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

**Last updated:** 20/02/2025





## 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

First published: 01/02/2024

Last updated: 01/02/2024

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