, known abuse of alcohol or drugs, legal incompetence

- Participation in another trial either parallel to this trial or within the last 30 days before enrollment into this trial

- **except drug studies for relapse in the observation period.**

Addresses

■ **Primary Sponsor**

Janssen-Cilag G.m.b.H

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Janssen-Cilag G.m.b.H
Janssen-Cilag G.m.b.H. Clinical Trial

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Public Queries**

Janssen-Cilag G.m.b.H
Janssen-Cilag G.m.b.H. Clinical Trial

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Sources of Monetary or Material Support

■ **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2009/06/01**

Trial Publications, Results and other documents