

# VESUVE (beta) - Velcade: study of real-life use

Head :Fourrier-Reglat Annie, Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen

Moore Nicholas, Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen

Last update : 09/05/2017 | Version : 3 | ID : 3195

## General

### Identification

Detailed name Velcade: study of real-life use

Sign or acronym VESUVE (beta)

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CCTI-RS 05 375, CNIL 1133894

### General Aspects

Medical area Cancer research  
Hematology

Keywords Multiple myeloma, Velcade®, Bortezomib, survival, conditions of use, pharmacoepidemiology, cohort, Department of Pharmacology, Bordeaux

### Scientific investigator(s) (Contact)

Name of the director Fourrier-Reglat

Surname Annie

Address Bât du Tondu - Case 41 - 146, Rue Léo Saignat - 33076 BORDEAUX Cedex

Phone + 33(0)5 57 57 46 75

Email Annie.fourrier@pharmaco.u-bordeaux2.fr

Unit Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen

Organization Université Bordeaux

Name of the director Moore

Surname	Nicholas
Address	Bât du Tondu - Case 41 - 146, Rue Léo Saignat - 33076 BORDEAUX Cedex
Phone	+ 33 (0)5 57 57 46 75
Email	nicholas.moore@u-bordeaux.fr
Unit	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organization	Université Bordeaux

## Collaborations

## Funding

Funding status	Mixed
Details	Laboratoire Janssen-Cilag France (soutien inconditionnel) - Janssen-Cilag France (unconditional support)

## Governance of the database

Sponsor(s) or organisation(s) responsible	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organisation status	Public

## Additional contact

## Main features

Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
Database recruitment is carried out by an intermediary	A selection of health care professionals A selection of health institutions and services
Database recruitment is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Additional information regarding	All hospital pharmacies that purchased bortezomib

sample selection.

at the time of study implementation were contacted. Pharmacists of participating centres have, from nominative dispensation registers, identified patients who received a first prescription of bortezomib during the study period. The prescribing physicians were contacted and asked to participate in the study. Participating physicians informed patients of the study and gave access to medical records to the CRAs in charge of the data collection.

## Database objective

Main objective

The objectives are to evaluate the response and survival of patients treated by Velcade®, to describe the population of patients initiating treatment with Velcade® (socio-demographic data, previous treatments, indication), and describe the conditions of use Velcade® (dose, number and frequency of treatment cycles)

Inclusion criteria

Patients initiating Bortezomib treatment between 1 May 2004 and April 30 2006 (whether or not treatment is continued); Patient unexposed to bortezomib, including during a clinical trial or temporary use authorization; Patient followed by a hospital physician having agreed to participate in the study; Patient not participating in a clinical trial; Patient not objecting to data collection

## Population type

Age

Adulthood (19 to 24 years)  
Adulthood (25 to 44 years)  
Adulthood (45 to 64 years)  
Elderly (65 to 79 years)  
Great age (80 years and more)

Population covered

Sick population

Gender

Male  
Woman

Geography area

National

Detail of the geography area

Hospital pharmacists and physicians in metropolitan France

## Data collection

Dates

Date of first collection (YYYY or

2004

MM/YYYY)

Date of last collection (YYYY or MM/YYYY) 2006

## Size of the database

Size of the database (number of individuals) [500-1000] individuals

Details of the number of individuals 1310 patients identified by hospital pharmacists, including 924 patients for whom their physician agreed to participate in the study, and 793 patients were eligible for follow up.

## Data

Database activity Data collection completed

Type of data collected Clinical data

Clinical data (detail) Direct physical measures

Presence of a biobank No

Health parameters studied Health event/morbidity  
Health event/mortality  
Health care consumption and services

Care consumption (detail) Medicines consumption

## Procedures

Data collection method CRAs have collected data on site using a standardized electronic case report forms (e-CRF). The indication for treatment with bortezomib was collected for all patients, but only those treated for multiple myeloma were followed.

Participant monitoring Yes

Details on monitoring of participants Patients treated for multiple myeloma are followed over three years (from the date of first administration of Velcade®) using data available in medical records.

Links to administrative sources No

## Promotion and access

### Promotion

Link to the document

<http://www.ncbi.nlm.nih.gov/pubmed/23808815>

Link to the document

<http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview>

## Access

Terms of data access (charter for data provision, format of data, availability delay)

A confidential study report was submitted to the pharmaceutical company and sent to health authorities after validation by the study Scientific Committee. Ownership of study data was the subject of an agreement between the University of Bordeaux Segalen and the pharmaceutical company. Terms for third-party access to the database are to be defined.

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only