Evaluation of the Effectiveness of Risk Minimization Measures: A Survey Among Pharmacists to Assess the Impact of the RMP Material for Patients on Promoting the Proper use of NINLARO in Japan

First published: 22/05/2023

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Study Finalised

Administrative details

EU PAS number

EUPAS104398

Study ID

105390

DARWIN EU® study

No

Study countries

☐ Japan

Study description

This is a survey among pharmacists who have instructed NINLARO therapy in ixazomib, lenalidomide and dexamethasone (IRD) dosing to patients with relapsed/refractory multiple myeloma (rrMM).

The main aims of the study are:

• To assess the frequency of pharmacists who have provided patients with the contents of the RMP material for patients.

• To assess the frequency of pharmacists who have obtained the RMP material for patients.

• To evaluate the depth of understanding of proper usage of NINLARO among pharmacists.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Study Contact Takeda TrialDisclosures@takeda.com

Study contact

TrialDisclosures@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 31/01/2023

Study start date

Planned: 01/06/2023

Actual: 01/06/2023

Data analysis start date

Planned: 12/06/2023

Actual: 12/06/2023

Date of final study report

Planned: 01/06/2024

Actual: 23/10/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The primary objective of this study is to assess the frequency of pharmacists who have provided patients with the contents of the RMP material for patients.

Study drug and medical condition

Name of medicine

NINLARO

Study drug International non-proprietary name (INN) or common name

IXAZOMIB CITRATE

Anatomical Therapeutic Chemical (ATC) code

(L01XG03) ixazomib

ixazomib

Medical condition to be studied

Plasma cell myeloma refractory

Population studied

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)

Estimated number of subjects

300

Study design details

Outcomes

The primary outcome will assess the number of participants who have provided patients with the contents of the RMP material. The secondary outcomes will assess the number of pharmacists who received RMP material for patients, and understand the proper NINLARO dosing schedule and its importance of providing.

Data analysis plan

For each question in the web-based questionnaire, the number and/or percentage of participants who responded for each answer option will be calculated. Cross-tabulations will also be performed between participants' backgrounds and/or questions, as appropriate.

Documents

Study report

C16065-clinical-study-report-redact.pdf(723.79 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

The data will be collected in a web-based questionnaire, which will be filled in by the participating pharmacist.

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