# A Phase 3 Study Comparing JNJ-79635322 and an anti-BCMAxCD3 Bispecific Antibody 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 | 265 |
| **Resultados** | **Bajo nivel intervención** | **Enfermedad rara** |
| Sin resultados | No | No |
| **Cobertura geográfica** | **Ámbitos del ensayo** | **Terapia avanzada** |
| Sin determinar | eficacia | NO |

## Información

### Identificador
2025-522007-18-00 (CTIS)

### Cod. Protocolo
79635322MMY3001

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

### Enfermedad investigada
Relapsed or Refractory Multiple Myeloma

### Título Científico
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

## Justificación

No aportado

## Objetivo Principal

To compare the efficacy of JNJ-79635322 with a BCMAxCD3 bispecific antibody.

## Variables de Evaluación Primaria

Dual primary endpoints: overall response rate, progression-free survival

## Momentos temporales de evaluación primaria

No aportado

## Objetivo Secundario

To further compare the efficacy of JNJ-79635322 with a BCMAxCD3 bispecific antibody
To evaluate and characterize the overall safety profile of JNJ-79635322
To assess participants HRQoL, symptoms, and functioning through various PRO tools
To assess participants tolerability through PRO
To characterize the PK of JNJ-79635322
To assess the immunogenicity of JNJ-79635322

## Variables de Evaluación Secundaria

"VGPR or better CR or better Duration of response MRD-negative CR MRD-negative CR at 9 months Sustained MRD-negative CR (duration 12 months) PFS2 OS TTNT"
TEAE incidence and severity, laboratory results, and other safety parameters
Change from baseline in HRQoL, symptoms, and functioning using the MySIm-Q, EORTC QLQ-C30, and EQ-5D-5L scores Time to worsening in HRQoL, symptoms, and functioning using the MySIm-Q, EORTC QLQ-C30, and EQ-5D-5L scores Percent of participants with meaningful improvement in HRQoL symptoms, and functioning using the MySIm-Q, EORTC QLQ-C30, and EQ-5D-5L scores
Proportion of participants who report side effects burden on the EORTC IL46
JNJ-79635322 serum concentration
Presence of ADAs and neutralizing antibodies to JNJ-79635322

## 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). 10. Participants must agree, while on study treatment and for 6 months after the last dose of study treatment, to: Not breastfeed or be pregnant. Not donate gametes (ie, eggs or sperm) or freeze for future use for the purposes of assisted reproduction. Wear an external condom, when transmission of sperm/ejaculate can occur. If of childbearing potential, Have a negative highly sensitive (eg, -hCG) pregnancy test at screening and within 24 hours before the first dose of study treatment, and agree to further pregnancy tests, Practice at least 1 highly effective method of contraception; if oral contraceptives are used, a barrier method of contraception must also be used. If able to produce sperm and their partner is of childbearing potential, the partner must practice a highly effective method of contraception. See Section 10.3 for details. 11.Must provide informed consent as described in Section 10.2.3. 12. Be willing and able to adhere to the lifestyle restrictions specified in this protocol. 2.1 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 ii. Serum immunoglobulin FLC 10 mg/dL and abnormal serum immunoglobulin kappa lambda FLC ratio iii. Urine M-protein level 200 mg/24 hours NOTE: 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. 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. Refer to Section 10.7 for the definition of a line of therapy. 4. Documented evidence of PD or failure to achieve a response (ie, PR or better) to the last line of therapy based on investigators determination of response by the IMWG criteria. Relapsed or refractory disease as defined below: a. Relapsed disease is defined as an initial response to prior treatment, followed by confirmed PD by the IMWG response criteria >60 days after cessation of treatment. b. Refractory disease is defined as failure to achieve a response (ie, PR or better) or confirmed PD by the IMWG response criteria during previous treatment or 60 days after cessation of treatment 5. Have discontinued concurrent use of any other anticancer treatment (including nonpalliative radiotherapy) or investigational agent. Toxicity related to previous anticancer therapy must have resolved to resolved to Grade 1 or better (except 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). 7.1 Renal function: Have an eGFR, calculated with the CKD-epi creatinine formula (Section 10.12) of >30 mL/min during the screening period. 8. Hepatic function: 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: AST and ALT <2.5×ULN Total bilirubin <1.5×ULN Bilirubin in case of known congenital nonhemolytic hyperbilirubinemias such as Gilberts Syndrome: isolated total bilirubin 1.5×ULN with direct bilirubin <1.5×ULN 9. Hematologic values: 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: Hemoglobin 7.5 g/dL, without use of transfusion or growth factors within 7 days Neutrophils 0.75×103/L (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) Platelets 50×103/L, without use of transfusion or growth factors within 7 days

## Criterios de Exclusión

1. 2. Serious underlying medical conditions, such as: a. Evidence of active systemic viral, fungal, or bacterial infection requiring systemic antiviral, antifungal, or antimicrobial therapy and clinically relevant at the time of first dose. b. Active autoimmune disease requiring systemic immunosuppressive therapy within 6 months before start of study treatment. EXCEPTION: Participants with vitiligo, type I 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 or treatment. c. Overt clinical evidence of dementia or altered mental status d. Any of the following within 6 months prior to first dose of study treatment: severe or unstable angina, myocardial infarction, seizure, major thromboembolic events (eg, pulmonary embolism, cerebrovascular accident [including TIA and stroke]), clinically significant ventricular arrhythmias or heart failure New York Heart Association functional

classification Class III to IV. Uncomplicated deep vein thrombosis is not considered exclusionary. 10. 1 Prior or concurrent exposure to any of the following, in the specified time frame prior to randomization: a. T-cell redirection therapy (eg, CAR-T, bispecific antibody) within 6 months. b. History of receiving both BCMA and GPRC5D-directed therapy c. History of receiving a BCMA-directed bispecific antibody d. An allogenic stem cell transplant within 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. e. Received a cumulative dose of corticosteroids equivalent to 140 mg of prednisone within the 14 days prior to first dose of study drug. f. Treatment with an investigational drug, investigational intervention (including investigational vaccines) or used an invasive investigational medical device within 28 days or 5 half-lives, whichever is longer. 11. Received or plans to receive any live, attenuated vaccine within 4 weeks before the first dose of study treatment, during, or within 90 days after the last dose of study treatment. Non-live and non-replication-competent vaccines approved or authorized 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 (eg, compromise the well-being) or that could prevent, limit, or confound the protocol-specified assessments. 2. Active hepatitis of infectious origin. a. 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 hepatitis B core 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, Hepatitis B Virus Screening) b. Known hepatitis C infection or positive serologic testing for hepatitis C virus (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. c. Other clinically active liver disease of infectious origin. 3.Participants who are HIV-positive and meet any of the following: a. Detectable viral load (ie, 50 copies/mL) at screening b. CD4+ count 300 cells/mm3 at screening c. Acquired immunodeficiency syndrome (AIDS)-defining opportunistic infection within 6 months of screening d. Receive treatment other than continued HAART. A change in HAART due to resistance/progression must occur at least 3 months prior to screening. A change in HAART due to toxicity is allowed up to 4 weeks prior to screening. Note: HAART that could interfere with study treatment is excluded (consult the sponsor for a review of medications prior to enrollment). 4.Plasma cell leukemia at the time of screening (5% circulating PCs in peripheral blood smear), Waldenstroms macroglobulinemia, POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes), or primary amyloid light chain amyloidosis. 5. Known active or prior CNS involvement or exhibits clinical signs of meningeal involvement of MM. If either is suspected, negative whole brain MRI and lumbar cytology are required. 6.1 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. The only allowed exceptions are: i. Any malignancy that was not progressing nor requiring treatment change in the last 12 months and not considered at high risk or recurrence requiring systemic therapy. ii. Malignancies treated within the last 12 months and considered at very low risk of recurrence: a. Non-muscle invasive bladder cancer (solitary Ta-papillary urothelial neoplasm of low malignant potential or low-grade, <3 cm, no carcinoma in situ) b.Non-melanoma skin cancers treated with curative therapy or localized melanoma treated with curative surgical resection alone c. Non-invasive cervical cancer d. Breast cancer: adequately treated lobular carcinoma in situ or ductal carcinoma in situ, or history of localized breast cancer (anti-hormonal therapy is permitted) e. Localized prostate cancer (M0, N0) with a Gleason Score 7a, treated locally only (Radical Prostatectomy/Radiotherapy/focal treatment) iii. Other malignancy that is considered cured with minimal risk of recurrence NOTE: In the event of any questions, consult with the sponsor prior to enrolling a participant. 7.Suspected or known allergies, hypersensitivity, or intolerance to the excipients of JNJ-79635322 (refer to the IB). 8.1 Major surgery, (eg, requiring general anesthesia) within 2 weeks before first dose, or will not have fully recovered from surgery, or has surgery planned during the time the participant is expected to participate in the study. Note: Participants with planned surgical procedures to be conducted under local anesthesia may participate. 9. Suspected or known allergies, hypersensitivity, or intolerance to teclistamab or its excipients (TECVAYLI USPI 2024).

# Calendario

(Última actualización: 21/09/2026)

| Autorización | Inicio de Ensayo | Inclusión Primer Paciente | Interrumpido | Reiniciado |
|---|---|---|---|---|
| 22/05/2026 | 01/06/2026 | 25/06/2026 | 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

**C/ Doctor Martín Lagos, s/n - Ciudad Universitaria 28040 Madrid**

**ceic.hcsc@salud.madrid.org**

**917044160**

# Centros

Activo (01/06/2026)

**Hospital Clinic De Barcelona**

Barcelona

BARCELONA

Hematology

Activo (30/07/2026)

**Hospital De Galdakao Usansolo**

Galdakao

VIZCAYA/BIZKAIA

Hematology

Activo (11/06/2026)

**Hospital Germans Trias I Pujol**

Badalona

BARCELONA

Hematology

Activo (16/07/2026)

**Hospital Universitari Vall D Hebron**

Barcelona

BARCELONA

Hematology

Activo (01/06/2026)

**Hospital Universitario De Salamanca**

Salamanca

SALAMANCA

Hematology

Activo (24/07/2026)

**Hospital Universitario Quironsalud Madrid**

Pozuelo De Alarcon

MADRID

Hematology

Activo (01/06/2026)

**Hospital Universitario Virgen De Las Nieves**

Granada

GRANADA

Hematology

Activo (04/06/2026)

**Hospital Universitario Y Politecnico La Fe**

Valencia

VALENCIA

Hematology

Activo (04/06/2026)

**Hospital Universitario 12 De Octubre**

Madrid

MADRID

Hematology

# Medicamentos

**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

**JNJ-79635322**
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

**Principios Activos: N/A**

Huérfano

Experimental

# Sin resultados

# A Phase 3 Study Comparing JNJ-79635322 and an anti-BCMAxCD3 Bispecific Antibody 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 | 265 |
| **Results** | **Low level of intervention** | **Rare disease** |
| No results | No | No |
| **Geographic coverage** | **Areas of the study** | **Advanced therapy** |
| Undetermined | effectiveness | NO |

## Information

### Identifier
2025-522007-18-00 (CTIS)

### Protocol Code
79635322MMY3001

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

### Investigated Disease
Relapsed or Refractory Multiple Myeloma

### 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

## Rationale

Not provided

## Main Objective

To compare the efficacy of JNJ-79635322 with a BCMAxCD3 bispecific antibody.

## Primary Endpoints

Dual primary endpoints: overall response rate, progression-free survival

## Temporary moments of secondary assessment

Not provided

## Secondary Objective

To further compare the efficacy of JNJ-79635322 with a BCMAxCD3 bispecific antibody
To evaluate and characterize the overall safety profile of JNJ-79635322
To assess participants HRQoL, symptoms, and functioning through various PRO tools
To assess participants tolerability through PRO
To characterize the PK of JNJ-79635322
To assess the immunogenicity of JNJ-79635322

## Secondary Endpoints

"VGPR or better CR or better Duration of response MRD-negative CR MRD-negative CR at 9 months Sustained MRD-negative CR (duration 12 months) PFS2 OS TTNT"
TEAE incidence and severity, laboratory results, and other safety parameters
Change from baseline in HRQoL, symptoms, and functioning using the MySIm-Q, EORTC QLQ-C30, and EQ-5D-5L scores Time to worsening in HRQoL, symptoms, and functioning using the MySIm-Q, EORTC QLQ-C30, and EQ-5D-5L scores Percent of participants with meaningful improvement in HRQoL symptoms, and functioning using the MySIm-Q, EORTC QLQ-C30, and EQ-5D-5L scores
Proportion of participants who report side effects burden on the EORTC IL46
JNJ-79635322 serum concentration
Presence of ADAs and neutralizing antibodies to JNJ-79635322

## 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). 10. Participants must agree, while on study treatment and for 6 months after the last dose of study treatment, to: Not breastfeed or be pregnant. Not donate gametes (ie, eggs or sperm) or freeze for future use for the purposes of assisted reproduction. Wear an external condom, when transmission of sperm/ejaculate can occur. If of childbearing potential, Have a negative highly sensitive (eg, -hCG) pregnancy test at screening and within 24 hours before the first dose of study treatment, and agree to further pregnancy tests, Practice at least 1 highly effective method of contraception; if oral contraceptives are used, a barrier method of contraception must also be used. If able to produce sperm and their partner is of childbearing potential, the partner must practice a highly effective method of contraception. See Section 10.3 for details. 11.Must provide informed consent as described in Section 10.2.3. 12. Be willing and able to adhere to the lifestyle restrictions specified in this protocol. 2.1 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 ii. Serum immunoglobulin FLC 10 mg/dL and abnormal serum immunoglobulin kappa lambda FLC ratio iii. Urine M-protein level 200 mg/24 hours NOTE: 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. 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. Refer to Section 10.7 for the definition of a line of therapy. 4. Documented evidence of PD or failure to achieve a response (ie, PR or better) to the last line of therapy based on investigators determination of response by the IMWG criteria. Relapsed or refractory disease as defined below: a. Relapsed disease is defined as an initial response to prior treatment, followed by confirmed PD by the IMWG response criteria >60 days after cessation of treatment. b. Refractory disease is defined as failure to achieve a response (ie, PR or better) or confirmed PD by the IMWG response criteria during previous treatment or 60 days after cessation of treatment 5. Have discontinued concurrent use of any other anticancer treatment (including nonpalliative radiotherapy) or investigational agent. Toxicity related to previous anticancer therapy must have resolved to resolved to Grade 1 or better (except 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). 7.1 Renal function: Have an eGFR, calculated with the CKD-epi creatinine formula (Section 10.12) of >30 mL/min during the screening period. 8. Hepatic function: 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: AST and ALT <2.5×ULN Total bilirubin <1.5×ULN Bilirubin in case of known congenital nonhemolytic hyperbilirubinemias such as Gilberts Syndrome: isolated total bilirubin 1.5×ULN with direct bilirubin <1.5×ULN 9. Hematologic values: 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: Hemoglobin 7.5 g/dL, without use of transfusion or growth factors within 7 days Neutrophils 0.75×103/L (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) Platelets 50×103/L, without use of transfusion or growth factors within 7 days

## Exclusion criteria

1. 2. Serious underlying medical conditions, such as: a. Evidence of active systemic viral, fungal, or bacterial infection requiring systemic antiviral, antifungal, or antimicrobial therapy and clinically relevant at the time of first dose. b. Active autoimmune disease requiring systemic immunosuppressive therapy within 6 months before start of study treatment. EXCEPTION: Participants with vitiligo, type I 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 or treatment. c. Overt clinical evidence of dementia or altered mental status d. Any of the following within 6 months prior to first dose of study treatment: severe or unstable angina, myocardial infarction, seizure, major thromboembolic events (eg, pulmonary embolism, cerebrovascular accident [including TIA and stroke]), clinically significant ventricular arrhythmias or heart failure New York Heart Association functional

classification Class III to IV. Uncomplicated deep vein thrombosis is not considered exclusionary. 10. 1 Prior or concurrent exposure to any of the following, in the specified time frame prior to randomization: a. T-cell redirection therapy (eg, CAR-T, bispecific antibody) within 6 months. b. History of receiving both BCMA and GPRC5D-directed therapy c. History of receiving a BCMA-directed bispecific antibody d. An allogenic stem cell transplant within 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. e. Received a cumulative dose of corticosteroids equivalent to 140 mg of prednisone within the 14 days prior to first dose of study drug. f. Treatment with an investigational drug, investigational intervention (including investigational vaccines) or used an invasive investigational medical device within 28 days or 5 half-lives, whichever is longer. 11. Received or plans to receive any live, attenuated vaccine within 4 weeks before the first dose of study treatment, during, or within 90 days after the last dose of study treatment. Non-live and non-replication-competent vaccines approved or authorized 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 (eg, compromise the well-being) or that could prevent, limit, or confound the protocol-specified assessments. 2. Active hepatitis of infectious origin. a. 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 hepatitis B core 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, Hepatitis B Virus Screening) b. Known hepatitis C infection or positive serologic testing for hepatitis C virus (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. c. Other clinically active liver disease of infectious origin. 3.Participants who are HIV-positive and meet any of the following: a. Detectable viral load (ie, 50 copies/mL) at screening b. CD4+ count 300 cells/mm3 at screening c. Acquired immunodeficiency syndrome (AIDS)-defining opportunistic infection within 6 months of screening d. Receive treatment other than continued HAART. A change in HAART due to resistance/progression must occur at least 3 months prior to screening. A change in HAART due to toxicity is allowed up to 4 weeks prior to screening. Note: HAART that could interfere with study treatment is excluded (consult the sponsor for a review of medications prior to enrollment). 4.Plasma cell leukemia at the time of screening (5% circulating PCs in peripheral blood smear), Waldenstroms macroglobulinemia, POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes), or primary amyloid light chain amyloidosis. 5. Known active or prior CNS involvement or exhibits clinical signs of meningeal involvement of MM. If either is suspected, negative whole brain MRI and lumbar cytology are required. 6.1 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. The only allowed exceptions are: i. Any malignancy that was not progressing nor requiring treatment change in the last 12 months and not considered at high risk or recurrence requiring systemic therapy. ii. Malignancies treated within the last 12 months and considered at very low risk of recurrence: a. Non-muscle invasive bladder cancer (solitary Ta-papillary urothelial neoplasm of low malignant potential or low-grade, <3 cm, no carcinoma in situ) b.Non-melanoma skin cancers treated with curative therapy or localized melanoma treated with curative surgical resection alone c. Non-invasive cervical cancer d. Breast cancer: adequately treated lobular carcinoma in situ or ductal carcinoma in situ, or history of localized breast cancer (anti-hormonal therapy is permitted) e. Localized prostate cancer (M0, N0) with a Gleason Score 7a, treated locally only (Radical Prostatectomy/Radiotherapy/focal treatment) iii. Other malignancy that is considered cured with minimal risk of recurrence NOTE: In the event of any questions, consult with the sponsor prior to enrolling a participant. 7.Suspected or known allergies, hypersensitivity, or intolerance to the excipients of JNJ-79635322 (refer to the IB). 8.1 Major surgery, (eg, requiring general anesthesia) within 2 weeks before first dose, or will not have fully recovered from surgery, or has surgery planned during the time the participant is expected to participate in the study. Note: Participants with planned surgical procedures to be conducted under local anesthesia may participate. 9. Suspected or known allergies, hypersensitivity, or intolerance to teclistamab or its excipients (TECVAYLI USPI 2024).

# Calendar

(Last Update: 21/09/2026)

| Authorization | Start of Trial | First patient inclusion | Halted | Restarted |
|---|---|---|---|---|
| 22/05/2026 | 01/06/2026 | 25/06/2026 | 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

### CEIm Hospital Clínico San Carlos

**C/ Doctor Martín Lagos, s/n - Ciudad Universitaria 28040 Madrid**

**ceic.hcsc@salud.madrid.org**

**917044160**

# Sites

Active (01/06/2026)

**Hospital Clinic De Barcelona**

Barcelona

BARCELONA

Hematology

Active (30/07/2026)

**Hospital De Galdakao Usansolo**

Galdakao

VIZCAYA/BIZKAIA

Hematology

Active (11/06/2026)

**Hospital Germans Trias I Pujol**

Badalona

BARCELONA

Hematology

Active (16/07/2026)

**Hospital Universitari Vall D Hebron**

Barcelona

BARCELONA

Hematology

Active (01/06/2026)

**Hospital Universitario De Salamanca**

Salamanca

SALAMANCA

Hematology

Active (24/07/2026)

**Hospital Universitario Quironsalud Madrid**

Pozuelo De Alarcon

MADRID

Hematology

Active (01/06/2026)

**Hospital Universitario Virgen De Las Nieves**

Granada

GRANADA

Hematology

Active (04/06/2026)

**Hospital Universitario Y Politecnico La Fe**

Valencia

VALENCIA

Hematology

Active (04/06/2026)

**Hospital Universitario 12 De Octubre**

Madrid

MADRID

Hematology

# Medication

**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

**JNJ-79635322**
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Active Principles: N/A

Orphan

Experimental

# No results