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A study comparing JNJ-79635322 and an anti-B-cell maturation antigen (BCMA)xCD3 bispecific antibody in participants with relapsed or refractory multiple myeloma (Trilogy-4)

Submission date
03/02/2026

Recruitment status
Recruiting

Registration date
08/04/2026

Overall study status
Ongoing

Last Edited
26/10/2026

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Relapsed or refractory multiple myeloma (RRMM) is a blood cancer that forms in a type of white blood cells called plasma cells. Relapsed means cancer comes back after treatment. Refractory means cancer does not respond to treatment.
The study treatment, JNJ-79635322 bind to proteins called B-cell maturation antigen (i) and G protein-coupled receptor family C Group 5 member D (ii) found on cancer cells, and cluster of differentiation 3 found on T-cells. Upon binding, it activates T-cells and which may lead to killing of MM cells.
(i) Protein present on the surface of normal immune cells as well as myeloma cells and helps to promote normal immune activity
(ii) Protein found mainly on the surface of myeloma cells and its normal function is not known.

Relapsed or refractory multiple myeloma (RRMM) is a type of blood cancer that forms in plasma cells. Plasma cells are a type of white blood cells (WBCs) found in the bone marrow (tissue inside bones where blood cells are produced) and help the body to fight infections. In multiple myeloma (MM), these plasma cells grow out of control and become cancerous. When a cancer returns after it has responded to treatment, it is called relapsed. If it does not respond to treatment or stops responding, it is called refractory. The study treatment, JNJ-79635322 binds to specific proteins found on cancerous plasma cells and T-cells. T-cells are another type of WBCs that help fight infections. By bringing these cells together, the treatment activates T-cells and may help them recognize and destroy the cancer cells. In this study, researchers want to evaluate how well JNJ-79635322 works when compared with an anti-BCMAxCD3 bispecific antibody (teclistamab).

Who can participate?
Participants aged 18 years or older with RRMM previously treated with at least three different types of anti-cancer therapies.

What does the study involve?
The study will be conducted as:
1.Screening phase (up to 28 days)
2.Treatment phase: Participants will be randomly divided into either of the 2 arms. This means each person has an equal chance of being in either treatment group:
2.1. Arm A: Participants will receive JNJ-79635322 by injection under the skin.
2.2. Arm B: Participants will receive teclistamab by injection under the skin.
3.Follow-up phase: Participants will be monitored for their health.

Safety assessments include physical examinations, vital signs (basic health measurements like temperature, blood pressure), monitoring of new cancers at other parts of body and laboratory tests. All side effects will be recorded till study ends. The overall duration of the study will be around 5 years.

What are the possible benefits and risks of participating?
There is no established benefit to participants of this study. Based on scientific theory, taking JNJ-79635322 may improve RRMM. However, this cannot be guaranteed because JNJ-79635322 is still under investigation as a treatment and it is not known whether JNJ-79635322 will work. In addition, if participants are put into the BCMAxCD3 bispecific antibody (Teclistamab) treatment group they will not receive JNJ-79635322 but BCMAxCD3 bispecific antibody (Teclistamab) is already on the market.
Participants may experience some benefit from participation in the study that is not due to receiving study drug, but due to regular visits and assessments monitoring overall health. Participation may help other people with RRMM in the future.
Participants may have side effects from the drugs or procedures used in this study that may be mild to severe and even life-threatening, and they can vary from person to person. The most common, known risks are getting symptoms such as cytokine release syndrome (inflammation condition that may occur after treatment with some types of immunotherapy, such as monoclonal antibodies), immune effector cell-associated neurotoxicity syndrome (neurological side effects may occur that include headaches or a condition of brain), infections, hypogammaglobulinemia (low protein in blood that fights infection), immune-mediated toxicity, oral toxicity, skin and nail toxicity, injection site reactions, tumor lysis syndrome (cancer cells breaking down and releasing their contents into bloodstream), cytopenia (reduction in blood cells) after getting the study drug or comparator drug. There are other, less frequent risks. The participant information sheet and informed consent form, which will be signed by every participant agreeing to participate in the study, includes a detailed section outlining the known risks to participating in the study.
Not all possible side effects and risks related to JNJ-79635322 are known at this moment. During the study, the sponsor may learn new information about JNJ-79635322. The study doctor will tell participants as soon as possible about any new information that might make them change their mind about being in the study, such as new risks.
To minimize the risk associated with taking part in the study, participants are frequently reviewed for any side effects and other medical events. Participants are educated to report any such events to their study doctor who will provide appropriate medical care. Any serious side effects that are reported to the sponsor are thoroughly reviewed by a specialist drug safety team.
There are no costs to participants to be in the study. The sponsor will pay for the study drug and tests that are part of the study. The participant will receive reasonable reimbursement for study-related costs (e.g., travel/parking costs).

Where is the study run from?
Janssen-Cilag International NV

When is the study starting and how long is it expected to run for?
February 2026 to September 2031

Who is funding the study?
Janssen-Cilag International NV

Who is the main contact?
JanssenUKRegistryQueries@its.jnj.com

Contact information

Type(s)
Public

Contact name
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Janssen Research & Development (Janssen-Cilag Ltd), 20 Grenfell Road
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Type(s)
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Contact details
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT07258511

Clinical Trials Information System (CTIS)
2025-522007-18

Integrated Research Application System (IRAS)
1013495

Central Portfolio Management System (CPMS)
69766

Sponsor's protocol code number
79635322MMY3001

Study information

Scientific Title
A phase 3 randomized study comparing JNJ-79635322 and an anti-BCMAxCD3 bispecific antibody in participants with relapsed or refractory multiple myeloma who have received at least 3 prior lines of therapy including a PI, an IMiD, and an anti-CD38 antibody

Acronym
Trilogy-4

Study objectives
Primary objective:
To assess how well JNJ-79635322 works (efficacy) when compared to BCMAxCD3 bispecificantibody.

Secondary objectives:
1. To further assess how well JNJ-79635322 works when compared to BCMAxCD3 bispecificantibody.
2. To evaluate how safe JNJ-79635322 is.
3. To assess how participants overall well-being (health-related quality of life), symptoms,and functioning through various patient reported outcome (PRO*) tools.
4. To understand how well participants are tolerating the treatment by asking them questionabout their health, symptoms, and daily activities.
5. To examine the process by which JNJ-79635322 gets absorbed, distributed in the body,and removal from the body (pharmacokinetics).
6. To assess the ability of JNJ-79635322 to trigger an immune response (immunogenicity).

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 07/04/2026, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; no telephone number provided; edgbaston.rec@hra.nhs.uk), ref: 26/WM/0033

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment, Safety

Study type(s)
Efficacy, Safety, Treatment, Other

Health condition(s) or problem(s) studied
Relapsed or refractory multiple myeloma

Interventions
Participants will randomly divided into either of the 2 arms:
Arm A: Experimental: JNJ-79635322 Participants will receive subcutaneous (SC) dose of JNJ-79635322 until progressive disease (PD) or intolerable toxicity.
Arm B: Active Comparator: Anti BCMAxCD3 Bispecific Antibody Participants will receive teclistamab (an AntiBCMAxCD3 bispecific anitbody) as a SC injection until PD or intolerable toxicity.
In the Follow-up phase Participants will be monitored for their health status.
The overall duration of the study will be around 5 years.

Participants are randomly placed into one of two treatment groups using a computer-generated schedule. The RTSM (Randomization and Trial Supply Management) system (for example, IWRS) assigns a unique treatment code that determines the participant’s treatment and the matching study kit.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)

JNJ-79635322, teclistamab

Primary outcome(s)

1. Overall Response Rate (ORR) measured using the percentage of participants who achieve partial response (PR) or better, according to the international myeloma working group (IMWG) response criteria at up to 5 years and 4 months

2. Progression-Free Survival (PFS) measured using the duration from the date of randomization to either progressive disease (PD) or death, whichever comes first. Disease progression will be determined according to the IMWG response criteria at up to 5 years and 4 months

Key secondary outcome(s)

1. Very Good Partial Response (VGPR) or Better defined as the percentage of participants achieving VGPR, complete response (CR), or stringent complete response (sCR) prior to subsequent antimyeloma therapy in accordance with the IMWG criteria during or after the study treatment. [Time Frame: Up to 5 years and 4 months]
2. Complete Response (CR) or Better defined as the percentage of participants achieving CR or sCR prior to subsequent antimyeloma therapy in accordance with the IMWG criteria during or after the study treatment. [Time Frame: Up to 5 years and 4 months]
3. Duration of Response (DoR) defined as the time interval between the date of initial documentation of a response (partial response [PR] or better) to the date of first documented evidence of progressive disease according to the IMWG response criteria or death due to any cause, whichever occurs first. [Time Frame: Up to 5 years and 4 months]
4. Minimal Residual Disease (MRD)-negative CR defined as the percentage of participants who achieve MRD-negative status, as determined by next-generation flow cytometry (NGF), at any time point after randomization and prior to PD or subsequent antimyeloma therapy and who achieve CR or better. [Time Frame: Up to 5 years and 4 months]
5. MRD-negative CR at 9 months defined as the participants who achieve MRD-negative status at 9 months, as determined by NGF prior to PD or subsequent anti-myeloma therapy and who also achieve CR or better, according to IMWG criteria.[Time Frame: 9 months]
6. Sustained MRD-negative CR defined as participants with confirmed CR or better who sustain MRD-negative status, as determined by NGF, for at least 12 months without any examination showing MRD-positive status or progressive disease in between. [Time Frame: Up to 5 years and 4 months]
7. Progression-Free Survival on the First Subsequent Line of Antimyeloma Therapy (PFS2) defined as the time interval between the date of randomization and date of event, which is defined as progressive disease as assessed by investigator on the first subsequent line of antimyeloma therapy, or death from any cause, whichever occurs first. Those who are alive and for whom a second disease progression has not been observed are censored at the last date of follow-up. [Time Frame: Up to 5 years and 4 months]
8. Overall Survival (OS) defined as the time from the date of randomization to the date of the participant’s death due to any cause. [Time Frame: Up to 5 years and 4 months]
9. Time To Next Line of Therapy (TTNT) defined as the time from randomization to the start of subsequent antimyeloma treatment. Death due to progressive disease without the start of any subsequent antimyeloma therapy will be considered as an event. [Time Frame: Up to 5 years and 4 months]
10. Number of Participants With Treatment-Emergent Adverse Events (TEAE) by Severity. An AE is any untoward medical occurrence in a clinical study participant administered a pharmaceutical (investigational or non investigational) product. An AE does not necessarily have a causal relationship with the treatment. Any new or worsening AE occurring at or after the initial administration of study treatment through the day of last dose plus 30 days or prior to the start

of subsequent anticancer therapy, whichever is earlier, or any follow-up AE with onset date and time beyond 30 days after the last dose of study treatment but prior to the start of subsequent therapy or any AE that is considered treatment-related regardless of the start date of the event is considered to be treatment-emergent. TEAEs will be graded according to the National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 6.0. Severity scale ranges from Grade 1= mild, Grade 2= moderate, Grade 3=severe, Grade 4= life-threatening, to Grade 5= death related to adverse event. [Time Frame: Up to 5 years and 4 months]
11. Number of Participants with Abnormalities in Clinical Laboratories Results (serum chemistry and hematology) will be reported. [Time Frame: Up to 5 years and 4 months]
12. Change from Baseline in Symptoms, Functioning, and Health-related Quality of Life (HRQoL) as Assessed by
Multiple Myeloma Symptom and Impact Questionnaire (MySIm-Q). [Time Frame: Baseline up to 5 years and 4 months]
13. Change from Baseline in Symptoms, Functioning, and HRQoL as Assessed by European Organization for Research
and Treatment of Cancer Quality of life Questionnaire Core 30 (EORTC-QLQ-C30). [Time Frame: Baseline up to 5 years and 4 months]
14. Change from Baseline in Symptoms, Functioning, and HRQoL as Assessed by European Quality of Life 5-Dimensions 5-Level Version (EQ-5D-5L) Score. [Time Frame: Baseline up to 5 years and 4 months]
15. Time to Worsening in Symptoms, Functioning, and HRQoL as Assessed by MySIm-Q Score. [Time Frame: Up to 5 years and 4 months]
16. Time to Worsening in Symptoms, Functioning, and HRQoL as Assessed by EORTC-QLQ-C30 Score. [Time Frame: Up to 5 years and 4 months]
17. Time to Worsening in Symptoms, Functioning, and HRQoL as Assessed by EQ-5D-5L Score. [Time Frame: Up to 5 years and 4 months]
18. Percentage of Participants With Meaningful Improvement in Symptoms, Functioning, and HRQoL as Assessed by MySIm-Q Score. [Time Frame: Up to 5 years and 4 months]
19. Percentage of Participants With Meaningful Improvement in Symptoms, Functioning, and HRQoL as Assessed by EORTC-QLQ-C30 Score. [Time Frame: Up to 5 years and 4 months]
20. Percentage of Participants With Meaningful Improvement in Symptoms, Functioning, and HRQoL as Assessed by EQ-5D-5L Score. [Time Frame: Up to 5 years and 4 months]
21. Percentage of Participants With Side Effects Burden on the European Organization for Research and Treatment of Cancer Item List 46 (EORTC IL46). [Time Frame: Up to 5 years and 4 months]
22. Serum Concentrations for JNJ-79635322. [Time Frame: Up to 5 years and 4 months]
23. Number of Participants With Anti-drug Antibodies (ADA) to JNJ-79635322. Serum samples will be analyzed for the detection of ADA to JNJ-79635322 using a validated assay method. [Time Frame: Up to 5 years and 4 months]
24. Number of Participants With Neutralizing Antibodies (NAb) to JNJ-79635322. [Time Frame: Up to 5 years and 4 months]

Completion date
30/09/2031

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 16/04/2026:

1. At the time of informed consent, be aged ≥18 years or at least the legal age of majority in the jurisdiction in which the study is taking place
2. Documented diagnosis of MM as defined by the criteria below
2.1. MM diagnosis according to the IMWG diagnostic criteria (Rajkumar 2014)
2.2. Measurable disease at screening as assessed by central laboratory, defined by any of the following
2.2.1. Serum M protein level ≥0.5 g/dL
2.2.2. Serum immunoglobulin FLC ≥10 mg/dL and abnormal serum immunoglobulin kappa lambda FLC ratio
2.2.3. Urine M protein level ≥200 mg per 24 hours
2.3. In exceptional circumstances and after discussion with and written approval by the sponsor, local laboratory results may be used to determine initial eligibility, but only if the local results are clearly ≥25% above the thresholds for measurability
2.4. In such cases, central laboratory results should still be obtained from samples collected prior to the start of study treatment to establish baseline values and confirm the results from the local laboratory
3. Received at least 3 prior lines of antimyeloma therapy including a PI, an IMiD, and an anti-CD38 antibody
4. Documented evidence of PD or failure to achieve a response, meaning PR or better, to the last line of therapy based on investigator's determination of response by the IMWG criteria
4.1. Relapsed disease is defined as an initial response to prior treatment, followed by confirmed PD by the IMWG response criteria more than 60 days after cessation of treatment
4.2. Refractory disease is defined as failure to achieve a response, meaning PR or better, or confirmed PD by the IMWG response criteria during previous treatment or 60 days or less after cessation of treatment
5. Toxicity related to previous anticancer therapy must have resolved to Grade 1 or better. Exceptions are alopecia, skin fibrosis or discoloration, dry mouth, endocrinopathy managed with replacement therapy, peripheral neuropathy, and dysgeusia, which must be Grade 2 or better
6. Have an ECOG performance status score of 0 to 2 at screening and immediately before the start of study treatment administration (Oken 1982)
7. Renal function
7.1. Have an eGFR calculated with the CKD EPI creatinine formula of greater than 30 mL/min during the screening period
8. Hepatic function
8.1. Participants are eligible if they have the following laboratory values during the screening period and within 1 day of the start of administration of study treatment
8.2. AST and ALT less than 2.5 times ULN
8.3. Total bilirubin less than 1.5 times ULN
8.4. In case of known congenital nonhemolytic hyperbilirubinemias such as Gilbert's syndrome, isolated total bilirubin ≥1.5 times ULN with direct bilirubin less than 1.5 times ULN
9. Hematologic values
9.1. Participants are eligible if they have the following laboratory values during the screening period and within 1 day of the start of administration of study treatment
9.2. Hemoglobin ≥7.5 g/dL without use of transfusion or growth factors within 7 days
9.3. Neutrophils ≥0.75 × 10^3 per µL
9.3.1. Prior growth factor support is permitted but must be without support for 7 days for G CSF or GM CSF and for 14 days for pegylated G CSF prior to the laboratory test
9.4. Platelets ≥50 × 10^3 per µL without use of transfusion or growth factors within 7 days
10. Participants must agree, while on study treatment and for 6 months after the last dose of study treatment, to the following
10.1. Not breastfeed or be pregnant
10.2. Not donate gametes, meaning eggs or sperm, or freeze for future use for the purposes of

assisted reproduction
10.3. Wear an external condom when transmission of sperm or ejaculate can occur
10.4. If of childbearing potential, have a negative highly sensitive pregnancy test such as β hCG at screening and within 24 hours before the first dose of study treatment, and agree to further pregnancy tests
10.5. Practice at least 1 highly effective method of contraception
10.5.1. If oral contraceptives are used, a barrier method of contraception must also be used
10.6. If able to produce sperm and their partner is of childbearing potential, the partner must practice a highly effective method of contraception
11. Must provide informed consent
12. Be willing and able to adhere to the lifestyle restrictions specified in this protocol

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2.2. Measurable disease at screening as assessed by central laboratory, defined by any of the following
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2.2.3. Urine M protein level ≥200 mg per 24 hours
2.3. In exceptional circumstances and after discussion with and written approval by the sponsor, local laboratory results may be used to determine initial eligibility, but only if the local results are clearly ≥25% above the thresholds for measurability
2.4. In such cases, central laboratory results should still be obtained from samples collected prior to the start of study treatment to establish baseline values and confirm the results from the local laboratory
3. Received at least 3 prior lines of antimyeloma therapy including a PI, an IMiD, and an anti-CD38 antibody
4. Documented evidence of PD or failure to achieve a response, meaning PR or better, to the last line of therapy based on investigator’s determination of response by the IMWG criteria
4.1. Relapsed disease is defined as an initial response to prior treatment, followed by confirmed PD by the IMWG response criteria more than 60 days after cessation of treatment
4.2. Refractory disease is defined as failure to achieve a response, meaning PR or better, or confirmed PD by the IMWG response criteria during previous treatment or 60 days or less after cessation of treatment
5. Have discontinued concurrent use of any other anticancer treatment, including nonpalliative radiotherapy, or investigational agent
5.1. Toxicity related to previous anticancer therapy must have resolved to Grade 1 or better
5.2. Exceptions are alopecia, skin fibrosis or discoloration, dry mouth, endocrinopathy managed with replacement therapy, peripheral neuropathy, and dysgeusia, which must be Grade 2 or better
6. Have an ECOG performance status score of 0 to 2 at screening and immediately before the start of study treatment administration (Oken 1982)
7. Renal function
7.1. Have an eGFR calculated with the CKD EPI creatinine formula of greater than 30 mL/min during the screening period

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8.1. Participants are eligible if they have the following laboratory values during the screening period and within 1 day of the start of administration of study treatment
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10.1. Not breastfeed or be pregnant
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10.3. Wear an external condom when transmission of sperm or ejaculate can occur
10.4. If of childbearing potential, have a negative highly sensitive pregnancy test such as β hCG at screening and within 24 hours before the first dose of study treatment, and agree to further pregnancy tests
10.5. Practice at least 1 highly effective method of contraception
10.5.1. If oral contraceptives are used, a barrier method of contraception must also be used
10.6. If able to produce sperm and their partner is of childbearing potential, the partner must practice a highly effective method of contraception
11. Must provide informed consent
12. Be willing and able to adhere to the lifestyle restrictions specified in this protocol

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 16/04/2026:

1. Serious underlying medical conditions
2. Active hepatitis of infectious origin
3. Participants who are HIV positive and meet any of the following
3.1. Detectable viral load, meaning ≥50 copies/mL, at screening
3.2. CD4+ count ≤300 cells per mm3 at screening
3.3. Acquired immunodeficiency syndrome defining opportunistic infection within 6 months of screening
3.4. Receipt of treatment other than continued HAART
3.4.1. A change in HAART due to resistance or progression must have occurred at least 3 months prior to screening
3.4.2. A change in HAART due to toxicity is allowed up to 4 weeks prior to screening
4. Plasma cell leukemia at the time of screening, defined as ≥5% circulating plasma cells in a peripheral blood smear, Waldenström's macroglobulinemia, POEMS syndrome, meaning polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes, or primary amyloid light chain amyloidosis
5. Known active or prior CNS involvement or clinical signs of meningeal involvement of MM
5.1. If either is suspected, a negative whole brain MRI and negative lumbar cytology are required
6. Presence of any of the following
6.1. Any ongoing myelodysplastic syndrome or B cell malignancy other than MM
6.2. Any history of malignancy other than MM that is considered at high risk of recurrence requiring systemic therapy
6.3. Other malignancy that is considered cured with minimal risk of recurrence
7. Suspected or known allergies, hypersensitivity, or intolerance to the excipients of JNJ-79635322, refer to the investigator's brochure
8. Major surgery, for example requiring general anesthesia, within 2 weeks before the first dose of study treatment, not fully recovered from surgery, or surgery planned during the time the participant is expected to participate in the study
9. Suspected or known allergies, hypersensitivity, or intolerance to teclistamab or its excipients (TECVAYLI USPI 2024)
10. Prior or concurrent exposure to any of the following within the specified time frame prior to randomization
10.1. T cell redirection therapy, such as CAR T cell therapy or bispecific antibodies, within 6 months
10.2. History of receiving both BCMA directed therapy and GPRC5D directed therapy
10.3. History of receiving a BCMA directed bispecific antibody
10.4. Allogeneic stem cell transplant within 6 months before the first dose of study treatment
10.4.1. Participants who received an allogeneic transplant must be off all immunosuppressive medications for at least 6 weeks before the start of study treatment administration and have no signs of graft versus host disease
10.5. Received a cumulative dose of corticosteroids equivalent to ≥140 mg of prednisone within 14 days prior to the first dose of study treatment
10.6. Epigenetic therapy, or treatment with an investigational drug, investigational intervention (including investigational vaccines) or used an invasive investigational medical device within 21 days or ≥5 half-lives, whichever is less.
10.7. Conventional chemotherapy within 21 days.
10.8. Proteasome inhibitor therapy within 14 days.
10.9. Immunomodulatory agent therapy within 7 days.
10.10. Monoclonal antibody therapy within 21 days.
10.11. Radiotherapy within 14 days of first dose of study drug. However, if palliative focal radiation is used, the subject is eligible irrespective of the end date of radiotherapy.
11. Received or plans to receive any live or attenuated vaccine within 4 weeks before the first

dose of study treatment, during study treatment, or within 90 days after the last dose of study treatment
11.1. Non live and non replication competent vaccines approved or authorised for emergency use by local health authorities are allowed
12. Any condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant, for example compromising well being, or could prevent, limit, or confound the protocol specified assessments

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Previous key exclusion criteria:

1. Serious underlying medical conditions
2. Active hepatitis of infectious origin
3. Participants who are HIV positive and meet any of the following
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3.4. Receipt of treatment other than continued HAART
3.4.1. A change in HAART due to resistance or progression must have occurred at least 3 months prior to screening
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5. Known active or prior CNS involvement or clinical signs of meningeal involvement of MM
5.1. If either is suspected, a negative whole brain MRI and negative lumbar cytology are required
6. Presence of any of the following
6.1. Any ongoing myelodysplastic syndrome or B cell malignancy other than MM
6.2. Any history of malignancy other than MM that is considered at high risk of recurrence requiring systemic therapy
6.3. Other malignancy that is considered cured with minimal risk of recurrence
7. Suspected or known allergies, hypersensitivity, or intolerance to the excipients of JNJ-79635322, refer to the investigator's brochure
8. Major surgery, for example requiring general anesthesia, within 2 weeks before the first dose of study treatment, not fully recovered from surgery, or surgery planned during the time the participant is expected to participate in the study
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10.3. History of receiving a BCMA directed bispecific antibody
10.4. Allogeneic stem cell transplant within 6 months before the first dose of study treatment
10.4.1. Participants who received an allogeneic transplant must be off all immunosuppressive medications for at least 6 weeks before the start of study treatment administration and have no signs of graft versus host disease
10.5. Received a cumulative dose of corticosteroids equivalent to ≥140 mg of prednisone within

14 days prior to the first dose of study treatment
11. Received or plans to receive any live or attenuated vaccine within 4 weeks before the first dose of study treatment, during study treatment, or within 90 days after the last dose of study treatment
11.1. Non live and non replication competent vaccines approved or authorised for emergency use by local health authorities are allowed
12. Any condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant, for example compromising well being, or could prevent, limit, or confound the protocol specified assessments

Date of first enrolment
04/02/2026

Date of final enrolment
14/06/2027

Locations

Countries of recruitment
United Kingdom

England

Scotland

Australia

Brazil

Canada

China

France

Germany

Greece

Israel

Italy

Japan

Netherlands

Norway

Spain

United States of America

Study participating centre
Kent and Canterbury Hospital
Ethelbert Road
Canterbury
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CT1 3NG

Study participating centre
Royal Marsden Hospital
Downs Road
Sutton
England
SM2 5PT

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
England
PO6 3LY

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
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CF14 4XW

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
Scotland
DD1 9SY

Study participating centre

University College London Hospitals NHS Foundation Trust
250 Euston Road
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NW1 2PG

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
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NG5 1PB

Sponsor information

Organisation
Janssen-Cilag International NV

Funder(s)

Funder type

Funder Name
Janssen-Cilag International NV

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available