A global, prospective, non-interventional, observational study of presentation, treatment patterns, and outcomes in multiple myeloma patients - the INSIGHT-MM study

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Last updated: 25/06/2025

Study Finalised

Administrative details

EU PAS number

EUPAS41735

Study ID

48872

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ Brazil

- [ ] China
- [ ] Colombia
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Israel
- [ ] Italy
- [ ] Mexico
- [ ] Spain
- [ ] Taiwan
- [ ] Türkiye
- [ ] United Kingdom
- [ ] United States

Study description

The purpose of this study is to describe contemporary, real-world patterns of patient characteristics, clinical disease presentation, therapeutic regimen chosen, and clinical outcomes in participants with newly diagnosed ND multiple myeloma (MM) and participants with relapsed/refractory R/R MM.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Multiple centres: 134 centres are involved in the study

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: 30/06/2016

Study start date

Actual: 01/07/2016

Data analysis start date
Actual: 03/07/2021

Date of final study report
Planned: 11/08/2022

Actual: 08/08/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

NSMM-5001 INSIGHT MM Protocol-Redacted.pdf(1.59 MB)

NSMM-5001 INSIGHT MM Protocol Amend 2-Redacted.pdf(1.59 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

Methodological aspects

Study type

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study is to describe contemporary, real-world disease and patient presentation, therapies, and clinical outcomes in participants with ND MM and participants with R/R MM.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Plasma cell myeloma

Additional medical condition(s)

Newly diagnosed multiple myeloma within 3 months from initiation of treatment. Relapsed/refractory multiple myeloma who have received 1-3 prior lines of treatment.

Population studied

Short description of the study population

The study included both newly diagnosed and relapsed/refractory multiple myeloma patients aged 18 years or older between July 2016 and November 2018 at 136 centers in 15 countries.

Inclusion Criteria:

• Is 18 years of age or older.

• Is experiencing one of the following:

a) Newly diagnosed multiple myeloma (MM) within 3 months from initiation of treatment with documented month and year of diagnosis, criteria met for diagnosis, stage, and MM-directed treatment history, including duration.

b) Relapsed/refractory MM who have received 1 to 3 prior lines of therapy with documented data in the medical record regarding diagnosis (month and year), the regimens used in 1st, 2nd, and 3rd line as applicable, whether stem cell transplant was part of 1st, 2nd, and 3rd line of therapy, whether consolidation/maintenance was part of 1st, 2nd, and 3rd line of therapy, also whether investigational therapy/treated on a clinical trial was part of any of these regimens.

• Patients willing and able to complete PROs in accordance with local regulatory and data protection requirements will be enrolled.

• Is willing and able to sign informed consent to participate.

Exclusion Criteria:

• Patients reporting to a site in this study for a second opinion (consultation only) or patients whose frequency of consult and follow-up are not adequate for quarterly electronic case report form (eCRF) completion.
• Participation in another study (observational or interventional) that prohibits participation in this study.

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

Renal impaired

Special population of interest, other

Relapsed/refractory multiple myeloma patients

Estimated number of subjects

4200

Study design details

Outcomes

The primary outcomes will assess the number of participants with co-morbidities, diagnosed and with symptoms of ND MM and R/R MM, sites of disease, ECOG performance status, frailty index, participants evaluated for

laboratory test, duration for treatment, overall survival, progression status, response to each regimen, time to next therapy and participants with stem cell transplant. Secondary outcomes are treatment combinations,sequencing,rechallenge,clinical outcomes for different strategies,between continuous and intermittent,triggers of treatment initiation at relapse,biochemical progression/symptomatic progression,reasons for treatment modifications,HRQoL,HRU,associations between presentation,disease characteristics,choice of therapy and clinical outcomes,SAE and non-SAE.

Data analysis plan

Population characteristics (including demographics, medical conditions, duration of disease, and types of therapy used at study entry) and all relevant primary and secondary outcomes measures will be summarized as mean, standard deviation, minimum, maximum, median, 25th and 75th percentile, and 95% confidence interval (CI) of the mean for continuous variables, and count and proportion with 95% CI of the proportion for categorical data as appropriate. Descriptive statistics will be used to describe treatment patterns, safety assessments, clinical outcomes, economic outcomes, and HRQoL self-reported outcomes observed during the study period. Outcomes of interest (DOT, PFS, TTNT, OS) will be analyzed using Kaplan Meier methods/estimates and will be adjusted using Cox PH regression models to account for covariantes that could impact treatment regimen assignment and outcomes.

Documents

Study results

NSMM-5001_RDS CSR Synopsis (including 2 Addendums)_2022-Sep-28.pdf (1008.53 KB)

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

Prospective patient-based data collection, Data collection will be done prospectively as per the standard schedule of routine office visits for MM participants.

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