Trial record **1 of 1** for: SAR650984 (TCD13983)

Previous Study | Return to List | Next Study

Study of Isatuximab Combined With Bortezomib + Cyclophosphamide + Dexamethasone (VCD) and Bortezomib + Lenalidomide + Dexamethasone (VRD) in Newly Diagnosed Multiple Myeloma (MM) Non Eligible for Transplant (CyBorDSAR)

This study is currently recruiting participants.

See Contacts and Locations

Verified November 2017 by Sanofi

Sponsor:
Sanofi

ClinicalTrials.gov Identifier:
NCT02513186

First Posted: July 31, 2015
Last Update Posted: November 9, 2017

Information provided by (Responsible Party):
Sanofi

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

Purpose

Primary Objective:

- To determine the maximum tolerated dose (MTD) and recommended dose (RD) of isatuximab when administered in combination with bortezomib, cyclophosphamide, and dexamethasone (VCDI) based on the dose-limiting toxicity(ies) (DLTs) observed in patients with newly diagnosed multiple myeloma non-eligible for transplantation.
- To evaluate safety and preliminary efficacy (overall response rate, complete response rate and duration of response) of isatuximab in combination with 2 bortezomib-based regimens (VCDI) and isatuximab with bortezomib, dexamethasone, and lenalidomide (VRDI).

Secondary Objectives:

- To characterize the overall safety profile of isatuximab in combination with each bortezomib-based regimen, including cumulative toxicities.
- To characterize the pharmacokinetic (PK) profile of isatuximab and each combination drug in each isatuximab/bortezomib-based regimen.
- To evaluate the immunogenicity of isatuximab in combination treatments.
- To evaluate the preliminary efficacy of both bortezomib-based regimens in terms of duration of response and overall survival.
- To assess the relationship between clinical effects (adverse event [AE] and/or tumor response) and CD38 receptor density.

Condition	Intervention	Phase
Plasma Cell Myeloma	Drug: lenalidomide Drug: bortezomib Drug: cyclophosphamide Drug: dexamethasone Drug: isatuximab **SAR650984**	Phase 1

Study Type: Interventional

Study Design: Intervention Model: Single Group Assignment
Masking: None (Open Label)
Primary Purpose: Treatment

Official Title: A Dose Escalation, Safety, Pharmacokinetic, Pharmacodynamic and Preliminary Efficacy Study of **SAR650984** (Isatuximab) Administered Intravenously in Combination With Bortezomib - Based Regimens in Adult Patients With Newly Diagnosed Multiple Myeloma Non Eligible for Transplantation

Resource links provided by NLM:

Genetics Home Reference related topics: multiple myeloma

MedlinePlus related topics: Multiple Myeloma

Drug Information available for: Cyclophosphamide Bortezomib Lenalidomide

Genetic and Rare Diseases Information Center resources: Multiple Myeloma

U.S. FDA Resources

Further study details as provided by Sanofi:

Primary Outcome Measures:

- Assessment of dose-limiting toxicities (DLTs) in VCDI cohort [Time Frame: Up to 6 weeks per treated patient]
- Overall response rate (VCDI) [Time Frame: Up to 34 weeks of treatment (induction phase)]
- Complete response rate (VCDI) [Time Frame: Up to 34 weeks of treatment (induction phase)]
- Overall response rate (VRDI) [Time Frame: Up to 36 weeks of treatment (induction and maintenance phase)]
- Complete response rate (VRDI) [Time Frame: Up to 36 weeks of treatment (induction and maintenance phase)]

Secondary Outcome Measures:

- Number of patients with adverse events (AEs) [Time Frame: VCDI: Up to approximately 106 weeks, VRDI: Up to approximately 80 weeks]
- Number of patients with clinically significant changes in laboratory tests according to the National Cancer Institute - Common Toxicity Criteria (NCI-CTC) version 4.03 grade scaling [Time Frame: VCDI: Up to approximately 106 weeks, VRDI: Up to approximately 80 weeks]
- Number of patients with clinically significant changes in vital signs according to the NCI-CTC version 4.03 grade scaling [Time Frame: VCDI: Up to approximately 106 weeks, VRDI: Up to approximately 80 weeks]
- Assessment of PK parameter: Partial area under the serum concentration time curve (AUC) [Time Frame: VCDI: Up to approximately 42 weeks, VRDI: Up to approximately 48 weeks]
- Assessment of PK parameter: Maximum observed concentration (Cmax) [Time Frame: VCDI: Up to approximately 42 weeks, VRDI: Up to approximately 48 weeks]

- Levels of human antidrug antibodies (ADA) [Time Frame: VCDI: Up to approximately 42 weeks, VRDI: Up to approximately 48 weeks]
- Duration of response - time [Time Frame: VCDI: Up to approximately 90 weeks, VRDI: Up to approximately 80 weeks]

Estimated Enrollment:	44
Study Start Date:	September 30, 2015
Estimated Study Completion Date:	November 18, 2024
Estimated Primary Completion Date:	November 18, 2024 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Isatuximab Isatuximab (escalating dose) + bortezomib + cyclophosphamide + dexamethasone (VCDI): Induction phase will be 50 weeks (12 cycles). The duration of a cycle will be 42 days (6 weeks) for Cycle 1 (C1) and 28 days (4 weeks) for subsequent cycles. The duration of a cycle of the maintenance phase will be 28 days (4 weeks). After C12, isatuximab will be administered at its initial assigned dose and dexamethasone once every 28 days. Isatuximab + bortezomib + dexamethasone + lenalidomide (VRDI): Induction phase will be 24 weeks (4 cycles at 6 weeks/cycle). The duration of a cycle of the maintenance phase will be 28 days (4 weeks). Maintenance therapy may continue until disease progression, unacceptable AE or patient willingness to discontinue. Enrollment to begin after the VCDI cohort is completed.	Drug: lenalidomide Pharmaceutical form: tablet Route of administration: oral Other Name: Revlimid Drug: bortezomib Pharmaceutical form: lyophilized powder for subcutaneous injection Route of administration: subcutaneous Other Name: Velcade Drug: cyclophosphamide Pharmaceutical form: tablet Route of administration: oral Other Name: Endoxan Drug: dexamethasone Pharmaceutical form: tablet or solution for infusion Route of administration: oral or intravenous Drug: isatuximab **SAR650984**

	Pharmaceutical form: solution for infusion Route of administration: intravenous

Detailed Description:

The duration of the study for an individual patient will include:

- A period to assess eligibility (screening or baseline period) of up to 3 weeks for VCDI cohort, up to 28 days for VRDI cohort;
- for patients in the VCDI cohort: a treatment period including up to 12 induction treatment cycles (50-week duration).
- for patients in the VRDI cohort: a treatment period including up to 4 induction cycles (24 week duration).
- Following induction, both cohorts have maintenance periods consisting of 4 week cycles until progression, unacceptable AE, or patient willingness to discontinue and an end-of-treatment visit at least 30 days following the last administration of treatment.
- Patients that discontinue therapy for reasons other than progression will have follow-up visits until progression or until the patient receives another anticancer therapy, whichever is earlier.

Eligibility

Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion criteria:

Newly diagnosed patients with measurable multiple myeloma defined as at least one of the following:

- Serum M protein ≥1 g/dL (≥10 g/L).
- Urine M protein ≥200 mg/24 hours.
- Serum free light chain (sFLC) assay: involved free light chain assay ≥10 mg/dL (≥100 mg/L) and an abnormal sFLC ratio (<0.26 or >1.65).

Patients with ultra-high risk smoldering multiple myeloma fulfilling the International Myeloma Working Group criteria are eligible.

Patients not eligible for transplant (age and comorbidities at the Investigator's discretion).

Exclusion criteria:

Eastern Cooperative Oncology Group performance status >2.

Poor bone marrow reserve.

Poor organ function.

The above information is not intended to contain all considerations relevant to a patient's potential participation in a clinical trial.

Contacts and Locations

Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02513186***

Contacts

Contact: For site information, send an email with site number to Contact-Us@sanofi.com

Locations

France

Investigational Site Number 250003 **Recruiting**
Pierre Benite, France, 69310

Investigational Site Number 250001 **Recruiting**
Toulouse Cedex 9, France, 31059

Germany

Investigational Site Number 276003 **Recruiting**
Berlin, Germany, 12200

Investigational Site Number 276002 **Recruiting**
Leipzig, Germany, 04103

Investigational Site Number 276004 **Recruiting**
München, Germany, 81675

Italy

Investigational Site Number 380002 **Recruiting**
Roma, Italy, 00161

Investigational Site Number 380001 **Recruiting**
Torino, Italy, 10126

Spain

Investigational Site Number 724003 **Recruiting**
Madrid, Spain, 28041

Investigational Site Number 724001 **Recruiting**
Pamplona, Spain, 31008

Investigational Site Number 724002 **Recruiting**
Salamanca, Spain, 37007

Sponsors and Collaborators

Sanofi

Investigators

Study Director: Clinical Sciences & Operations Sanofi

More Information

Responsible Party:	Sanofi
ClinicalTrials.gov Identifier:	NCT02513186 History of Changes
Other Study ID Numbers:	**TCD13983** 2014-001251-23 (EudraCT Number) U1111-1154-6102 (Other Identifier: UTN)
First Submitted:	July 16, 2015
First Posted:	July 31, 2015
Last Update Posted:	November 9, 2017
Last Verified:	November 2017

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Yes

Plan Description: Individual participant data (IPD) and supporting clinical documents are available for request at clinicalstudydatarequest.com. While making information available Sanofi continues to protect the privacy of the participants in clinical trials and to remove commercially confidential information (CCI). Details on Data Sharing criteria and process for requesting access can be found at this web address: clinicalstudydatarequest.com

Additional relevant MeSH terms:

Multiple Myeloma
Neoplasms, Plasma Cell
Neoplasms by Histologic Type
Neoplasms
Hemostatic Disorders
Vascular Diseases
Cardiovascular Diseases
Paraproteinemias
Blood Protein Disorders
Hematologic Diseases
Hemorrhagic Disorders
Lymphoproliferative Disorders
Immunoproliferative Disorders
Immune System Diseases
Dexamethasone acetate
Dexamethasone
Lenalidomide
Cyclophosphamide
Thalidomide
Bortezomib
BB 1101
Anti-Inflammatory Agents
Antiemetics
Autonomic Agents
Peripheral Nervous System Agents
Physiological Effects of Drugs
Gastrointestinal Agents
Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists