

# A clinical study to evaluate the long-term safety of daratumumab in combination with standard bone marrow cancer treatment regimens

<b>Submission date</b> 27/09/2023	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/09/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/02/2026	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Janssen Cilag International NV, the sponsor, is running a Phase 3b, multicentre, open-label Daratumumab long-term extension study, designed to collect long-term safety data for participants treated with daratumumab, and to provide ongoing access to daratumumab and other treatment for patients who are currently enrolled in daratumumab or other multiple myeloma program studies that have been completed according to the parent study, are actively receiving treatment, and who continue to benefit from treatment.

Daratumumab has been investigated in multiple myeloma studies as an IV infusion and by SC injection by itself and in combination with other therapies. Daratumumab IV is approved for people to receive in over 90 countries for the treatment of multiple myeloma. Daratumumab SC is approved for people to receive in over 50 countries for the treatment of multiple myeloma.

Daratumumab is being developed for the treatment of participants with multiple myeloma including newly diagnosed, relapsed/refractory, and smoldering multiple myeloma, participants with aberrant plasma cells in systemic light chain amyloidosis, and pediatric participants with acute lymphocytic leukemia.

Daratumumab will be administered through:

- an IV infusion where the needle is put into a vein of the arm through a small tube attached to a needle, or
- a SC injection where the medication is given in the abdomen and manually injected through a small tube or needle that goes directly under the skin.

This study will evaluate if long-term treatment with daratumumab may cause hepatitis B virus reactivation. Reactivation occurs when the hepatitis B virus becomes active after a long period of being inactive in the body. This can occur when the immune system becomes weakened and leads to other medical problems.

### Who can participate?

About 500 patients will take part in this study worldwide, all from different previous Janssen studies.

### What does the study involve?

Participants will receive the same treatment as they received in their previous research study during Screening and the Treatment Period.

For any participant receiving daratumumab IV, the study doctor will review the option to change to daratumumab SC on the first day of any cycle.

### What are the possible benefits and risks of participating?

The potential risks and burdens for this study are provided in the Participant Information Sheet and Informed Consent Form(s) (PIS-ICF[s]). The participants will therefore be informed about these risks and burdens prior to taking part in the study. Due to the character limit for this question please refer to the PIS-ICF(s) for the risks and burdens. The management of these risks and burdens is presented below. Section 2.3.1 of the Protocol also outlines risks for study participation.

### MANAGEMENT OF RISKS

Safety evaluations will be performed as clinically indicated and according to local institutional practice.

### Where is the study run from?

Janssen Cilag International NV (Netherlands)

### When is the study starting and how long is it expected to run for?

January 2022 to April 2029

### Who is funding the study?

Janssen Cilag International NV (Netherlands)

### Who is the main contact?

JanssenUKRegistryQueries@its.jnj.com

## Contact information

### Type(s)

Scientific

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Principal investigator

**Contact name**

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**Additional identifiers****ClinicalTrials.gov (NCT)**

NCT05438043

**Clinical Trials Information System (CTIS)**

2022-500138-27-00

**Integrated Research Application System (IRAS)**

1008068

**Central Portfolio Management System (CPMS)**

57832

**Protocol serial number**

54767414MMY3030

**Study information****Scientific Title**

A phase 3b multicenter, open-label study for participants enrolled in daratumumab-containing trials

## Study objectives

The primary objective of this study is to collect long-term safety data for participants treated with daratumumab, and to provide ongoing access to daratumumab or other treatment for participants who are currently enrolled in daratumumab or other multiple myeloma program studies that have been completed according to the parent protocol (eg, final analysis has been performed), are actively receiving treatment, and who continue to benefit from treatment.

## Ethics approval required

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## Ethics approval(s)

approved 05/08/2024, London - Central Research Ethics Committee (3rd Floor 3 Piccadilly Place, London Road, Manchester, M1 3BN, United Kingdom; +44 207 104 8061; londoncentral.rec@hra.nhs.uk), ref: 24/LO/0503

## Study design

Interventional non-randomized

## Primary study design

Interventional

## Study type(s)

Safety

## Health condition(s) or problem(s) studied

Multiple myeloma

## Interventions

Daratumumab will be administered at a dose of 16 mg/kg intravenous (IV) or 1800 mg subcutaneous (SC) as monotherapy or in combination with other study treatment, including but not limited to pomalidomide and dexamethasone, lenalidomide and dexamethasone, carfilzomib, and dexamethasone.

## Intervention Type

Drug

## Phase

Phase III

## Drug/device/biological/vaccine name(s)

Darzalex [daratumumab]

## Primary outcome(s)

Measured using patient records at end of study:

1. Number of Participants with Serious Adverse Events (SAEs)
2. Number of Participants with AEs of Special Interest (AESI) (HBV infection)
3. Number of Participants with Pregnancies or Partner Pregnancies
4. Number of Participants with Abnormal Pregnancies as SAE

## Key secondary outcome(s)

There are no secondary outcome measures

**Completion date**

30/04/2029

**Eligibility****Key inclusion criteria**

1. Participants must:

- be actively receiving daratumumab (either as monotherapy or in combination with other therapy) in a Janssen R&D-sponsored daratumumab study for participants with multiple myeloma which has reached clinical cutoff for final analysis,
- be enrolled in the parent study for a minimum of 12 months prior to rolling over,
- continue to benefit from study treatment,
- not have experienced disease progression or unmanageable toxicity while receiving daratumumab,
- not have met the withdrawal criteria set forth in the parent study, and
- have had the last dose of daratumumab within the previous 3 months.

2. Investigator's assessment that the benefit of continued daratumumab therapy will outweigh the risks.

3. A female participant of childbearing potential must have a negative pregnancy test at screening and must agree to further serum or urine pregnancy tests during the study.

4. A female participant must be either of the following:

a. Not of childbearing potential, or

b. Of childbearing potential and practicing at least 1 highly effective method of contraception throughout the study and through 3 months after the last dose of daratumumab.

5. A female participant must agree not to donate eggs (ova, oocytes) or freeze for future use for the purposes of assisted reproduction during the study for specified periods after the last dose of study treatment.

6. A male participant must wear a condom when engaging in any activity that allows for passage of ejaculate to another person during the study and for specified periods after the last dose of study treatment.

If partner is a female of childbearing potential, the male participant must use condom with spermicide and the partner must also be practicing a highly effective method of contraception. A male participant who is vasectomized must still use a condom (with or without spermicide), but the partner is not required to use contraception.

7. A male participant must agree not to donate sperm for the purpose of reproduction during the study and for a minimum of 3 months after receiving the last dose of study treatment.

8. Must sign an informed consent form (ICF; or their legally acceptable representative must sign) indicating that the participant understands the purpose of, and procedures required for, the study and is willing to participate in the study.

9. Willing and able to adhere to the lifestyle restrictions specified in this protocol.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

120 years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

1. Has taken any disallowed therapies or treatment for the disease under study between the completion of the parent study and the planned first dose of study treatment.
2. Any condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant (e.g., compromise the well-being) or that could prevent, limit, or confound the protocol-specified assessments.
3. Known allergies, hypersensitivity, or intolerance to study treatments or their excipients (refer to the daratumumab IB and local country prescribing information for dexamethasone, carfilzomib, pomalidomide, and lenalidomide).
4. Vaccinated with an investigational vaccine (except for COVID-19) or live attenuated or replicating viral vector vaccines within 4 weeks prior to enrolment.

**Date of first enrolment**

06/10/2024

**Date of final enrolment**

30/11/2026

**Locations****Countries of recruitment**

United Kingdom

Belgium

Denmark

France

Germany

Greece

Italy

Korea, South

Poland

Spain

Türkiye

United States of America

**Study participating centre**

**Leeds Teaching Hospitals NHS Trust**

St. James's University Hospital

Beckett Street

Leeds

England

LS9 7TF

**Study participating centre**

**The Royal Marsden Hospital (surrey)**

Downs Road

Sutton

England

SM2 5PT

**Study participating centre**

**New Cross Hospital**

Wolverhampton Road

Heath Town

Wolverhampton

England

WV10 0QP

**Study participating centre**

**Leicester Royal Infirmary**

Infirmary Square

Leicester

England

LE1 5WW

## **Sponsor information**

**Organisation**

## Funder(s)

### Funder type

Industry

### Funder Name

Cilag

### Alternative Name(s)

Janssen-Cilag, Cilag AG

### Funding Body Type

Private sector organisation

### Funding Body Subtype

For-profit companies (industry)

### Location

Switzerland

## Results and Publications

### Individual participant data (IPD) sharing plan

The data sharing policy of the Janssen Pharmaceutical Companies of Johnson & Johnson is available at [www.janssen.com/clinical-trials/transparency](http://www.janssen.com/clinical-trials/transparency). Requests for access to the study data can be submitted through Yale Open Data Access (YODA) Project site at [yoda.yale.edu](http://yoda.yale.edu)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes