A First-in-Human Dose Escalation Study of JNJ-79635322, in Participants with Relapsed or Refractory Multiple Myeloma or Previously Treated AL Amyloidosis

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I	15
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, dosis	NO

Información

Identificador
2023-503679-12-00 (CTIS)

Cod. Protocolo
79635322MMY1001

Transicionado 2022-001465-12

Área terapéutica
Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada
Relapsed or Refractory Multiple Myeloma
Previously Treated AL Amyloidosis

Título Científico
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

Justificación

No aportado

Objetivo Principal

Part 1 (Dose Escalation) - to identify the recommended Phase 2 dose(s) and schedule(s) to be safe for JNJ-79635322.
Part 2 (Dose Expansion) - to characterize the safety and tolerability of JNJ-79635322 at the RP2D(s) selected and in disease subgroups (eg, prior BCMA/GPRC5D directed therapy, EMD, earlier lines of therapy etc.), as appropriate

Variables de Evaluación Primaria

Part 1 (Dose Escalation): Frequency and type of DLTs; incidence and severity of AEs
Part 2 (Dose Expansion): Frequency and severity of AEs and assessment of laboratory values

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

No aportado

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

For participants with relapsed or refractory multiple myeloma: 1) 18 years of age (or the legal age of consent in the jurisdiction in which the study is taking place) at the time of informed consent. For participants with relapsed or refractory multiple myeloma: 10) 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 3 months after receiving the last dose of study treatment. If partner is a female person of childbearing potential, the male participant must use condom (with or without spermicide) and the partner must also be practicing a highly effective method of contraception (see Appendix

10.5). A male participant who is vasectomized must still use a condom (with or without spermicide), but the partner is not required to use contraception. For participants with relapsed or refractory multiple myeloma: 9) 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 and for a period of 6 months after last dose of study treatment. Female participants should consider preservation of eggs prior to study treatment as anticancer treatments may impair fertility For participants with relapsed or refractory multiple myeloma: 3) Part 1: Have relapsed or refractory disease and have been treated with a proteasome inhibitor, IMiD agent, and an anti-CD38-based therapy for the treatment of MM. Part 2: Part 2A: Have relapsed or refractory disease and have been treated with a proteasome inhibitor, IMiD agent, and an anti-CD38-based therapy for the treatment of MM. OR Part 2B: Have relapsed or refractory disease and have received 1 to 3 prior line(s) of therapy, including a PI and lenalidomide. OR Part 2C: Have relapsed or refractory disease and have received autologous BCMAdirected CAR-T within 2 to 5 months of first dose of study treatment. These participants must also have one of the following disease characteristics: a. Stage 3 by ISS, and/or b. High risk cytogenetics (del 17p, t(14;16), t(4;14), amp1Q), and/or c. Presence of EMD prior to CAR-T administration For participants with relapsed or refractory multiple myeloma: 4) Have measurable disease at screening as defined by at least 1 of the following: a. Serum M-protein level 0.5 g/dL; or b. Urine M-protein level 200 mg/24 hours; or c. Light chain multiple myeloma: Serum Ig FLC 10 mg/dL and abnormal serum Ig kappa lambda FLC ratio. d. For participants without measurable disease in the serum, urine, or involved FLC, presence of 1 or more focus of 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 PET-CT (or whole body MRI approved by sponsor), and not previously radiated. NOTE: Part 2C participants are NOT required to have measurable disease. For participants with relapsed or refractory multiple myeloma: 7) A female participant of childbearing potential must have a negative highly sensitive serum pregnancy test (eg. -hCG) at screening and a negative urine or serum pregnancy test within 72 hours before the start of study treatment administration and must agree to further serum or urine pregnancy tests during the study. For participants with relapsed or refractory multiple myeloma: 12) Must sign an ICF indicating that the participant understands the purpose of, and procedures required for, the study and is willing to participate in the study. For participants with relapsed or refractory multiple myeloma: 11) 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 drug. Male participants should consider preservation of sperm prior to study treatment as anticancer treatments may impair fertility For participants with relapsed or refractory multiple myeloma: 13) Be willing and able to adhere to the lifestyle restrictions specified in this protocol For participants with previously treated AL amyloidosis: Initial histopathological diagnosis of amyloidosis For participants with previously treated AL amyloidosis: 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 For participants with previously treated AL amyloidosis: Pretreatment serum albumin >=2.5g/dL For participants with previously treated AL amyloidosis: Measurable disease at screening defined by at least 1 of the following: serum involved free light chain (iFLC) >=50mg/L or difference between involved and uninvolved free light chains (dFLC) >=50mg/L, or serum m-protein >= 0.5g/dL For participants with previously treated AL amyloidosis: One or more organs impacted by systemic AL amyloidosis For participants with previously treated AL amyloidosis: Left ventricular ejection fraction (LVEF) >=45% For participants with previously treated AL amyloidosis: A female participant of childbearing potential must have a negative highly sensitive serum pregnancy test (eg. -hCG) at screening and a negative urine or serum pregnancy test within 72 hours before the start of study treatment administration and must agree to further serum or urine pregnancy tests during the study. For participants with previously treated AL amyloidosis: Must sign an ICF indicating that the participant understands the purpose of, and procedures required for, the study and is willing to participate in the study. For participants with relapsed or refractory multiple myeloma: 2) Have documented initial diagnosis of multiple myeloma according to IMWG diagnostic criteria (Appendix 10.9) For participants with previously treated AL amyloidosis: Clinical laboratory values meeting the following criteria prior to treatment as listed in the protocol For participants with previously treated AL amyloidosis: Must have an ECOG status of 0 or 1 For participants with previously treated AL amyloidosis: Be willing and able to adhere to the lifestyle restrictions specified in this protocol For participants with relapsed or refractory multiple myeloma: 5) Clinical laboratory values meeting the following criteria prior to treatment For participants with relapsed or refractory multiple myeloma: 6) Must have an ECOG status of 0 or 1 For participants with relapsed or refractory multiple myeloma: 8) A female participant must be a. Not of childbearing potential, or b. Of childbearing potential and practicing at least 1 highly effective method of contraception and agrees to remain on a highly effective method while receiving study drug and until 6 months after last dose. The investigator should evaluate the potential for contraceptive method failure (eg, noncompliance, recently initiated) in relationship to the first dose of study drug. Note: If a female participant becomes of childbearing potential after the start of the study, the female participant must

comply with (b.).

Criterios de Exclusión

For participants with relapsed or refractory multiple myeloma: 1) Central nervous system involvement or clinical signs of meningeal involvement of multiple myeloma. If either is suspected, whole brain MRI and lumbar cytology are required during screening For participants with previously treated AL amyloidosis: 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 For participants with previously treated AL amyloidosis: 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) For participants with relapsed or refractory multiple myeloma: 18) Active hepatitis C infection as measured by positive HCV RNA testing. Participants with a history of Hepatitis C virus antibody positivity must undergo HCV RNA testing. For participants with previously treated AL amyloidosis: Known history of HIV infection For participants with previously treated AL amyloidosis: Active hepatitis B and hepatitis C infection For participants with previously treated AL amyloidosis: Body weight <40kg at screening or at the time of the first administration of study drug For participants with relapsed or refractory multiple myeloma: 11) Nonhematologic toxicity from prior anticancer therapy that has not resolved to baseline level or to less than or equal to Grade 1 (except alopecia, tissue post-RT fibrosis [any grade] or peripheral neuropathy3) For participants with previously treated AL amyloidosis: Trauma or major surgery (eg, requiring general anesthesia) within 2 weeks, or participant will not have fully recovered from surgery, or participant has surgery planned during the time he or she is expected to participate in the study. Participants with planned surgical procedures to be conducted under local anesthesia may participate. For participants with previously treated AL amyloidosis: Plans to father a child while enrolled in this study or within 3 months after the last dose of study drug For participants with relapsed or refractory multiple myeloma: 4) Any serious underlying medical conditions, such as: a. Evidence of active viral, bacterial, or systemic fungal infection requiring ongoing antiviral, antibacterial, or antifungal treatment. b. Active autoimmune disease requiring systemic immunosuppressive therapy within 6 months before start of study treatment. EXCEPTION: Participants with vitiligo, type I diabetes, and prior autoimmune thyroiditis that is currently euthyroid based on clinical symptoms and laboratory testing are eligible regardless of when these conditions were diagnosed. c. Disabling psychiatric conditions, substance abuse (eg, alcohol or drug abuse), severe dementia, or altered mental status d. Any other issue that would impair the ability of the participant to receive or tolerate the planned treatment at the investigational site, to understand the informed consent, or any condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant (eg, compromise the well-being of the participant) or that could prevent, limit, or confound the protocolspecified assessments. For participants with previously treated AL amyloidosis: 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 For participants with relapsed or refractory multiple myeloma: 5) Have a prior or concurrent second malignancy (other than the disease under study) which natural history or treatment is likely to interfere with any study endpoints of safety or the efficacy of the study treatment(s) For participants with relapsed or refractory multiple myeloma: 6) History of stroke or seizure within 6 months prior to the first dose of study treatment For participants with relapsed or refractory multiple myeloma: 19) Received live attenuated vaccine within 4 weeks before first dose of treatment For participants with relapsed or refractory multiple myeloma: 7) History of any of the following cardiac conditions a. New York Heart Association stage III or IV congestive heart failure. b. Myocardial infarction, unstable angina, or coronary artery bypass graft 6 months prior to enrollment. c. History of clinically significant ventricular arrhythmia or unexplained syncope not believed to be vasovagal in nature or due to dehydration. d. History of severe nonischemic cardiomyopathy. e. Screening 12-lead triplicate ECG showing an average baseline QTcF interval of >480 msec For participants with relapsed or refractory multiple myeloma: 8) Known allergies, hypersensitivity, or intolerance to excipients of JNJ-79635322 For participants with relapsed or refractory multiple myeloma: 12) Stem cell transplantation: a. Allogeneic stem cell transplant within 6 months before the start of study treatment administration. Participants who received an allogeneic transplant must be off all immunosuppressive medications for 42 days without signs of graft-versus-host disease. b. Received an autologous stem cell transplant 12 weeks before the start of study treatment administration.. For participants with relapsed or refractory multiple myeloma: 13) Trauma or major surgery (eg, requiring general anesthesia) within 2 weeks, or participant will not have fully recovered from surgery, or participant has surgery planned during the time he or she is expected to participate in the study. Participants with planned surgical procedures to be conducted under

local anesthesia may participate. For participants with relapsed or refractory multiple myeloma: 16) Known history of HIV infection For participants with relapsed or refractory multiple myeloma: 17) Active hepatitis B and hepatitis C infection For participants with relapsed or refractory multiple myeloma: 15) Plans to father a child while enrolled in this study or within 3 months after the last dose of study drug For participants with previously treated AL amyloidosis: Previous or current diagnosis of symptomatic multiple myeloma For participants with relapsed or refractory multiple myeloma: 2) Active plasma cell leukemia, Waldenström's macroglobulinemia, POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, Mprotein, and skin changes), or primary light chain amyloidosis. For participants with relapsed or refractory multiple myeloma: 20) Body weight <40kg at screening or at the time of the first administration of study drug For participants with previously treated AL amyloidosis: CNS involvement or clinical signs of meningeal involvement of AL amyloidosis. If either is suspected, whole brain MRI and lumbar cytology are required For participants with previously treated AL amyloidosis: Any form of non-AL amyloidosis, including but not limited to transthyretin (ATTR) amyloidosis For participants with previously treated AL amyloidosis: Active plasma cell leukemia, Waldenstrom's macroglobulinemia, or POEMS syndrome For participants with previously treated AL amyloidosis: Pulmonary compromise requiring supplemental oxygen use For participants with relapsed or refractory multiple myeloma: 9) Prior antitumor therapy as follows, in the specified time frame prior to the first dose of study treatment: a. Targeted therapy, epigenetic therapy, mAb treatment, or treatment with an investigational drug or an invasive investigational medical device within 21 days or at least 5 half-lives, whichever is less. b. Gene-modified adoptive cell therapy (eg, CAR modified T cells, natural killer cells) within 90 days. Does NOT apply to Part 2C participants. c. Prior treatment with CD3-redirecting therapy within 21 days prior to first dose of study treatment. Does NOT apply to Part 2B or Part 2C participants. Note: Prior exposure to BCMA or GPRC5D targeting agents may be allowed after discussion with the sponsor. d. Conventional chemotherapy within 21 days. e. PI therapy within 14 days. f. Immunomodulatory agent therapy within 7 days. g. Radiotherapy within 14 days. However, if palliative focal radiation was used, the participant is eligible irrespective of the end date of radiotherapy. For participants with relapsed or refractory multiple myeloma: 14) Pregnant, breastfeeding, or planning to become pregnant while enrolled in this study or within 6 months after the last dose of study drug. Female participants who are breastfeeding cannot be enrolled even if they stop breastfeeding during the lactation period. Female participants who are assessed by investigator as possibly in the early pregnancy despite the negative pregnancy test are also excluded. For participants with relapsed or refractory multiple myeloma: 44) Part 2B participants: Had prior CD3-redirecting antibody therapy. Have not received autologous stem cell transplant, CAR-T, anti-CD38 monoclonal antibody if eligible, available, and accessible. For participants with relapsed or refractory multiple myeloma: 45) Part 2C participants, had progressive disease or refractory disease per IMWG after CAR-T administration. For participants with relapsed or refractory multiple myeloma: 10) Received a cumulative dose of corticosteroids equivalent to >140 mg of prednisone within the 14-day period before the start of study treatment administration For participants with previously treated AL amyloidosis: Pregnant, breastfeeding, or planning to become pregnant while enrolled in this study or within 6 months after the last dose of study drug. Female participants who are breastfeeding cannot be enrolled even if they stop breastfeeding during the lactation period. Female participants who are assessed by investigator as possibly in the early pregnancy despite the negative pregnancy test are also excluded. For participants with previously treated AL amyloidosis: Macroglossia that impairs swallowing difficulty For participants with previously treated AL amyloidosis: Received a cumulative dose of corticosteroids equivalent to > 140 mg of prednisone within the 14-day period before the start of study treatment administration For participants with previously treated AL amyloidosis: 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) For participants with relapsed or refractory multiple myeloma: 3) Pulmonary compromise requiring supplemental oxygen used to maintain adequate oxygenation For participants with previously treated AL amyloidosis: Live, attenuated vaccine within 4 weeks before the first dose of study treatment

Calendario

(Última actualización: 19/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
09/12/2022	13/02/2023	21/04/2023	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
No aportado	No aportado	No aportado	No aportado	No aportado

Promotor

Janssen - Cilag International Belgium

Turnhoutseweg 30

Contact Person

CTIS Point of Contact

+31717996133

CTISadmin@its.jnj.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm de la Comunidad Foral de Navarra

C/ Irunlarrea, 3 31008 Pamplona

ceic@cfnavarra.es

Centros

Activo (27/02/2023)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Ensayos clínicos de hematología

Activo (01/03/2023)

Complejo Asistencial Universitario De Salamanca

Salamanca

SALAMANCA

ensayos clinicos de hematología

Activo (22/02/2023)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

NA

Activo (04/05/2023)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

NA

Activo (13/02/2023)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

NA

Medicamentos

Privigen 100 mg/ml solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

Código ATC: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR
Principios Activos: N/A

Experimental

KIOVIG 100 mg/ml solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

Código ATC: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR
Principios Activos: N/A

Experimental

JNJ-79635322
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-
Principios Activos: N/A

Experimental

Privigen 100 mg/ml solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

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SOLUTION FOR INJECTION
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Principios Activos: N/A

Experimental

Sin resultados

A First-in-Human Dose Escalation Study of JNJ-79635322, in Participants with Relapsed or Refractory Multiple Myeloma or Previously Treated AL Amyloidosis

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I	15
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics, dose	NO

Information

Identifier
2023-503679-12-00 (CTIS)

Protocol Code
79635322MMY1001

Transitioned 2022-001465-12

Therapeutic area
Diseases [C] - Cancer [C04]|

Investigated Disease
Relapsed or Refractory Multiple Myeloma
Previously Treated AL Amyloidosis

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

Rationale

Not provided

Main Objective

Part 1 (Dose Escalation) - to identify the recommended Phase 2 dose(s) and schedule(s) to be safe for JNJ-79635322.
Part 2 (Dose Expansion) - to characterize the safety and tolerability of JNJ-79635322 at the RP2D(s) selected and in disease subgroups (eg, prior BCMA/GPRC5D directed therapy, EMD, earlier lines of therapy etc.), as appropriate

Primary Endpoints

Part 1 (Dose Escalation): Frequency and type of DLTs; incidence and severity of AEs
Part 2 (Dose Expansion): Frequency and severity of AEs and assessment of laboratory values

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

For participants with relapsed or refractory multiple myeloma: 1) 18 years of age (or the legal age of consent in the jurisdiction in which the study is taking place) at the time of informed consent. For participants with relapsed or refractory multiple myeloma: 10) 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 3 months after receiving the last dose of study treatment. If partner is a female person of childbearing potential, the male participant must use condom (with or without spermicide) and the partner must also be practicing a highly effective method of contraception (see Appendix

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OR Part 2B: Have relapsed or refractory disease and have received 1 to 3 prior line(s) of therapy, including a PI and lenalidomide. OR Part 2C: Have relapsed or refractory disease and have received autologous BCMAdirected CAR-T within 2 to 5 months of first dose of study treatment. These participants must also have one of the following disease characteristics: a. Stage 3 by ISS, and/or b. High risk cytogenetics (del 17p, t(14;16), t(4;14), amp1Q), and/or c. Presence of EMD prior to CAR-T administration For participants with relapsed or refractory multiple myeloma: 4) Have measurable disease at screening as defined by at least 1 of the following: a. Serum M-protein level 0.5 g/dL; or b. Urine M-protein level 200 mg/24 hours; or c. Light chain multiple myeloma: Serum Ig FLC 10 mg/dL and abnormal serum Ig kappa lambda FLC ratio. d. For participants without measurable disease in the serum, urine, or involved FLC, presence of 1 or more focus of 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 PET-CT (or whole body MRI approved by sponsor), and not previously radiated. NOTE: Part 2C participants are NOT required to have measurable disease. For participants with relapsed or refractory multiple myeloma: 7) A female participant of childbearing potential must have a negative highly sensitive serum pregnancy test (eg. -hCG) at screening and a negative urine or serum pregnancy test within 72 hours before the start of study treatment administration and must agree to further serum or urine pregnancy tests during the study. 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Of childbearing potential and practicing at least 1 highly effective method of contraception and agrees to remain on a highly effective method while receiving study drug and until 6 months after last dose. The investigator should evaluate the potential for contraceptive method failure (eg, noncompliance, recently initiated) in relationship to the first dose of study drug. Note: If a female participant becomes of childbearing potential after the start of the study, the female participant must

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Exclusion criteria

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Disabling psychiatric conditions, substance abuse (eg, alcohol or drug abuse), severe dementia, or altered mental status d. Any other issue that would impair the ability of the participant to receive or tolerate the planned treatment at the investigational site, to understand the informed consent, or any condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant (eg, compromise the well-being of the participant) or that could prevent, limit, or confound the protocolspecified assessments. For participants with previously treated AL amyloidosis: 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 For participants with relapsed or refractory multiple myeloma: 5) Have a prior or concurrent second malignancy (other than the disease under study) which natural history or treatment is likely to interfere with any study endpoints of safety or the efficacy of the study treatment(s) For participants with relapsed or refractory multiple myeloma: 6) History of stroke or seizure within 6 months prior to the first dose of study treatment For participants with relapsed or refractory multiple myeloma: 19) Received live attenuated vaccine within 4 weeks before first dose of treatment For participants with relapsed or refractory multiple myeloma: 7) History of any of the following cardiac conditions a. New York Heart Association stage III or IV congestive heart failure. b. Myocardial infarction, unstable angina, or coronary artery bypass graft 6 months prior to enrollment. c. History of clinically significant ventricular arrhythmia or unexplained syncope not believed to be vasovagal in nature or due to dehydration. d. History of severe nonischemic cardiomyopathy. e. Screening 12-lead triplicate ECG showing an average baseline QTcF interval of >480 msec For participants with relapsed or refractory multiple myeloma: 8) Known allergies, hypersensitivity, or intolerance to excipients of JNJ-79635322 For participants with relapsed or refractory multiple myeloma: 12) Stem cell transplantation: a. Allogeneic stem cell transplant within 6 months before the start of study treatment administration. Participants who received an allogeneic transplant must be off all immunosuppressive medications for 42 days without signs of graft-versus-host disease. b. Received an autologous stem cell transplant 12 weeks before the start of study treatment administration.. For participants with relapsed or refractory multiple myeloma: 13) Trauma or major surgery (eg, requiring general anesthesia) within 2 weeks, or participant will not have fully recovered from surgery, or participant has surgery planned during the time he or she is expected to participate in the study. Participants with planned surgical procedures to be conducted under

local anesthesia may participate. For participants with relapsed or refractory multiple myeloma: 16) Known history of HIV infection For participants with relapsed or refractory multiple myeloma: 17) Active hepatitis B and hepatitis C infection For participants with relapsed or refractory multiple myeloma: 15) Plans to father a child while enrolled in this study or within 3 months after the last dose of study drug For participants with previously treated AL amyloidosis: Previous or current diagnosis of symptomatic multiple myeloma For participants with relapsed or refractory multiple myeloma: 2) Active plasma cell leukemia, Waldenström's macroglobulinemia, POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, Mprotein, and skin changes), or primary light chain amyloidosis. For participants with relapsed or refractory multiple myeloma: 20) Body weight <40kg at screening or at the time of the first administration of study drug For participants with previously treated AL amyloidosis: CNS involvement or clinical signs of meningeal involvement of AL amyloidosis. If either is suspected, whole brain MRI and lumbar cytology are required For participants with previously treated AL amyloidosis: Any form of non-AL amyloidosis, including but not limited to transthyretin (ATTR) amyloidosis For participants with previously treated AL amyloidosis: Active plasma cell leukemia, Waldenstrom's macroglobulinemia, or POEMS syndrome For participants with previously treated AL amyloidosis: Pulmonary compromise requiring supplemental oxygen use For participants with relapsed or refractory multiple myeloma: 9) Prior antitumor therapy as follows, in the specified time frame prior to the first dose of study treatment: a. Targeted therapy, epigenetic therapy, mAb treatment, or treatment with an investigational drug or an invasive investigational medical device within 21 days or at least 5 half-lives, whichever is less. b. Gene-modified adoptive cell therapy (eg, CAR modified T cells, natural killer cells) within 90 days. Does NOT apply to Part 2C participants. c. Prior treatment with CD3-redirecting therapy within 21 days prior to first dose of study treatment. Does NOT apply to Part 2B or Part 2C participants. Note: Prior exposure to BCMA or GPRC5D targeting agents may be allowed after discussion with the sponsor. d. Conventional chemotherapy within 21 days. e. PI therapy within 14 days. f. Immunomodulatory agent therapy within 7 days. g. Radiotherapy within 14 days. However, if palliative focal radiation was used, the participant is eligible irrespective of the end date of radiotherapy. For participants with relapsed or refractory multiple myeloma: 14) Pregnant, breastfeeding, or planning to become pregnant while enrolled in this study or within 6 months after the last dose of study drug. Female participants who are breastfeeding cannot be enrolled even if they stop breastfeeding during the lactation period. Female participants who are assessed by investigator as possibly in the early pregnancy despite the negative pregnancy test are also excluded. For participants with relapsed or refractory multiple myeloma: 44) Part 2B participants: Had prior CD3-redirecting antibody therapy. Have not received autologous stem cell transplant, CAR-T, anti-CD38 monoclonal antibody if eligible, available, and accessible. For participants with relapsed or refractory multiple myeloma: 45) Part 2C participants, had progressive disease or refractory disease per IMWG after CAR-T administration. For participants with relapsed or refractory multiple myeloma: 10) Received a cumulative dose of corticosteroids equivalent to >140 mg of prednisone within the 14-day period before the start of study treatment administration For participants with previously treated AL amyloidosis: Pregnant, breastfeeding, or planning to become pregnant while enrolled in this study or within 6 months after the last dose of study drug. Female participants who are breastfeeding cannot be enrolled even if they stop breastfeeding during the lactation period. Female participants who are assessed by investigator as possibly in the early pregnancy despite the negative pregnancy test are also excluded. For participants with previously treated AL amyloidosis: Macroglossia that impairs swallowing difficulty For participants with previously treated AL amyloidosis: Received a cumulative dose of corticosteroids equivalent to > 140 mg of prednisone within the 14-day period before the start of study treatment administration For participants with previously treated AL amyloidosis: 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) For participants with relapsed or refractory multiple myeloma: 3) Pulmonary compromise requiring supplemental oxygen used to maintain adequate oxygenation For participants with previously treated AL amyloidosis: Live, attenuated vaccine within 4 weeks before the first dose of study treatment

Calendar

(Last Update: 19/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
09/12/2022	13/02/2023	21/04/2023	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
Not aported	Not aported	Not aported	Not aported	Not aported

Sponsor

Janssen - Cilag International Belgium

Turnhoutseweg 30

Contact Person

CTIS Point of Contact

+31717996133

CTISadmin@its.jnj.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm de la Comunidad Foral de Navarra

C/ Irunlarrea, 3 31008 Pamplona

ceic@cfnavarra.es

Sites

Active (27/02/2023)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Ensayos clínicos de hematología

Active (01/03/2023)

Complejo Asistencial Universitario De Salamanca

Salamanca

SALAMANCA

ensayos clinicos de hematología

Active (22/02/2023)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

NA

Active (04/05/2023)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

NA

Active (13/02/2023)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

NA

Medication

Privigen 100 mg/ml solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

ATC code: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR
Active Principles: N/A

Experimental

KIOVIG 100 mg/ml solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

ATC code: J06BA02 - INMUNOGLOBULINAS HUMANAS NORMALES PARA ADM. INTRAVASCULAR
Active Principles: N/A

Experimental

JNJ-79635322
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-
Active Principles: N/A

Experimental

Privigen 100 mg/ml solution for infusion
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SOLUTION FOR INJECTION
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INTRAVENOUS USE

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Active Principles: N/A

Experimental

No results