Real-life efficacy and safety of patients treated with ixazomib in combination with lenalidomide and dexamethasone, for relapsed and/or refractory multiple myeloma: a prospective, non-interventional, real-life study (REMIX)

First published: 10/11/2017

Last updated: 31/01/2023

Study Finalised

Administrative details

EU PAS number

EUPAS21443

Study ID

50768

DARWIN EU® study

No

Study countries

☐ France

Study description

REMIX is a non-interventional, multicentre study conducted in France in sites specialized in the management of multiple myeloma. It aims to evaluate ixazomib use in combination with lenalidomide and dexamethasone in real life within its market authorization. The primary objective is to evaluate median progression-free survival (PFS) of ixazomib in combination with lenalidomide and dexamethasone in patients treated for relapsed and/or refractory multiple myeloma. Secondary objectives are to evaluate mPFS and overall survival rate of these patients at different time points (i.e. 12, 24 and 36 months), to evaluate response to treatment, to describe the safety of these patients and the health care resource use of these patients for management of multiple myeloma. Analyzes will be made globally and according to subgroups of interest (age of patients, number of previous line of treatment, presence or absence of renal failure, presence of comorbidities, participation or not in compassionate use program). A total number of 500 patients is expected in the study. Patients will be followed up for a minimum duration of 24 months (for the last patient in). Patients' follow-up will be continued up to the end of the study or death, to collect long-term efficacy and safety data (total follow-up duration between 24 and 48 months). Response and progression will be evaluated periodically and will be determined by the study site on the basis of assessments at its disposal. Visits will be completed every 3 months during the first 24 months then every 6 months after 24 months as per standard practice at sites.

Study status

Finalised

Research institutions and networks

Institutions

Kappa Santé

France

First published: 20/09/2010

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Multiple centres: 60 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Stéphane SCHÜCK

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 04/09/2017

Study start date
Planned: 22/12/2017

Actual: 17/01/2018

Data analysis start date
Planned: 31/01/2022

Date of interim report, if expected
Planned: 31/03/2020

Date of final study report
Planned: 31/12/2022

Actual: 18/10/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda France

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective is to evaluate median progression-free survival (PFS) of ixazomib in combination with lenalidomide and dexamethasone in patients treated for relapsed and/or refractory multiple myeloma

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, real-life study

Study drug and medical condition

Name of medicine

NINLARO

Medical condition to be studied

Plasma cell myeloma

Population studied

Short description of the study population

The study population involved patients with relapsed and/or refractory multiple myeloma received treatment with ixazomib in combination with lenalidomide and dexamethasone.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Relapsed and/or refractory multiple myeloma patients

Estimated number of subjects

500

Study design details

Data analysis plan

This study is observational and epidemiological methods will be employed for data analyses. Descriptive analysis of qualitative and ordinal variables will comprise sample size and the frequency of each modality. All patients included in the study will be described. The reference population for the analysis of the primary endpoint will correspond to patients meeting the eligibility criteria. The safety analysis will be carried out on all patients having received at least one dose of ixazomib.For the primary endpoints, PFS will be assessed using the Kaplan-Meier method. This method will be applied to derive, survival curves, median event time and a 95% confidence interval for the median. Kaplan-Meier estimates will also be provided for sub-group analysis of interest.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No