C16050: A national, prospective, non-interventional study of using NINLARO® in real world clinical practice

First published: 28/10/2019

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Study Ongoing

Administrative details

EU PAS number

EUPAS30733

Study ID

44146

DARWIN EU® study

No

Study countries

☐ China

Study description

This is a non-interventional and prospective study in Chinese patients.
This study will review the data of patients who are undergoing treatment with NINLARO (of less than 3 months from initial treatment with NINLARO) or to be prescribed with NINLARO to collect all patient safety information related to the post-marketing use of drug.
The study will enroll approximately 3000 patients.
The patients will be enrolled in 2 cohorts: Cohort 1 and Cohort 2.
Cohort 1 will enroll patients with relapsed refractory multiple myeloma (RRMM) who have received at least one dose of Ixazomib plus lenalidomide - low dose dexamethasone (IRd) treatment.
Cohort 2 will enroll patients with newly diagnosed multiple myeloma (NDMM) patients who have received at least one dose of Ixazomib-based regimen treatment, RRMM patients who have received at least one dose non-IRd Ixazomib-based regimens treatment, and non-myeloma patients who have received at least one dose of Ixazomib-based regimens treatment.
This study will be conducted in China. The overall time for the study will be approximately 57 months after the last site initiation.
All patients will be followed-up for 21 months unless withdrawal of Informed Consent Form, lost or death, whichever comes first.

Study status

Ongoing

Research institutions and networks

Institutions

The First Affiliated Hospital of Soochow University

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Depei Wu

West China Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Shanghai Jiao Tong University School of Medicine - Xinhua Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

The First Affiliated Hospital of Soochow University

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Harbin Medical University Cancer Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Beijing Chao-Yang Hospital, Capital Medical University

First published: 01/02/2024

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Institution

Peking Union Medical College Hospital

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Institution

The first affiliated hospital of Soochow University, Beijing Chaoyang hospital, Capital Medical

University, Ruijin Hospital, School of Medicine, Shanghai Jiao Tong University China, West China Hospital, Sichuan University, Zhabei central hospital, jing 'an district, Sun Yat-sen University cancer center China, Henan Cancer Hospital, the Fourth Hospital of Hebei Medical University, Jinhua Municipal Central Hospital China, Tianjin Medical University General Hospital, Zhujiang Hospital of Southern Medical University, Beijing Chaoyang hospital, Capital Medical University (the West Hospital) China, Beijing Jishuitan Hospital, Peking University Third Hospital, The first affiliated hospital of Dalian Medical University China, The second hospital of Dalian Medical University, Harbin Medical University Cancer Hospital, The First Affiliated Hospital, Sun Yat-sen University China, Shandong Provincial Hospital, The First Hospital of Jilin University, Southern Medical University Nanfang Hospital China, Renji Hospital,

Shanghai Jiaotong University, School of Medicine, Shanghai sixth people's hospital, Yijishan Hospital of Wannan Medical College China, Peking University First Hospital, The First affiliated hospital of Harbin Medical University, Harbin Institute of Hematology & Oncology, Harbin the First Hospital China, The third hospital of Hebei Medical University, Shanxi Cancer Hospital, Peking Union Medical College Hospital China

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Wu Depei

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 09/10/2019

Actual: 21/02/2019

Study start date
Planned: 17/04/2020

Actual: 18/05/2020

Data analysis start date
Planned: 31/10/2024

Date of final study report
Planned: 30/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

The primary objective of the study is to evaluate the safety profile of NINLARO to fulfill the regulatory authority's requirement of intensive drug monitoring (IDM) in Chinese population.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

NINLARO

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

IXAZOMIB CITRATE

LENALIDOMIDE

DEXAMETHASONE

Anatomical Therapeutic Chemical (ATC) code

(L01XG03) ixazomib

ixazomib

Medical condition to be studied

Oncologic complication

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

3000

Study design details

Outcomes

The primary outcomes will include assessment of the adverse events (AEs). The secondary outcomes will include assessment of the serious adverse events (SAEs), adverse drug reactions (ADRs), adverse event of special interests (AESI), dose adjustment, demographics, clinical and disease characteristics, and

overall survival (OS).

Data analysis plan

Descriptive statistics will be used. If necessary, Fisher's exact test, x^2 test, or t-test will be used to examine differences in AEs occurrence between subgroups.

Disease and patient presentation, therapies, and clinical Outcome measures will be summarized descriptively by patient characteristics, disease characteristics, and predictors of treatment choice.

Also, treatment patterns will be summarized according to subgroups based on clinically relevant factors.

Kaplan-Meier survival analysis, Cox regression or Log-rank regression for drug efficiency may also be applied. Incidence of AEs, SAEs, ADRs, and AESI will be analyzed by 95% of confidence interval. Logistic regression models to identify critical factors may be used.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Information will be collected as part of routine clinical visits in electronic case report form (eCRF) and recorded in electronic data capture system (EDC).

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