An open label, multicenter, Phase 2, pilot study, evaluating early treatment with bispecific T-cell redirectors (teclistamab and talquetamab) in the therapy of newly diagnosed high -risk 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 II	30
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia	NO

Información

Identificador
2024-514016-26-00 (CTIS)

Cod. Protocolo
GEM-TECTAL

Transicionado 2022-000598-15

Área terapéutica
Enfermedades [C] - Hematología [C15]|

Enfermedad investigada
Multiple Myeloma

Título Científico
An open label, multicenter, Phase 2, pilot study, evaluating early treatment with bispecific T-cell redirectors (teclistamab and talquetamab) in the frontline therapy of newly diagnosed high-risk multiple myeloma

Justificación

No aportado

Objetivo Principal

To evaluate efficacy in terms of MRD negative CR rate after Teclistamab - Daratumumab intensification

Variables de Evaluación Primaria

MRD measured by NGF (sensitivity level of 10-6) and FDG PET-CT scan using the Deauville score and CR evaluated per IMWG 2016 response criteria after 6 cycles of Tec-Dara therapy

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate MRD negative CR rate after D-VRD induction.
To evaluate MRD negativity after Tec-Dara intensification using alternative methods.
To evaluate MRD conversion after early rescue intervention with Tal- Dara.
To evaluate MRD conversion after Tec-Dara intensification.
To evaluate sustained MRD negativity during maintenance treatment in both Tec-Dara and Tal-Dara treatment arms
To assess reappearance of MRD positivity or relapse from CR in patients during the Tec-Dara treatment
To assess Time to event data
To assess the safety of the treatment described in the protocol
Immune profiling and genetic characterization

Variables de Evaluación Secundaria

MRD measured by NGF (sensitivity level of 10-6) and FDG PET-CT scan using the Deauville score and CR evaluated per IMWG 2016 response criteria after 4 cycles of D-VRD induction
MRD negative rates measured by NGS, and QIP-MS-FLC after 6 cycles of Tec-Dara therapy
Percentage of patients converting from positive MRD to negative MRD evaluated by NGF, NGS, QIP-MS-FLC and FDG-PET-CT scan.
Percentage of patients converting from positive MRD after D-VRD induction to negative MRD evaluated by NGF, NGS, QIP-MS-FLC and FDG-PET-CT scan after Tec-Dara intensification.
Proportion of patients with persistent MRD negative disease at month 6, 12, 18 and 24 of maintenance treatment in both Tec-Dara and Tal-Dara treatment, by NGF, NGS, QIP-MS-FLC and FDG-PET-CT scan and annually thereafter
Proportion of patients relapsing from MRD negative CR to MRD positive or who relapse from CR (not fulfilling criteria for disease progression) during any phase of Tec-Dara treatment (intensification or maintenance)
PFS, EFS, TNT, DoR and OS
Incidence of treatment-emergent adverse events

Analysis of immune subpopulation and genetic markers.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Patient is, in the investigator's opinion, willing and able to comply with the protocol requirements Age between 18 80 years regardless of transplant eligibility at the time of inclusion. Patient has documented diagnosis of multiple myeloma according to IMWG diagnostic criteria, with at least one of the following high-risk features: a)High-risk FISH: del(1p), del(17p), t(4;14), t(14;16) and 1q amplifications. b)R-ISS 3. c)Presence of extramedullary disease, defined as presence of paramedullary lesions or extramedullary plasmacytoma. Patient has measurable secretory disease defined as either serum monoclonal protein of 0.5 g/dL or urine monoclonal (light chain) protein 200 mg/24 h. For patients whose disease is only measurable by serum FLC, the involved FLC should be 10mg/dL (100 mg/L), with an abnormal serum FLC ratio. Human inmunodeficiency virus-positive patients are elegible if they meet all of the following: a. No detectable viral load (ie, < 50 copies/mL) at screening b. CD4+ count > 300 cells/mm3 at screening c. No AIDS defining opportunistic infection within 6 months of screening d. Receiving HAART. Any changes in HAART due to resistance/progression should occur at least 3 months prior to screening. A change in HAART due to toxicity is allowed up to 4 weeks prior to screening. Patient has an ECOG performance status of 0, 1 or 2. Patient must have adequate organ function, defined in: Hemoglobin 8 g/dL, Platelets 75 x 109/L in participants in whom <50% of bone marrow nucleated cells are plasma cells and 50×109/L in participants in whom 50% of bone marrow nucleated cells are plasma cells (without transfusion support or thrombopoietin receptor agonist within 7 days before the laboratory test), ANC 1.0 x 109 /L, ALT and AST 2.5 x upper limit normal, eGFR 30 mL/min based on Modified Diet in Renal Disease Formula calculation or creatine clearance measured by a 24-hour urine collection, Total bilirubin 1.5 x ULN (isolated total bilirubin 1.5 x ULN with conjugated [direct] bilirubin < 1.5 x ULN is allowed for those patients Corrected serum calcium 14 mg/dL (3.5 mmol/L) or free ionized calcium 6.5 mg/dL (1.6 mmol/L) A female of childbearing potential must have a negative highly sensitive urine or serum (human chorionic gonadotropin [-hCG]) pregnancy test at screening and 24h prior to the start of study treatment and must agree to further urine or serum pregnancy tests during the study and within 6 months after receiving the last dose of study treatment A woman must be: a. Not of childbearing potential, or b. Of childbearing potential and i. Practicing true abstinence; or ii. Have a sole partner who is vasectomized; or iii. Practicing 2 methods of contraception (at least 1 highlyeffective) A female patient must agree not to donate eggs (ova, oocytes) or freeze for future use for the purposes of assisted reproduction during the study and for 6 months after receiving the last dose of study treatment A male patient must wear a condom when engaging in any activity that allows for passage of ejaculate to another person during the study and for a minimum of 3 months after receiving the last dose of study treatment. Male participants must also be advised of the benefit for a female partner to use a highly effective method of contraception as condoms may break or leak. A male patients 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 treatment. Patient must be willing and able to adhere to the lifestyle restrictions specified in the protocol (Section 4.3) All prior treatment-related toxicities (defined by National Cancer Institute- Common Toxicity Criteria for Adverse Events [NCI-CTCAE], Version 5.0 must be Grade 1 at the time of enrolment except for alopecia. Patient has given voluntary written informed consent before performance of any study-related procedure nor part of normal medical care, with the understanding that consent may be withdrawn by the patient at any time without prejudice to their future medical care.

Criterios de Exclusión

Prior or current systemic therapy or SCT for any plasma cell dyscrasia, with the exception of 1 cycle of antimyeloma treatment or the emergency use of a short course of corticosteroids before treatment while waiting for results of

genetic analysis Patient has CNS or exhibits clinical signs of meningeal involvement of MM Patient is pregnant, breastfeeding, or planning to become pregnant while enrolled in this study or within 6 months after the last dose of study treatment Patient plans to father a child while enrolled in this study or within 3 months after the last dose of study treatment Patient is simultaneously enrolled in other interventional CT Patient has received prior radiotherapy within 2 weeks of start of study therapy. Patients must have recovered from all radiation-related toxicities, not require corticosteroids, and not have had radiation pneumonitis. A 1-week washout is permitted for palliative radiation (2 weeks of radiotherapy) to non CNS disease Prior or concurrent exposure to any of the following: -Investigational vaccine other than SARS CoV-2 vaccine approved/ in use under emergency approval within 4 weeks -Live, attenuated vaccine within 4 weeks, before enrollment.Non-life vaccines authorized for emergency use (eg. COVID-19) and allowed (APPENDIX 22). - Monoclonal antibody therapy within 21 days (not use for the treatment of MM) Received a strong CYP3A4 inducer within 5 half-lives prior to starting study treatment A maximum cumulative dose of corticosteroids of 140 mg of prednisone or equivalent within 14 day period before the first dose of Tec-Dara or Tal-Dara 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 Presence of the following cardiac conditions: a) New York Heart Association stage III or IV congestive heart failure (APPENDIX 19) b) Myocardial infarction or coronary artery bypass graft 6 months prior to starting study treatment c) History of clinically significant ventricular arrhythmia or unexplained syncope, not believed to be vasovagal in nature or due to dehydration d) Uncontrolled cardiac arrhythmia or clinically significant ECG abnormalities. Plasmapheresis within 28 days of starting study treatment defined as C1D1 of D-VRD. Stroke, transient ischemic attack or seizure within 6 months prior to signing ICF Any of the following: -Hepatitis B infection (ie, HBsAg or HBV-DNA +). In the event the infection status is unclear, quantitative viral levels are necessary to determine the infection status -Active hepatitis C infection as measured by + HCV-RNA testing. Patients with a history of HCV antibody + must undergo HCV-RNA testing. If a patient with history of chronic hepatitis C infection (HCV antibody and HCV-RNA positive) completed antiviral therapy and has undetectable HCV-RNA for at least 12 weeks following the completion of therapy, the patient is eligible for the study Concurrent medical or psychiatric condition or disease that is likely to interfere with study procedures or results, or that in the opinion of the investigator would constitute a hazard for participating in this study COPD with a FEV1 < 50% of predicted normal. Note that FEV1 testing is required for patients with known or suspected of having COPD or asthma and patients must be excluded if FEV1 < 50% of predicted normal Moderate or severe persistent asthma within the past 24 months, or uncontrolled asthma of any classification Patient has a known immediate or delayed hypersensitivity reaction or idiosyncrasy to other molecular antibodies. Major surgery or significant traumatic injury within 2 weeks prior to the start of administration of study treatment, or will not have fully recovered from surgery, or major surgery planned during the time the patient is expected to be treated in the study or within 2 weeks after administration of the last dose of study treatment Peripheral neuropathy or neuropathic pain Grade 2 Patient has a diagnosis of primary light chain amyloidosis, MGUS, SMM, plasma cell leukemia or active POEMS syndrome at the time of screening. Myelodysplastic syndrome or active malignancies (progressing or requiring treatment change in the last 24 months) other than relapsed/refractory MM. Exceptions: malignancies treated within the last 24 months that are considered completely cured: -Non-muscle invasive bladder cancer -Skin cancer: non-melanoma skin cancers treated with curative therapy or localized melanoma treated with curative surgical resection alone -Noninvasive cervical cancer -Localized prostate cancer, Gleason score of 7a, treated locally only -Breast cancer: adequately treated lobular carcinoma in situ or ductal carcinoma in situ, localized breast cancer and receiving antihormonal agents -Other malignancy that is considered cured with minimal risk of recurrence

Calendario

(Última actualización: 07/05/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
12/01/2023	No aportado	21/09/2023	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

Fundacion Pethema Spain

Calle De Santa Balbina 2 Oficinas 3 4 5

Contact Person

Juan José Lahuerta Palacios

+34916266232

gerencia@fundacionpethema.es

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIM Área de Salud de Salamanca

Pº San Vicente nº 55-182 37007 Salamanca

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923291100

Centros

Activo (22/06/2023)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Servicio de Hematología

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

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Activo (08/09/2023)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Servicio de Hematología

Activo (15/12/2023)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Servicio de Hematología

Activo (18/07/2023)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASIST. UNIVERSIT.SA)

Salamanca

SALAMANCA

Servicio de Hematología

Activo (13/07/2023)

HOSPITAL CLINICO UNIVERSITARIO VIRGEN DE LA ARRIXACA

Murcia

MURCIA

Servicio de Hematología

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

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Hematology

Activo (23/10/2023)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

Servicio de Hematología

Activo (27/07/2023)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Servicio de Hematología

Activo (20/11/2023)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Servicio de Hematología

Activo (12/07/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematología

Activo (14/12/2023)

Institut Catala D'oncologia

Badalona

BARCELONA

Servicio de Hematología

Medicamentos

DEXAMETHASONE
TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

LENALIDOMIDE
CAPSULE, HARD
ORAL USE

-

Principios Activos: N/A

Experimental

LENALIDOMIDE
HARD CAPSULES
ORAL USE

-

Principios Activos: N/A

Experimental

TALVEY 2 mg/mL solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Principios Activos: N/A

Experimental

TECVAYLI 10 mg/mL solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

Código ATC: L01FX24 - TECLISTAMAB

Principios Activos: N/A

Experimental

TALVEY 40 mg/mL solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Principios Activos: N/A

Experimental

LENALIDOMIDE
CAPSULE, HARD
ORAL USE

-

Principios Activos: N/A

Experimental

LENALIDOMIDE
CAPSULE, HARD
ORAL USE

-

Principios Activos: N/A

Experimental

LENALIDOMIDE
CAPSULE, HARD
ORAL USE

-

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

Experimental

TECVAYLI 90 mg/mL solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

Código ATC: L01FX24 - TECLISTAMAB
Principios Activos: N/A

Experimental

Sin resultados

An open label, multicenter, Phase 2, pilot study, evaluating early treatment with bispecific T-cell redirectors (teclistamab and talquetamab) in the therapy of newly diagnosed high -risk multiple myeloma

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	30
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness	NO

Information

Identifier
2024-514016-26-00 (CTIS)

Protocol Code
GEM-TECTAL

Transitioned 2022-000598-15

Therapeutic area
Diseases [C] - Hemic and Lymphatic Diseases [C15]|

Investigated Disease
Multiple Myeloma

Scientific Title
An open label, multicenter, Phase 2, pilot study, evaluating early treatment with bispecific T-cell redirectors (teclistamab and talquetamab) in the frontline therapy of newly diagnosed high-risk multiple myeloma

Rationale

Not provided

Main Objective

To evaluate efficacy in terms of MRD negative CR rate after Teclistamab - Daratumumab intensification

Primary Endpoints

MRD measured by NGF (sensitivity level of 10-6) and FDG PET-CT scan using the Deauville score and CR evaluated per IMWG 2016 response criteria after 6 cycles of Tec-Dara therapy

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate MRD negative CR rate after D-VRD induction.
To evaluate MRD negativity after Tec-Dara intensification using alternative methods.
To evaluate MRD conversion after early rescue intervention with Tal- Dara.
To evaluate MRD conversion after Tec-Dara intensification.
To evaluate sustained MRD negativity during maintenance treatment in both Tec-Dara and Tal-Dara treatment arms
To assess reappearance of MRD positivity or relapse from CR in patients during the Tec-Dara treatment
To assess Time to event data
To assess the safety of the treatment described in the protocol
Immune profiling and genetic characterization

Secondary Endpoints

MRD measured by NGF (sensitivity level of 10-6) and FDG PET-CT scan using the Deauville score and CR evaluated per IMWG 2016 response criteria after 4 cycles of D-VRD induction
MRD negative rates measured by NGS, and QIP-MS-FLC after 6 cycles of Tec-Dara therapy
Percentage of patients converting from positive MRD to negative MRD evaluated by NGF, NGS, QIP-MS-FLC and FDG-PET-CT scan.
Percentage of patients converting from positive MRD after D-VRD induction to negative MRD evaluated by NGF, NGS, QIP-MS-FLC and FDG-PET-CT scan after Tec-Dara intensification.
Proportion of patients with persistent MRD negative disease at month 6, 12, 18 and 24 of maintenance treatment in both Tec-Dara and Tal-Dara treatment, by NGF, NGS, QIP-MS-FLC and FDG-PET-CT scan and annually thereafter
Proportion of patients relapsing from MRD negative CR to MRD positive or who relapse from CR (not fulfilling criteria for disease progression) during any phase of Tec-Dara treatment (intensification or maintenance)
PFS, EFS, TNT, DoR and OS
Incidence of treatment-emergent adverse events

Analysis of immune subpopulation and genetic markers.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Patient is, in the investigator's opinion, willing and able to comply with the protocol requirements Age between 18 80 years regardless of transplant eligibility at the time of inclusion. Patient has documented diagnosis of multiple myeloma according to IMWG diagnostic criteria, with at least one of the following high-risk features: a)High-risk FISH: del(1p), del(17p), t(4;14), t(14;16) and 1q amplifications. b)R-ISS 3. c)Presence of extramedullary disease, defined as presence of paramedullary lesions or extramedullary plasmacytoma. Patient has measurable secretory disease defined as either serum monoclonal protein of 0.5 g/dL or urine monoclonal (light chain) protein 200 mg/24 h. For patients whose disease is only measurable by serum FLC, the involved FLC should be 10mg/dL (100 mg/L), with an abnormal serum FLC ratio. Human inmunodeficiency virus-positive patients are elegible if they meet all of the following: a. No detectable viral load (ie, < 50 copies/mL) at screening b. CD4+ count > 300 cells/mm3 at screening c. No AIDS defining opportunistic infection within 6 months of screening d. Receiving HAART. Any changes in HAART due to resistance/progression should occur at least 3 months prior to screening. A change in HAART due to toxicity is allowed up to 4 weeks prior to screening. Patient has an ECOG performance status of 0, 1 or 2. Patient must have adequate organ function, defined in: Hemoglobin 8 g/dL, Platelets 75 x 109/L in participants in whom <50% of bone marrow nucleated cells are plasma cells and 50×109/L in participants in whom 50% of bone marrow nucleated cells are plasma cells (without transfusion support or thrombopoietin receptor agonist within 7 days before the laboratory test), ANC 1.0 x 109 /L, ALT and AST 2.5 x upper limit normal, eGFR 30 mL/min based on Modified Diet in Renal Disease Formula calculation or creatine clearance measured by a 24-hour urine collection, Total bilirubin 1.5 x ULN (isolated total bilirubin 1.5 x ULN with conjugated [direct] bilirubin < 1.5 x ULN is allowed for those patients Corrected serum calcium 14 mg/dL (3.5 mmol/L) or free ionized calcium 6.5 mg/dL (1.6 mmol/L) A female of childbearing potential must have a negative highly sensitive urine or serum (human chorionic gonadotropin [-hCG]) pregnancy test at screening and 24h prior to the start of study treatment and must agree to further urine or serum pregnancy tests during the study and within 6 months after receiving the last dose of study treatment A woman must be: a. Not of childbearing potential, or b. Of childbearing potential and i. Practicing true abstinence; or ii. Have a sole partner who is vasectomized; or iii. Practicing 2 methods of contraception (at least 1 highlyeffective) A female patient must agree not to donate eggs (ova, oocytes) or freeze for future use for the purposes of assisted reproduction during the study and for 6 months after receiving the last dose of study treatment A male patient must wear a condom when engaging in any activity that allows for passage of ejaculate to another person during the study and for a minimum of 3 months after receiving the last dose of study treatment. Male participants must also be advised of the benefit for a female partner to use a highly effective method of contraception as condoms may break or leak. A male patients 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 treatment. Patient must be willing and able to adhere to the lifestyle restrictions specified in the protocol (Section 4.3) All prior treatment-related toxicities (defined by National Cancer Institute- Common Toxicity Criteria for Adverse Events [NCI-CTCAE], Version 5.0 must be Grade 1 at the time of enrolment except for alopecia. Patient has given voluntary written informed consent before performance of any study-related procedure nor part of normal medical care, with the understanding that consent may be withdrawn by the patient at any time without prejudice to their future medical care.

Exclusion criteria

Prior or current systemic therapy or SCT for any plasma cell dyscrasia, with the exception of 1 cycle of antimyeloma treatment or the emergency use of a short course of corticosteroids before treatment while waiting for results of

genetic analysis Patient has CNS or exhibits clinical signs of meningeal involvement of MM Patient is pregnant, breastfeeding, or planning to become pregnant while enrolled in this study or within 6 months after the last dose of study treatment Patient plans to father a child while enrolled in this study or within 3 months after the last dose of study treatment Patient is simultaneously enrolled in other interventional CT Patient has received prior radiotherapy within 2 weeks of start of study therapy. Patients must have recovered from all radiation-related toxicities, not require corticosteroids, and not have had radiation pneumonitis. A 1-week washout is permitted for palliative radiation (2 weeks of radiotherapy) to non CNS disease Prior or concurrent exposure to any of the following: -Investigational vaccine other than SARS CoV-2 vaccine approved/ in use under emergency approval within 4 weeks -Live, attenuated vaccine within 4 weeks, before enrollment.Non-life vaccines authorized for emergency use (eg. COVID-19) and allowed (APPENDIX 22). - Monoclonal antibody therapy within 21 days (not use for the treatment of MM) Received a strong CYP3A4 inducer within 5 half-lives prior to starting study treatment A maximum cumulative dose of corticosteroids of 140 mg of prednisone or equivalent within 14 day period before the first dose of Tec-Dara or Tal-Dara 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 Presence of the following cardiac conditions: a) New York Heart Association stage III or IV congestive heart failure (APPENDIX 19) b) Myocardial infarction or coronary artery bypass graft 6 months prior to starting study treatment c) History of clinically significant ventricular arrhythmia or unexplained syncope, not believed to be vasovagal in nature or due to dehydration d) Uncontrolled cardiac arrhythmia or clinically significant ECG abnormalities. Plasmapheresis within 28 days of starting study treatment defined as C1D1 of D-VRD. Stroke, transient ischemic attack or seizure within 6 months prior to signing ICF Any of the following: -Hepatitis B infection (ie, HBsAg or HBV-DNA +). In the event the infection status is unclear, quantitative viral levels are necessary to determine the infection status -Active hepatitis C infection as measured by + HCV-RNA testing. Patients with a history of HCV antibody + must undergo HCV-RNA testing. If a patient with history of chronic hepatitis C infection (HCV antibody and HCV-RNA positive) completed antiviral therapy and has undetectable HCV-RNA for at least 12 weeks following the completion of therapy, the patient is eligible for the study Concurrent medical or psychiatric condition or disease that is likely to interfere with study procedures or results, or that in the opinion of the investigator would constitute a hazard for participating in this study COPD with a FEV1 < 50% of predicted normal. Note that FEV1 testing is required for patients with known or suspected of having COPD or asthma and patients must be excluded if FEV1 < 50% of predicted normal Moderate or severe persistent asthma within the past 24 months, or uncontrolled asthma of any classification Patient has a known immediate or delayed hypersensitivity reaction or idiosyncrasy to other molecular antibodies. Major surgery or significant traumatic injury within 2 weeks prior to the start of administration of study treatment, or will not have fully recovered from surgery, or major surgery planned during the time the patient is expected to be treated in the study or within 2 weeks after administration of the last dose of study treatment Peripheral neuropathy or neuropathic pain Grade 2 Patient has a diagnosis of primary light chain amyloidosis, MGUS, SMM, plasma cell leukemia or active POEMS syndrome at the time of screening. Myelodysplastic syndrome or active malignancies (progressing or requiring treatment change in the last 24 months) other than relapsed/refractory MM. Exceptions: malignancies treated within the last 24 months that are considered completely cured: -Non-muscle invasive bladder cancer -Skin cancer: non-melanoma skin cancers treated with curative therapy or localized melanoma treated with curative surgical resection alone -Noninvasive cervical cancer -Localized prostate cancer, Gleason score of 7a, treated locally only -Breast cancer: adequately treated lobular carcinoma in situ or ductal carcinoma in situ, localized breast cancer and receiving antihormonal agents -Other malignancy that is considered cured with minimal risk of recurrence

Calendar

(Last Update: 07/05/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
12/01/2023	Not aported	21/09/2023	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

Fundacion Pethema Spain

Calle De Santa Balbina 2 Oficinas 3 4 5

Contact Person

Juan José Lahuerta Palacios

+34916266232

gerencia@fundacionpethema.es

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIM Área de Salud de Salamanca

Pº San Vicente nº 55-182 37007 Salamanca

comite.etico.husa@saludcastillayleon.es

923291100

Sites

Active (22/06/2023)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Servicio de Hematología

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

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Active (08/09/2023)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Servicio de Hematología

Active (15/12/2023)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Servicio de Hematología

Active (18/07/2023)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASIST. UNIVERSIT.SA)

Salamanca

SALAMANCA

Servicio de Hematología

Active (13/07/2023)

HOSPITAL CLINICO UNIVERSITARIO VIRGEN DE LA ARRIXACA

Murcia

MURCIA

Servicio de Hematología

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

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Hematology

Active (23/10/2023)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

Servicio de Hematología

Active (27/07/2023)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Servicio de Hematología

Active (20/11/2023)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Servicio de Hematología

Active (12/07/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematología

Active (14/12/2023)

Institut Catala D'oncologia

Badalona

BARCELONA

Servicio de Hematología

Medication

DEXAMETHASONE
TABLET
ORAL USE

-

Active Principles: N/A

Experimental

LENALIDOMIDE
CAPSULE, HARD
ORAL USE

-

Active Principles: N/A

Experimental

LENALIDOMIDE
HARD CAPSULES
ORAL USE

-

Active Principles: N/A

Experimental

TALVEY 2 mg/mL solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Active Principles: N/A

Experimental

TECVAYLI 10 mg/mL solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

ATC code: L01FX24 - TECLISTAMAB

Active Principles: N/A

Experimental

TALVEY 40 mg/mL solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Active Principles: N/A

Experimental

LENALIDOMIDE
CAPSULE, HARD
ORAL USE

-

Active Principles: N/A

Experimental

LENALIDOMIDE
CAPSULE, HARD
ORAL USE

-

Active Principles: N/A

Experimental

LENALIDOMIDE

CAPSULE, HARD

ORAL USE

-

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

Experimental

TECVAYLI 90 mg/mL solution for injection

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

ATC code: L01FX24 - TECLISTAMAB

Active Principles: N/A

Experimental

No results