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A study of JNJ-79635322 in participants with relapsed or refractory multiple myeloma or previously treated amyloid light-chain (AL) amyloidosis

Submission date
16/12/2022

Recruitment status
Recruiting

Registration date
03/01/2023

Overall study status
Ongoing

Last Edited
22/01/2025

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
Multiple myeloma (MM) and AL amyloidosis are blood cancers that affects certain type of white blood cells called plasma cells. Despite improvement in treatment options MM and AL amyloidosis remain incurable. Patients whose MM or AL amyloidosis has returned after treatment (relapsed) or hasn't responded to treatment (refractory), additional treatments are needed to help patients live longer.

The study aims to assess the safety of JNJ-79635322 (study drug) given to participants with relapsed or refractory MM or previously treated AL amyloidosis. It will also examine blood levels of JNJ-79635322 and its effect on participant's MM or previously treated AL amyloidosis.

Who can participate?
18 years or older participants with relapsed/refractory multiple myeloma (RRMM) or previously treated AL amyloidosis, who are not suitable for the available AL amyloidosis treatment that are established to be beneficial. Participants of multiple myeloma previously treated with certain medications (proteosome inhibitor, immunomodulatory drugs and anti-CD38 based therapy). In Part 2, 2 additional cohorts of participants with RRMM may be enrolled who have previously received 1-3 lines of therapy, or who have received autologous (BCMA)-directed (CAR-T) * therapy. *Treatment strategy with high response rates in myeloma.

What does the study involve?
Study has two parts. In part 1, participants will get JNJ-79635322 with increasing doses. The goal of increasing dose is to study safety of each dose and to establish a safe dose for further evaluation in part 2. In part 2, participants will get treatment at recommended dose of JNJ-79635322 from part 1.
The study will consist of a screening period (up to 28 days) followed by treatment period. During treatment period, participants will be treated with JNJ-79635322 until worsening of multiple myeloma or AL amyloidosis, development of serious side effects, death or withdrawal from the

study. After discontinuation of treatment, participants will be followed up to 16 weeks.
Study includes vital signs, blood, bone marrow and pregnancy tests.

What are the possible benefits and risks of participating?
JNJ-79635322 has not been given to people before.
It is unknown if there is clinical benefit associated with JNJ-79635322 treatment. This means that taking part in this study may improve the multiple myeloma, may keep it stable or may make it worse.
It is unknown what side effects will occur with JNJ-79635322 treatment. However, potential side effects for JNJ-79635322, based on how the drug works and results from laboratory studies, include side effects related to immune cell activation, lowering of certain type of cells or antibodies in the blood, and infections. Other side effects may occur as well.
The participant information sheet and informed consent form, which will be signed by every participant agreeing to take part in the study, includes a detailed section outlining the risks to participating in the study. Participants may have none, some, or all of the possible side effects listed, and they may be mild, moderate, or severe. To minimize the risk associated with taking part, participants are frequently reviewed for any side effects and other medical events. If they have any side effects or are worried about them, or have any new or unusual symptoms, participants will be encouraged to talk with their study doctor. The study doctor will also be looking out for side effects and will provide appropriate medical care. There may also be side effects that the researchers do not expect or do not know about and that may be serious. Many side effects go away shortly after the intervention ends. However, sometimes side effects can be serious, long-lasting, or permanent. If a severe side effect or reaction occurs, the study doctor may need to stop the procedure. The study doctor will discuss the best way of managing any side effects with participants. There is always a chance that an unexpected or serious side effect may happen. This can happen to people who take this or any other drug.

Where is the study run from?
Janssen Research & Development (Belgium)

When is the study starting and how long is it expected to run for?
September 2022 to April 2027

Who is funding the study?
Janssen Research & Development (Belgium)

Who is the main contact?
Louis Bornman, janssenukregistryqueries@its.jnj.com

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2022-001465-12

IRAS number
1006143

ClinicalTrials.gov number
NCT05652335

Secondary identifying numbers
79635322MMY1001, IRAS 1006143, CPMS 53506

Study information

Scientific Title
Phase 1, first-in-human, dose escalation study of JNJ-79635322, a trispecific antibody, in participants with relapsed or refractory multiple myeloma or previously treated AL amyloidosis

Study objectives
Current hypothesis as of 05/11/2024:

Main objectives:
1. To identify the recommended Phase 2 dose/doses (RP2D[s]) and schedule to be safe for JNJ-79635322 (Dose Escalation- Part 1).
2. To characterize the safety and tolerability of JNJ-79635322 at the RP2Ds selected and in disease subgroups (Dose Expansion- Part 2).

Secondary objectives:
1. To assess the pharmacokinetics (what the body does to the drug) and immunogenicity (immune response against the drug) of JNJ-79635322.

2. To evaluate the preliminary anti-cancer activity of JNJ-79635322 in participants with relapsed or refractory multiple myeloma (MM) and previously treated AL amyloidosis, who are not suitable for the available AL amyloidosis treatment that are established to be beneficial.

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Previous hypothesis as of 02/01/2024:

Main objectives:
1. To identify the recommended Phase 2 dose/doses (RP2D[s]) and schedule to be safe for JNJ-79635322 (Dose Escalation- Part 1).
2. To characterize the safety and tolerability of JNJ-79635322 at the RP2Ds selected and in disease subgroups (Dose Expansion- Part 2).

Secondary objectives:
1. To assess the pharmacokinetics (what the body does to the drug) and immunogenicity (immune response against the drug) of JNJ-79635322.
2. To evaluate the preliminary anti-cancer activity of JNJ-79635322 in participants with relapsed or refractory multiple myeloma (MM) and previously treated AL amyloidosis.

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Previous hypothesis:

Main objectives:
1. To identify the recommended Phase 2 dose/doses (RP2D[s]) and schedule to be safe for JNJ-79635322 (Dose Escalation- Part 1).
2. To characterize the safety and tolerability of JNJ-79635322 at the RP2Ds (Dose Expansion- Part 2).

Secondary objectives:
1. To assess the pharmacokinetics (what the body does to the drug) and immunogenicity (immune response against the drug) of JNJ-79635322.
2. To evaluate the preliminary anti-cancer activity of JNJ-79635322 in participants with relapsed or refractory multiple myeloma (MM).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/11/2022, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 207 104 8143; gmsouth.rec@hra.nhs.uk), ref: 22/NW/0325

Study design
Multicenter interventional Phase I sequential assignment non-randomized no masking trial

Primary study design
Interventional

Secondary study design

Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Relapsed or refractory multiple myeloma or previously treated amyloid light-chain (AL) amyloidosis

Interventions
Part 1: Dose Escalation; Participants will receive JNJ-79635322. The dose will be escalated sequentially until the recommended phase 2 dose (RP2D) regimen(s) have been identified.
Part 2: Dose Expansion; Participants will receive JNJ-79635322 at the RP2D regimen(s) determined in Part 1.

Triple/quad-refractory multiple myeloma patients have an expected median overall survival of 9.2 months. The duration of follow-up is 16 weeks. The researchers anticipate the treatment to carry on for up to 2 years and 5 months.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
JNJ-79635322

Primary outcome measure
Part 1: Number of participants with dose-limiting toxicity (DLT); up to 2 years 5 months; DLTs are specific adverse events and are defined as any of the following: high-grade non-hematologic toxicity, or hematologic toxicity.
Parts 1 and 2: Number of participants with adverse events (AEs) by Severity; Up to 2 years 5 months; an adverse event is any untoward medical occurrence in a clinical study participant that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Severity will be graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 5.0. Severity scale ranges from grade 1 (mild) to grade 5 (death). Grade 1= mild, Grade 2= moderate, Grade 3= severe, Grade 4= life-threatening and Grade.
Part 2: Number of participants with abnormalities in laboratory values; up to 2 years 5 months; number of participants with abnormalities in laboratory values (hematology and chemistry) will be reported.

Secondary outcome measures

Current secondary outcome measures as of 02/01/2024:
1. Serum concentration of JNJ-79635322; Up to 2 years 5 months; serum samples will be analyzed to determine concentrations of JNJ-79635322.
2. Number of participants with the presence of anti-drug antibodies to JNJ-79635322; up to 2 years 5 months; number of participants with the presence of anti-drug antibodies to JNJ-79635322 will be reported.
3. Preliminary Anticancer Activity of JNJ-79635322 as Defined by International Myeloma Working Group (IMWG) 2016 Response Criteria; up to 2 years 5 months; assessed according to the International Myeloma Working Group (IMWG) 2016 response criteria.
4. Time to Response (TTR) as Defined by IMWG 2016 Response Criteria; up to 2 years 5 months; TTR is defined as the time between the date of the first dose of the study drug and the first efficacy evaluation at which the participant has met all criteria for PR or better as defined by IMWG 2016 response criteria.
5. Duration of Response (DOR) as Defined by IMWG 2016 Response Criteria; up to 2 years 5 months; DOR is defined as the time from the date of initial documentation of a response (PR or better) to the date of first documented evidence of progressive disease (PD), per IMWG 2016 response criteria, or death due to any cause, whichever occurs first.
6. Part 2: Time to Response (TTR) as Defined by International Amyloidosis Consensus Criteria; Up to 2 Years 5 months; TTR is defined as the time between date of first dose of study drug and the first efficacy evaluation at which the participant has met all criteria for PR or better as defined by International Amyloidosis Consensus Criteria.
7. Part 2: Duration of Response (DOR) as Defined by International Amyloidosis Consensus Criteria; Up to 2 Years 5 months; DOR is defined as time from date of initial documentation of a response (PR or better) to date of first documented evidence of progressive disease (PD), per International Amyloidosis Consensus Criteria or death due to any cause, whichever occurs first.
8. Part 2: Preliminary Anticancer Activity of JNJ-79635322 as Defined by International Amyloidosis Consensus Criteria; Up to 2 Years 5 months; Preliminary anticancer activity of JNJ-79635322 will be assessed according to the International Amyloidosis Consensus Criteria.

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Previous secondary outcome measures:
1. Serum concentration of JNJ-79635322; Up to 2 years 5 months; serum samples will be analyzed to determine concentrations of JNJ-79635322.
2. Number of participants with the presence of anti-drug antibodies to JNJ-79635322; up to 2 years 5 months; number of participants with the presence of anti-drug antibodies to JNJ-79635322 will be reported.
3. Preliminary anticancer activity of JNJ-79635322; up to 2 years 5 months; assessed according to the International Myeloma Working Group (IMWG) 2016 response criteria.
4. Time to Response (TTR); up to 2 years 5 months; TTR is defined as the time between the date of the first dose of the study drug and the first efficacy evaluation at which the participant has met all criteria for PR or better as defined by IMWG 2016 response criteria.
5. Duration of Response (DOR); up to 2 years 5 months; DOR is defined as the time from the date of initial documentation of a response (PR or better) to the date of first documented evidence of progressive disease (PD), per IMWG 2016 response criteria, or death due to any cause, whichever occurs first.

Overall study start date
07/09/2022

Completion date

19/04/2027

Eligibility

Key inclusion criteria

Current inclusion criteria as of 02/01/2024:

For participants with relapsed or refractory multiple myeloma:
1. Have a documented initial diagnosis of multiple myeloma according to International Myeloma Working Group (IMWG) diagnostic criteria
2. Have relapsed or refractory disease, have been treated with a proteasome inhibitor, immunomodulatory drug (IMiD) agent, and an anti-CD38-based therapy for the treatment of multiple myeloma (MM), and should have been treated with at least 3 prior lines of therapy, or are refractory to proteosome inhibitor, IMiD agent, and an anti-CD38-based therapy regardless of prior lines of therapy
3. Must have an Eastern Cooperative Oncology Group (ECOG) status of 0 or 1
4. Have measurable disease at screening as defined by at least 1 of the following:
4.1. Serum M-protein level ≥0.5 g/dL; or
4.2. Urine M-protein level ≥200 mg/24 h; or
4.3. Light chain multiple myeloma: Serum immunoglobulin (Ig) free light chain (FLC) ≥10 mg/dL and abnormal serum Ig kappa lambda FLC ratio
4.4. For participants without measurable disease in the serum, urine, or involved FLC, presence of 1 or more focus of extramedullary disease (EMD) which meets the following criteria: extramedullary plasmacytoma not contiguous with a bone lesion, at least 1 lesion ≥2 cm (at its greatest dimension) diameter on whole body Positron Emission Tomography and Computed Tomography (PET-CT) Scans (or whole body magnetic resonance imaging [MRI] approved by sponsor), and not previously radiated (added 05/11/2024: Part 2C participants are not required to have measurable disease)

For participants with previously treated AL amyloidosis:
5. Initial histopathological diagnosis of amyloidosis
6. Participant who is not a candidate for available AL amyloidosis therapy with established clinical benefit and should have received at least 3 cycles of 1 prior line of therapy or a total of at least 2 cycles of 2 or more prior lines of therapy for AL amyloidosis
7. Measurable disease at screening defined by at least 1 of the following: serum involved free light chain (iFLC) ≥50 mg/L or difference between involved and uninvolved free light chains (dFLC) ≥50 mg/L, or serum m-protein ≥0.5 g/dL
8. One or more organs impacted by systemic AL amyloidosis
9. Left ventricular ejection fraction (LVEF) ≥45%

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Previous inclusion criteria:

1. Have a documented initial diagnosis of multiple myeloma according to International Myeloma Working Group (IMWG) diagnostic criteria
2. Have relapsed or refractory disease and have been treated with a proteasome inhibitor, immunomodulatory drug (IMiD) agent, and an anti-CD38-based therapy for the treatment of multiple myeloma (MM)
3. Must have an Eastern Cooperative Oncology Group (ECOG) status of 0 or 1
4. Have measurable disease at screening as defined by at least 1 of the following:

4.1. Serum M-protein level greater than or equal to (>=) 0.5 grams per deciliter (g/dL); or
4.2. Urine M-protein level >=200 milligrams (mg)/24 hours; or
4.3. Light chain multiple myeloma: Serum immunoglobulin (Ig) free light chain (FLC) >=10 milligrams per deciliter (mg/dL) and abnormal serum Ig kappa lambda FLC ratio
4.4. For participants without measurable disease in the serum, urine, or involved FLC, presence of plasmacytomas (>=2 centimeters [cm])

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
180

Key exclusion criteria
Current exclusion criteria as of 05/11/2024:

For participants with relapsed or refractory multiple myeloma:
1. Central Nervous System (CNS) involvement or clinical signs of meningeal involvement of multiple myeloma. If either is suspected, brain magnetic resonance imaging (MRI) and lumbar cytology are required.
2. Active plasma cell leukemia, Waldenstrom's macroglobulinemia, POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, M-protein, and skin changes), or primary light chain amyloidosis
3. Received a cumulative dose of corticosteroids equivalent to >140 mg of prednisone within the 14-day period before the start of study treatment administration
4. Prior antitumor therapy as follows, in the specified time frame prior to the first dose of study treatment: (proteasome inhibitor [PI] therapy or radiotherapy within 14 days, immunomodulatory drug (IMiD) agent therapy within 7 days, gene-modified adoptive cell therapy within 90 days [not applicable for Part 2C participants], or CD3-redirecting therapy within 21 days[not applicable for Part 2B or 2C participants])
5. Prior allogeneic transplant within 6 months before the start of study treatment administration or autologous transplant within 12 weeks before the start of study treatment administration
6. Live, attenuated vaccine within 4 weeks before the first dose of study treatment
7. Non-hematologic toxicity from prior anticancer therapy that has not resolved to baseline levels or to Grade ≤1 (except alopecia, tissue post-RT fibrosis [any grade] or peripheral neuropathy to Grade ≤3)
8. The following medical conditions: pulmonary compromise requiring supplemental oxygen use to maintain adequate oxygenation, human immunodeficiency (HIV) infection, active hepatitis B or C infection, stroke or seizure within 6 months prior to the first dose of study treatment, autoimmune disease, serious active viral or bacterial infection, uncontrolled systemic fungal infection, cardiac conditions (myocardial infarction ≤6 months prior to enrollment, New York Heart Association stage III or IV congestive heart failure, etc)

9. Part 2C: have progressive disease or refractory disease per IMWG after CAR-T administration

For participants with previously treated AL amyloidosis:
10. CNS involvement or clinical signs of meningeal involvement of AL amyloidosis. If either is suspected, whole brain MRI and lumbar cytology are required.
11. Any form of non-AL amyloidosis, including but not limited to transthyretin (ATTR) amyloidosis
12. Active plasma cell leukemia, Waldenstrom's macroglobulinemia, or POEMS syndrome
13. Pulmonary compromise requiring supplemental oxygen use
14. Any serious medical conditions such as: active viral, bacterial, fungal infection; active autoimmune disease; HIV infection, active hepatitis B or C infection, stroke or seizure within 6 months prior to first dose of study treatment, significant cardiovascular conditions
15. Previous or current diagnosis of symptomatic multiple myeloma
16. Macroglossia that impairs swallowing difficulty
17. Received a cumulative dose of corticosteroids equivalent to >140 mg of prednisone within the 14-day period before the start of study treatment administration
18. Prior antitumor therapy within 21 days prior to the first dose of study treatment (PI therapy or radiotherapy within 14 days, IMiD agent therapy within 7 days, gene-modified adoptive cell therapy within 90 days, or CD3-redirecting therapy within 21 days)
19. Prior allogeneic transplant within 6 months before the start of study treatment administration or autologous transplant within 12 weeks before the start of study treatment administration
20. Live, attenuated vaccine within 4 weeks before the first dose of study treatment
21. Non-hematologic toxicity from prior anticancer therapy that has not resolved to baseline levels or to ≤1 (except alopecia, tissue post-RT fibrosis [any grade] or peripheral neuropathy to Grade ≤3)

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Previous exclusion criteria as of 02/01/2024:

For participants with relapsed or refractory multiple myeloma:
1. Central Nervous System (CNS) involvement or clinical signs of meningeal involvement of multiple myeloma. If either is suspected, brain magnetic resonance imaging (MRI) and lumbar cytology are required.
2. Active plasma cell leukemia, Waldenstrom's macroglobulinemia, POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, M-protein, and skin changes), or primary light chain amyloidosis
3. Received a cumulative dose of corticosteroids equivalent to >140 mg of prednisone within the 14-day period before the start of study treatment administration
4. Prior antitumor therapy within 21 days prior to the first dose of study treatment (proteasome inhibitor [PI] therapy or radiotherapy within 14 days, immunomodulatory drug (IMiD) agent therapy within 7 days, gene-modified adoptive cell therapy or CD-3 redirecting therapy within 90 days)
5. Prior allogeneic transplant within 6 months or autologous transplant within 12 weeks
6. Live, attenuated vaccine within 4 weeks before the first dose of study treatment
7. Non-hematologic toxicity from prior anticancer therapy that has not resolved to baseline levels or to Grade ≤1 (except alopecia, tissue post-RT fibrosis [any grade] or peripheral neuropathy to Grade ≤3)
8. The following medical conditions: pulmonary compromise requiring supplemental oxygen use to maintain adequate oxygenation, human immunodeficiency (HIV) infection, active hepatitis B or C infection, stroke or seizure within 6 months prior to the first dose of study treatment, autoimmune disease, serious active viral or bacterial infection, uncontrolled systemic fungal infection, cardiac conditions (myocardial infarction ≤6 months prior to enrollment, New York Heart Association stage III or IV congestive heart failure, etc)

For participants with previously treated AL amyloidosis:
9. CNS involvement or clinical signs of meningeal involvement of AL amyloidosis. If either is suspected, whole brain MRI and lumbar cytology are required.
10. Any form of non-AL amyloidosis, including but not limited to transthyretin (ATTR) amyloidosis
11. Active plasma cell leukemia, Waldenstrom's macroglobulinemia, or POEMS syndrome
12. Pulmonary compromise requiring supplemental oxygen use
13. Any serious medical conditions such as: active viral, bacterial, fungal infection; active autoimmune disease; HIV infection, active hepatitis B or C infection, stroke or seizure within 6 months prior to first dose of study treatment, significant cardiovascular conditions
14. Previous or current diagnosis of symptomatic multiple myeloma
15. Macroglossia that impairs swallowing difficulty
16. Received a cumulative dose of corticosteroids equivalent to >140 mg of prednisone within the 14-day period before the start of study treatment administration
17. Prior antitumor therapy within 21 days prior to the first dose of study treatment (PI therapy or radiotherapy within 14 days, IMiD agent therapy within 7 days, gene-modified adoptive cell therapy within 90 days, or CD3-redirecting therapy within 21 days)
18. Prior allogeneic transplant within 6 months before the start of study treatment administration or autologous transplant within 12 weeks before the start of study treatment administration
19. Live, attenuated vaccine within 4 weeks before the first dose of study treatment
20. Non-hematologic toxicity from prior anticancer therapy that has not resolved to baseline levels or to ≤1 (except alopecia, tissue post-RT fibrosis [any grade] or peripheral neuropathy to Grade ≤3)

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Previous exclusion criteria:

1. Central Nervous System (CNS) involvement or clinical signs of meningeal involvement of multiple myeloma. If either is suspected, brain magnetic resonance imaging (MRI) and lumbar cytology are required
2. Active plasma cell leukemia, Waldenstrom's macroglobulinemia, POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, M-protein, and skin changes), or primary light chain amyloidosis
3. Received a cumulative dose of corticosteroids equivalent to greater than (>) 140 mg of prednisone within the 14-day period before the start of study treatment administration
4. Prior antitumor therapy within 21 days prior to the first dose of study treatment (proteasome inhibitor [PI] therapy or radiotherapy within 14 days, immunomodulatory drug (IMiD) agent therapy within 7 days, gene-modified adoptive cell therapy or CD-3 redirecting therapy within 90 days)
5. Prior allogeneic transplant within 6 months or autologous transplant within 12 weeks
6. Live, attenuated vaccine within 4 weeks before the first dose of study treatment
7. Non-hematologic toxicity from prior anticancer therapy that has not resolved to baseline levels or to Grade less than or equal to (<=) 1 (except alopecia, tissue post-RT fibrosis [any grade] or peripheral neuropathy to Grade <=3)
8. The following medical conditions: pulmonary compromise requiring supplemental oxygen use to maintain adequate oxygenation, human immunodeficiency (HIV) infection, active hepatitis B or C infection, stroke or seizure within 6 months prior to the first dose of study treatment, autoimmune disease, serious active viral or bacterial infection, uncontrolled systemic fungal infection, cardiac conditions (myocardial infarction <=6 months prior to enrollment, New York Heart Association stage III or IV congestive heart failure, etc)

Date of first enrolment
22/11/2022

Date of final enrolment
28/08/2025

Locations

Countries of recruitment
Belgium

England

France

Netherlands

Spain

United Kingdom

Study participating centre
Ghent University Hospital
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Study participating centre
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Sponsor information

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Sponsor type
Industry

Website
https://www.janssen.com

Funder(s)

Funder type
Industry

Funder Name
Janssen Research & Development, LLC

Results and Publications

Publication and dissemination plan
Results of the study will be available to the wider scientific community via publication in scientific journals and presentation at scientific meetings. Study results will be available to participants via provision of a Plain Language Summary at the end of the study and in addition results will be published in the EudraCT database.

Intention to publish date
19/04/2028

Individual participant data (IPD) sharing plan
The data sharing policy of the Janssen Pharmaceutical Companies of Johnson & Johnson is available at https://www.janssen.com/clinical-trials/transparency. As noted on this site, requests for access to the study data can be submitted through Yale Open Data Access (YODA) Project site at yoda.yale.edu

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No