A Phase 3 Randomized Study Comparing JNJ-79635322 versus Teclistamab in Participants with Relapsed or Refractory Multiple Myeloma

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	494
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	eficacia	NO

Información

Identificador
2025-523815-12-00 (CTIS)

Cod. Protocolo
79635322MMY3002

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

Enfermedad investigada
Relapsed or Refractory Multiple Myeloma

Título Científico
"A Phase 3 Randomized Study Comparing JNJ-79635322 versus Teclistamab in Participants with Relapsed or Refractory Multiple Myeloma after 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Antibody and Lenalidomide"

Justificación

No aportado

Objetivo Principal

To compare the efficacy of JNJ-79635322 with teclistamab

Variables de Evaluación Primaria

Dual primary endpoints: CR or better, PFS

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

1. At the time of informed consent, be 18 years of age 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: a. MM diagnosis according to the IMWG diagnostic criteria (Rajkumar 2014) b. Measurable disease at screening as assessed by central laboratory, defined by any of the following: i. Serum M-protein level 0.5 g/dL; or ii. Serum Ig FLC 10 mg/dL and abnormal serum Ig kappa lambda FLC ratio; or iii. Urine M-protein level 200 mg/24 hours 3. Received 1 to 3 prior lines of antimyeloma therapy, including an anti-CD38 antibody and lenalidomide. The participant must have undergone at least 2 consecutive cycles of an anti-CD38 antibody at the approved dosing schedule (or a minimum of 6 doses if the anti-CD38 antibody was only part of a maintenance regimen) in any prior line and 2 consecutive cycles of lenalidomide in any prior line, unless PD was the best response to the line of therapy 4. Relapsed or refractory disease as defined below: i. Relapsed disease is defined as an initial response to prior treatment, followed by

confirmed PD by IMWG response criteria >60 days after cessation of treatment. ii. Refractory disease is defined as failure to achieve a response or confirmed PD by IMWG response criteria during previous treatment or 60 days after cessation of treatment. 5. Have an ECOG performance status of 0 to 2 at screening and immediately before the first dose of study medication

Criterios de Exclusión

1. Serious underlying medical conditions, such as: i. Evidence of active systemic viral, fungal or bacterial infection requiring systemic antiviral, antifungal, or antimicrobial therapy. ii. Active autoimmune disease requiring systemic immunosuppressive therapy within 6 months before start of treatment. EXCEPTION: Participants with vitiligo, Type 1 diabetes, or prior autoimmune thyroiditis that is currently euthyroid based on clinical symptoms and laboratory testing are eligible regardless of when these conditions were diagnosed. iii. Overt clinical evidence of dementia or altered mental status 5. Presence of any of the following: i. Any ongoing myelodysplastic syndrome or B-cell malignancy (other than MM). ii. Any history of malignancy, other than MM, that is considered at high risk of recurrence requiring systemic therapy. iii. Any active malignancy (ie, progressing or requiring treatment change in the last 24 months) other than MM. The only allowed exceptions are malignancies treated within the last 24 months that are considered cured: i. Non-muscle invasive bladder cancer (solitary Ta-papillary urothelial neoplasm of low malignant potential or low-grade, <3 cm, no carcinoma in situ). ii. Non-melanoma skin cancers treated with curative therapy or localized melanoma treated with curative surgical resection alone. iii. Non-invasive cervical cancer. iv. Breast cancer: adequately treated lobular carcinoma in situ or ductal carcinoma in situ, or history of localized breast cancer (anti-hormonal therapy is permitted). v. Localized prostate cancer (M0, N0) with a Gleason Score 7, treated locally only (radical prostatectomy/radiotherapy/focal treatment). vi. Other malignancy that is considered cured with minimal risk of recurrence in consultation with the sponsor. 9. Active hepatitis of infectious origin. i. Seropositive for hepatitis B: defined by a positive test for HBsAg. Participants with resolved infection (ie, participants who are HBsAg negative with positive antibodies to total HBc antigen [anti-HBc]) must be screened using RT-PCR measurement of HBV DNA levels. Those who are RT-PCR positive will be excluded. Participants with serologic findings suggestive of HBV vaccination (anti-HBs positivity as the only serologic marker) AND a known history of prior HBV vaccination, do not need to be tested for HBV DNA by RT-PCR (see Section 10.6). ii. Known hepatitis C infection or positive serologic testing for HCV (anti-HCV) antibody. Participants with positive hepatitis C antibody due to prior resolved disease can be enrolled only if a confirmatory negative hepatitis C RNA test is obtained at screening or within 3 months prior to first dose of study treatment. iii. Other clinically active liver disease of infectious origin 10. Concurrent use of any other anticancer treatment (including non-palliative radiotherapy) or investigational agent. For participants who received an allogeneic stem cell transplant, the transplant must be dated at least 6 months before first dose of study drug. Participants who received an allogeneic transplant must be off all immunosuppressive medications for 6 weeks before the start of study treatment administration without signs of graft-versus-host disease. Toxicity related to prior anticancer treatment must have resolved to Grade 1 or better. 11. Received prior or concurrent exposure to T-cell redirecting therapy (eg, CAR-T, bispecific antibodies), directed at BCMA or GPRC5D.

Calendario

(Última actualización: 24/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
03/07/2026	06/07/2026	14/07/2026	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 Hospital Clínico San Carlos

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ceic.hcsc@salud.madrid.org

917044160

Centros

No iniciado (--/--/----)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

No iniciado (--/--/----)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

No iniciado (--/--/----)

Complejo Asistencial Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

No iniciado (--/--/----)

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Hematology

No iniciado (--/--/----)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Activo (06/07/2026)

Hospital De Jerez De La Frontera

Jerez De La Frontera

CÁDIZ

Hematology

No iniciado (--/--/----)

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Hematology

No iniciado (--/--/----)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology

No iniciado (--/--/----)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

No iniciado (--/--/----)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

No iniciado (--/--/----)

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Activo (16/07/2026)

Hospital Universitario Reina Sofia

Cordoba

CÓRDOBA

Hematology

Activo (13/07/2026)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

No iniciado (--/--/----)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medicamentos

JNJ-79635322
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-
Principios Activos: N/A
Huérfano Experimental

teclistamab
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-
Principios Activos: N/A
Experimental

teclistamab
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-
Principios Activos: N/A
Experimental

JNJ-79635322
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-
Principios Activos: N/A
Huérfano Experimental

Sin resultados

A Phase 3 Randomized Study Comparing JNJ-79635322 versus Teclistamab in Participants with Relapsed or Refractory Multiple Myeloma

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	494
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	effectiveness	NO

Information

Identifier
2025-523815-12-00 (CTIS)

Protocol Code
79635322MMY3002

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

Investigated Disease
Relapsed or Refractory Multiple Myeloma

Scientific Title
"A Phase 3 Randomized Study Comparing JNJ-79635322 versus Teclistamab in Participants with Relapsed or Refractory Multiple Myeloma after 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Antibody and Lenalidomide"

Rationale

Not provided

Main Objective

To compare the efficacy of JNJ-79635322 with teclistamab

Primary Endpoints

Dual primary endpoints: CR or better, PFS

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. At the time of informed consent, be 18 years of age 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: a. MM diagnosis according to the IMWG diagnostic criteria (Rajkumar 2014) b. Measurable disease at screening as assessed by central laboratory, defined by any of the following: i. Serum M-protein level 0.5 g/dL; or ii. Serum Ig FLC 10 mg/dL and abnormal serum Ig kappa lambda FLC ratio; or iii. Urine M-protein level 200 mg/24 hours 3. Received 1 to 3 prior lines of antimyeloma therapy, including an anti-CD38 antibody and lenalidomide. The participant must have undergone at least 2 consecutive cycles of an anti-CD38 antibody at the approved dosing schedule (or a minimum of 6 doses if the anti-CD38 antibody was only part of a maintenance regimen) in any prior line and 2 consecutive cycles of lenalidomide in any prior line, unless PD was the best response to the line of therapy 4. Relapsed or refractory disease as defined below: i. Relapsed disease is defined as an initial response to prior treatment, followed by

confirmed PD by IMWG response criteria >60 days after cessation of treatment. ii. Refractory disease is defined as failure to achieve a response or confirmed PD by IMWG response criteria during previous treatment or 60 days after cessation of treatment. 5. Have an ECOG performance status of 0 to 2 at screening and immediately before the first dose of study medication

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Calendar

(Last Update: 24/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
03/07/2026	06/07/2026	14/07/2026	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

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917044160

Sites

not initialized (--/--/----)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

not initialized (--/--/----)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

not initialized (--/--/----)

Complejo Asistencial Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

not initialized (--/--/----)

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Hematology

not initialized (--/--/----)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Active (06/07/2026)

Hospital De Jerez De La Frontera

Jerez De La Frontera

CÁDIZ

Hematology

not initialized (--/--/----)

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Hematology

not initialized (--/--/----)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology

not initialized (--/--/----)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

not initialized (--/--/----)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

not initialized (--/--/----)

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Active (16/07/2026)

Hospital Universitario Reina Sofia

Cordoba

CÓRDOBA

Hematology

Active (13/07/2026)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

not initialized (--/--/----)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medication

JNJ-79635322
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Active Principles: N/A

Orphan Experimental

teclistamab
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Active Principles: N/A

Experimental

teclistamab
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Active Principles: N/A

Experimental

JNJ-79635322
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Active Principles: N/A

Orphan Experimental

No results