A Phase 3 Study Comparing Daratumumab, VELCADE (bortezomib), Lenalidomide, and Dexamethasone (D-VRd) with VELCADE, Lenalidomide, and Dexamethasone (VRd) in Subjects with Untreated Multiple Myeloma and for Whom Hematopoietic Stem Cell Transplant is Not Planned as Initial Therapy

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	238
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética	NO

Información

Identificador
2023-507312-13-00 (CTIS)

Cod. Protocolo
54767414MMY3019

Transicionado 2018-001545-13

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

Enfermedad investigada
Multiple Myeloma

Título Científico
A Phase 3 Study Comparing Daratumumab, VELCADE (bortezomib), Lenalidomide, and Dexamethasone (D-VRd)

with VELCADE, Lenalidomide, and Dexamethasone (VRd) in Subjects with Untreated Multiple Myeloma and for Whom Hematopoietic Stem Cell Transplant is Not Planned as Initial Therapy

Justificación

No aportado

Objetivo Principal

The primary objective is to determine if the addition of daratumumab to VRd will improve overall minimal residual disease (MRD) negativity rate compared with VRd alone

Variables de Evaluación Primaria

Overall MRD negativity rate, which is defined as the proportion of subjects who have achieved MRD negative status (at 10^-5) by bone marrow aspirate after randomization and prior to progressive disease (PD) or subsequent anti myeloma therapy. Subjects who have achieved MRD negative status on or after PD or after the switch to subsequent anti-myeloma therapy before PD, will not be considered MRD negative in the primary endpoint analysis

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. Newly diagnosed and not considered candidate for high-dose chemotherapy with stem cell transplantation due to: Being age 65years,or age 18-65years with presence of comorbid condition(s) likely to have a negative impact on

tolerability of high-dose chemotherapy with SCT or who refuse high-dose chemotherapy with SCT as initial treatment 10. Male subjects of reproductive potential must not donate sperm during the study or for 3months after the last dose of study treatment 11. Must sign an informed consent form (ICF) or their legally designated representative must sign indicating that he or she understands the purpose of, and procedures required for, the study and is willing to participate in the study 12. Able to adhere to the prohibitions and restrictions specified in this protocol 2. Diagnosis of multiple myeloma as documented per International Myeloma Working Group Criteria: Monoclonal plasma cells in the bone marrow 10% or presence of a biopsy proven plasmacytoma and documented multiple myeloma satisfying at least one of the calcium, renal, anemia, bone (CRAB) criteria or biomarkers of malignancy criteria: CRAB criteria: 1. Hypercalcemia: serum calcium >0.25mmol/L (>1mg/dL) higher than upper limit of normal (ULN) or >2.75mmol/L (>11mg/dL) 2. Renal insufficiency:creatinine clearance <40mL/min or serum creatinine >177 mol/L (>2mg/dL) 3. Anemia :hemoglobin >2g/dL below the lower limit of normal or hemoglobin <10g/dL 4. Bone lesions: one or more osteolytic lesions on skeletal radiography, computed tomography (CT), or positron emission tomography (PET)-CT Biomarkers of Malignancy: a. Clonal bone marrow plasma cell percentage 60% b. Involved: uninvolved serum free light chain (FLC) ratio 100 c. >1 focal lesion on magnetic resonance imaging (MRI) studies 3. Must have measurable disease, as assessed by central laboratory, defined by any of the following: - IgG, IgA, IgM, IgD,or IgE multiple myeloma: Serum monoclonal paraprotein (M-protein) level 1.0g/dL or urine M-protein level 200mg/24 hours;or - Light chain multiple myeloma without measurable disease in serum or urine: Serum Ig FLC 10mg/dL and abnormal serum Ig kappa lambda FLC ratio 4. Eastern cooperative oncology group (ECOG) performance status score of 0, 1 or 2 5. Clinical laboratory values meeting the following criteria during the Screening Phase: a. hemoglobin 7.5 g/dL (5 mmol/L) (without prior RBC transfusion within 7 days before the laboratory test; recombinant human erythropoietin use is permitted); b. absolute neutrophil count (ANC) 1.0 x 109/L (granulocyte colony stimulating factor [G-CSF] use is permitted) c. platelet count 70x109/L for subjects in whom <50% of bone marrow nucleated cells are plasma cells; otherwise platelet count >50×109/L (transfusions are not permitted within 7 days) d. aspartate aminotransferase (AST) 2.5 x ULN e. alanine aminotransferase (ALT) 2.5 x ULN f. total bilirubin 1.5 x ULN, except in subjects with congenital bilirubinemia,such as Gilbert syndrome (direct bilirubin 2.0 x ULN) g. Estimated creatinine clearance (CrCl) 30 mL/min.Creatinine clearance can be calculated using the Cockcroft-Gault formula or eGFR (MDRD;, or CKD-epi formula or for subjects with over- or underweight, CrCl may be measured from a 24-hours urine collection using the formula provided in Appendix 8 [Section 10.8]). If Cockcroft-Gault formula is used and body mass index (BMI) is 30 kg/m2 then adjusted body weight should be used in calculation. h. corrected serum calcium 13.5 mg/dL (3.4 mM/L); or free ionized calcium 6.5 mg/dL (1.6 mM/L) 6. Female subjects of reproductive childbearing potential must commit to either abstain continuously from heterosexual sexual intercourse or to use 2 methods of reliable birth control simultaneously during the Treatment Period,during any dose interruptions, and for 3 months after the last dose of any component of the treatment regimen .Sexual abstinence is considered a highly effective method only if defined as refraining from heterosexual intercourse during the entire period of risk associated with the study drug. This birth control method must include one highly effective form of contraception (tubal ligation, intrauterine device, hormonal [birth control pills, injections, hormonal patches, vaginal rings or implants] or partner's vasectomy) and one additional effective contraceptive method (male latex or synthetic condom, diaphragm, or cervical cap). Contraception must begin 4 weeks prior to dosing. Reliable contraception is indicated even where there has been a history of infertility, unless due to hysterectomy or bilateral oophorectomy 7. A woman of childbearing potential must have 2 negative serum or urine pregnancy tests at Screening, first within 10 to 14 days prior to dosing and the second within 24hours prior to dosing. For requirements during the Treatment Phase, refer to Section 5.3 8. A woman must agree not to donate eggs (ova, oocytes)for the purposes of assisted reproduction during the study and for a period of 3months after receiving the last dose of any component of the treatment regimen 9.Male subjects of reproductive potential who are sexually active with females of reproductive potential must always use a latex or synthetic condom during the study and for 3months after discontinuing study treatment (even after a successful vasectomy)

Criterios de Exclusión

Any potential subject who meets any of the following criteria will be excluded from participating in the study: 1. Frailty index of 2 according to Myeloma Geriatric Assessment score 10. Subject is: a. Known to be seropositive for human immunodeficiency virus (HIV). b. seropositive for hepatitis B (defined by a positive test for hepatitis B surface antigen [HBsAg]). Subjects with resolved infection (ie, subjects who are HBsAg negative but positive for antibodies to total hepatitis B core antigen [anti-HBc] and/or antibodies to hepatitis B surface antigen [anti-HBs]) must be screened

using real-time polymerase chain reaction (PCR) measurement of hepatitis B virus (HBV) DNA levels. Those who are PCR positive will be excluded. EXCEPTION: Subjects 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 PCR. c. Known to be seropositive for hepatitis C virus (HCV; anti-HCV antibody positive or HCV-RNA quantitation positive), except in the setting of a sustained virologic response (SVR), defined as aviremia at least 12 weeks after completion of antiviral therapy 11. Concurrent medical or psychiatric condition or disease (such as but not limited to, systemic amyloidosis, POEMS, active systemic infection, uncontrolled diabetes, acute diffuse infiltrative pulmonary disease) that is likely to interfere with study procedures or results, or that in the opinion of the investigator would constitute a hazard if enrolled in the study 12. Has clinically significant cardiac disease, including: Myocardial infarction within 6 months before signing the informed consent form (ICF), or unstable or uncontrolled disease/condition related to or affecting cardiac function (eg, unstable angina, congestive heart failure, New York Heart Association Class III-IV; Appendix 18) Uncontrolled cardiac arrhythmia or clinically significant electrocardiogram (ECG) abnormalities Screening 12-lead ECG showing a baseline QT interval as corrected by Frederica's formula (QTcF) >470 msec 13. Received a strong CYP3A4 inducer within 5 half-lives prior to randomization 14. Allergy, hypersensitivity, or intolerance to boron or mannitol, corticosteroids, monoclonal antibodies or human proteins, or their excipients, or sensitivity to mammalian-derived products or lenalidomide 2. Prior therapy for multiple myeloma other than a short course of corticosteroids (not to exceed 40 mg of dexamethasone, or equivalent per day, total of 160 mg dexamethasone or equivalent) 3. Prior or concurrent invasive malignancy (other than multiple myeloma) within 5 years of date of randomization (exceptions are adequately treated basal cell or squamous cell carcinoma of the skin, carcinoma in situ of the cervix or breast, or other noninvasive lesion that in the opinion of the investigator, with concurrence with the sponsor's medical monitor, is considered cured with minimal risk of recurrence within 3 years) 4. Peripheral neuropathy or neuropathic pain Grade 2 or higher, as defined by the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 5 5. Focal radiation therapy within 14 days of randomization with the exception of palliative radiotherapy for symptomatic pain management. Radiotherapy within 14 days prior to randomization on measurable extramedullary plasmacytoma is not permitted even in the setting of palliation for symptomatic management 6. Plasmapheresis within 28 days of randomization 7. Clinical signs of meningeal involvement of multiple myeloma 8. Chronic obstructive pulmonary disease (COPD) with a forced expiratory volume in 1 second (FEV1) <50% of predicted. (FEV1 testing is required for subjects suspected of having COPD) 9. Moderate or severe persistent asthma within the past 2 years, uncontrolled asthma of any classification. (Subjects who have controlled intermittent asthma or controlled mild persistent asthma are allowed in the study)

Calendario

(Última actualización: 24/04/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
23/10/2018	06/11/2018	15/11/2018	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
23/10/2019	No aportado	No aportado	30/10/2025	21/04/2026

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

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

Fundacio Assistencial De Mutua De Terrassa Fpc

Terrassa

BARCELONA

Hematology

Cerrado (26/01/2026)

HOSPITAL DEL MAR

Barcelona

BARCELONA

Servicio Hematología

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

Hospital Del Mar

Barcelona

BARCELONA

Hematology

Cerrado (06/04/2026)

HOSPITAL QUIRÓNSALUD MADRID

Pozuelo de Alarcón

MADRID

Servicio hematologia y hemoterapia

Cerrado (04/03/2026)

HOSPITAL UNIVERSITARI MÚTUA DE TERRASSA

Terrassa

BARCELONA

Servicio hematologia y hemoterapia

Cerrado (11/02/2020)

HOSPITAL UNIVERSITARIO DE GUADALAJARA

Guadalajara

GUADALAJARA

Servicio hematología

Cerrado (04/02/2026)

HOSPITAL UNIVERSITARIO FUNDACIÓN ALCORCÓN

Alcorcón

MADRID

Servicio hematologia

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

Hospital Universitario Fundacion Alcorcon

Madrid

MADRID

Hematology

Cerrado (25/10/2021)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

Majadahonda

MADRID

Servicio de Hematología

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

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Medicamentos

Revlimid 15 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

VELCADE 3.5 mg powder for solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

Código ATC: L01XG01 - BORTEZOMIB
Principios Activos: N/A

Experimental

DARZALEX 1800 mg solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

Código ATC: L01FC01 - DARATUMUMAB
Principios Activos: N/A

Huérfano
Experimental

Revlimid 5 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Revlimid 10 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Revlimid 15 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

-
-
ORAL

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A

Experimental

Dexamethason 4 mg JENAPHARM®
TABLET
ORAL

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A

Experimental

Revlimid 20 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Revlimid 5 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Revlimid 25 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Revlimid 10 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Sin resultados

A Phase 3 Study Comparing Daratumumab, VELCADE (bortezomib), Lenalidomide, and Dexamethasone (D-VRd) with VELCADE, Lenalidomide, and Dexamethasone (VRd) in Subjects with Untreated Multiple Myeloma and for Whom Hematopoietic Stem Cell Transplant is Not Planned as Initial Therapy

State	Type of participants	Age Ranges
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	238
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-507312-13-00 (CTIS)

Protocol Code
54767414MMY3019

Transitioned 2018-001545-13

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

Investigated Disease
Multiple Myeloma

Scientific Title
A Phase 3 Study Comparing Daratumumab, VELCADE (bortezomib), Lenalidomide, and Dexamethasone (D-VRd)

with VELCADE, Lenalidomide, and Dexamethasone (VRd) in Subjects with Untreated Multiple Myeloma and for Whom Hematopoietic Stem Cell Transplant is Not Planned as Initial Therapy

Rationale

Not provided

Main Objective

The primary objective is to determine if the addition of daratumumab to VRd will improve overall minimal residual disease (MRD) negativity rate compared with VRd alone

Primary Endpoints

Overall MRD negativity rate, which is defined as the proportion of subjects who have achieved MRD negative status (at 10^-5) by bone marrow aspirate after randomization and prior to progressive disease (PD) or subsequent anti myeloma therapy. Subjects who have achieved MRD negative status on or after PD or after the switch to subsequent anti-myeloma therapy before PD, will not be considered MRD negative in the primary endpoint analysis

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. Newly diagnosed and not considered candidate for high-dose chemotherapy with stem cell transplantation due to: Being age 65years,or age 18-65years with presence of comorbid condition(s) likely to have a negative impact on

tolerability of high-dose chemotherapy with SCT or who refuse high-dose chemotherapy with SCT as initial treatment 10. Male subjects of reproductive potential must not donate sperm during the study or for 3months after the last dose of study treatment 11. Must sign an informed consent form (ICF) or their legally designated representative must sign indicating that he or she understands the purpose of, and procedures required for, the study and is willing to participate in the study 12. Able to adhere to the prohibitions and restrictions specified in this protocol 2. Diagnosis of multiple myeloma as documented per International Myeloma Working Group Criteria: Monoclonal plasma cells in the bone marrow 10% or presence of a biopsy proven plasmacytoma and documented multiple myeloma satisfying at least one of the calcium, renal, anemia, bone (CRAB) criteria or biomarkers of malignancy criteria: CRAB criteria: 1. 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Must have measurable disease, as assessed by central laboratory, defined by any of the following: - IgG, IgA, IgM, IgD,or IgE multiple myeloma: Serum monoclonal paraprotein (M-protein) level 1.0g/dL or urine M-protein level 200mg/24 hours;or - Light chain multiple myeloma without measurable disease in serum or urine: Serum Ig FLC 10mg/dL and abnormal serum Ig kappa lambda FLC ratio 4. Eastern cooperative oncology group (ECOG) performance status score of 0, 1 or 2 5. Clinical laboratory values meeting the following criteria during the Screening Phase: a. hemoglobin 7.5 g/dL (5 mmol/L) (without prior RBC transfusion within 7 days before the laboratory test; recombinant human erythropoietin use is permitted); b. absolute neutrophil count (ANC) 1.0 x 109/L (granulocyte colony stimulating factor [G-CSF] use is permitted) c. platelet count 70x109/L for subjects in whom <50% of bone marrow nucleated cells are plasma cells; otherwise platelet count >50×109/L (transfusions are not permitted within 7 days) d. aspartate aminotransferase (AST) 2.5 x ULN e. alanine aminotransferase (ALT) 2.5 x ULN f. total bilirubin 1.5 x ULN, except in subjects with congenital bilirubinemia,such as Gilbert syndrome (direct bilirubin 2.0 x ULN) g. Estimated creatinine clearance (CrCl) 30 mL/min.Creatinine clearance can be calculated using the Cockcroft-Gault formula or eGFR (MDRD;, or CKD-epi formula or for subjects with over- or underweight, CrCl may be measured from a 24-hours urine collection using the formula provided in Appendix 8 [Section 10.8]). If Cockcroft-Gault formula is used and body mass index (BMI) is 30 kg/m2 then adjusted body weight should be used in calculation. h. corrected serum calcium 13.5 mg/dL (3.4 mM/L); or free ionized calcium 6.5 mg/dL (1.6 mM/L) 6. 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Reliable contraception is indicated even where there has been a history of infertility, unless due to hysterectomy or bilateral oophorectomy 7. A woman of childbearing potential must have 2 negative serum or urine pregnancy tests at Screening, first within 10 to 14 days prior to dosing and the second within 24hours prior to dosing. For requirements during the Treatment Phase, refer to Section 5.3 8. A woman must agree not to donate eggs (ova, oocytes)for the purposes of assisted reproduction during the study and for a period of 3months after receiving the last dose of any component of the treatment regimen 9.Male subjects of reproductive potential who are sexually active with females of reproductive potential must always use a latex or synthetic condom during the study and for 3months after discontinuing study treatment (even after a successful vasectomy)

Exclusion criteria

Any potential subject who meets any of the following criteria will be excluded from participating in the study: 1. Frailty index of 2 according to Myeloma Geriatric Assessment score 10. Subject is: a. Known to be seropositive for human immunodeficiency virus (HIV). b. seropositive for hepatitis B (defined by a positive test for hepatitis B surface antigen [HBsAg]). Subjects with resolved infection (ie, subjects who are HBsAg negative but positive for antibodies to total hepatitis B core antigen [anti-HBc] and/or antibodies to hepatitis B surface antigen [anti-HBs]) must be screened

using real-time polymerase chain reaction (PCR) measurement of hepatitis B virus (HBV) DNA levels. Those who are PCR positive will be excluded. EXCEPTION: Subjects 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 PCR. c. Known to be seropositive for hepatitis C virus (HCV; anti-HCV antibody positive or HCV-RNA quantitation positive), except in the setting of a sustained virologic response (SVR), defined as aviremia at least 12 weeks after completion of antiviral therapy 11. Concurrent medical or psychiatric condition or disease (such as but not limited to, systemic amyloidosis, POEMS, active systemic infection, uncontrolled diabetes, acute diffuse infiltrative pulmonary disease) that is likely to interfere with study procedures or results, or that in the opinion of the investigator would constitute a hazard if enrolled in the study 12. Has clinically significant cardiac disease, including: Myocardial infarction within 6 months before signing the informed consent form (ICF), or unstable or uncontrolled disease/condition related to or affecting cardiac function (eg, unstable angina, congestive heart failure, New York Heart Association Class III-IV; Appendix 18) Uncontrolled cardiac arrhythmia or clinically significant electrocardiogram (ECG) abnormalities Screening 12-lead ECG showing a baseline QT interval as corrected by Frederica's formula (QTcF) >470 msec 13. Received a strong CYP3A4 inducer within 5 half-lives prior to randomization 14. Allergy, hypersensitivity, or intolerance to boron or mannitol, corticosteroids, monoclonal antibodies or human proteins, or their excipients, or sensitivity to mammalian-derived products or lenalidomide 2. Prior therapy for multiple myeloma other than a short course of corticosteroids (not to exceed 40 mg of dexamethasone, or equivalent per day, total of 160 mg dexamethasone or equivalent) 3. Prior or concurrent invasive malignancy (other than multiple myeloma) within 5 years of date of randomization (exceptions are adequately treated basal cell or squamous cell carcinoma of the skin, carcinoma in situ of the cervix or breast, or other noninvasive lesion that in the opinion of the investigator, with concurrence with the sponsor's medical monitor, is considered cured with minimal risk of recurrence within 3 years) 4. Peripheral neuropathy or neuropathic pain Grade 2 or higher, as defined by the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 5 5. Focal radiation therapy within 14 days of randomization with the exception of palliative radiotherapy for symptomatic pain management. Radiotherapy within 14 days prior to randomization on measurable extramedullary plasmacytoma is not permitted even in the setting of palliation for symptomatic management 6. Plasmapheresis within 28 days of randomization 7. Clinical signs of meningeal involvement of multiple myeloma 8. Chronic obstructive pulmonary disease (COPD) with a forced expiratory volume in 1 second (FEV1) <50% of predicted. (FEV1 testing is required for subjects suspected of having COPD) 9. Moderate or severe persistent asthma within the past 2 years, uncontrolled asthma of any classification. (Subjects who have controlled intermittent asthma or controlled mild persistent asthma are allowed in the study)

Calendar

(Last Update: 24/04/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
23/10/2018	06/11/2018	15/11/2018	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
23/10/2019	Not aported	Not aported	30/10/2025	21/04/2026

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

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

Fundacio Assistencial De Mutua De Terrassa Fpc

Terrassa

BARCELONA

Hematology

Closed (26/01/2026)

HOSPITAL DEL MAR

Barcelona

BARCELONA

Servicio Hematología

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

Hospital Del Mar

Barcelona

BARCELONA

Hematology

Closed (06/04/2026)

HOSPITAL QUIRÓNSALUD MADRID

Pozuelo de Alarcón

MADRID

Servicio hematologia y hemoterapia

Closed (04/03/2026)

HOSPITAL UNIVERSITARI MÚTUA DE TERRASSA

Terrassa

BARCELONA

Servicio hematologia y hemoterapia

Closed (11/02/2020)

HOSPITAL UNIVERSITARIO DE GUADALAJARA

Guadalajara

GUADALAJARA

Servicio hematología

Closed (04/02/2026)

HOSPITAL UNIVERSITARIO FUNDACIÓN ALCORCÓN

Alcorcón

MADRID

Servicio hematologia

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

Hospital Universitario Fundacion Alcorcon

Madrid

MADRID

Hematology

Closed (25/10/2021)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

Majadahonda

MADRID

Servicio de Hematología

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

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Medication

Revlimid 15 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

VELCADE 3.5 mg powder for solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

ATC code: L01XG01 - BORTEZOMIB
Active Principles: N/A

Experimental

DARZALEX 1800 mg solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

ATC code: L01FC01 - DARATUMUMAB
Active Principles: N/A

Orphan
Experimental

Revlimid 5 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

Revlimid 10 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

Revlimid 15 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

-
-
ORAL

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A

Experimental

Dexamethason 4 mg JENAPHARM®
TABLET
ORAL

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A

Experimental

Revlimid 20 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

Revlimid 5 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

Revlimid 25 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

Revlimid 10 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

No results