MagnetisMM-5: A Phase 3 Study of Elranatamab (PF-06863135) Monotherapy and Elranatamab + Daratumumab Versus Daratumumab + Pomalidomide + Dexamethasone in Participants With Relapsed/Refractory Multiple Myeloma

Estado	Tipo de Participantes	Rangos de Edad
Interrumpido	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	500
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, dosis	NO

Información

Identificador
2023-509208-14-00 (CTIS)

Cod. Protocolo
C1071005

Transicionado 2021-000044-22

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

Enfermedad investigada
MULTIPLE MYELOMA

Título Científico
C1071005 - MAGNETISMM-5: AN OPEN-LABEL, 3-ARM, MULTICENTER, RANDOMIZED PHASE 3 STUDY TO EVALUATE THE EFFICACY AND SAFETY OF ELRANATAMAB (PF-06863135) MONOTHERAPY AND

ELRANATAMAB + DARATUMUMAB VERSUS DARATUMUMAB + POMALIDOMIDE + DEXAMETHASONE IN PARTICIPANTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST 1 PRIOR LINE OF THERAPY INCLUDING LENALIDOMIDE AND A PROTEASOME INHIBITOR

Justificación

No aportado

Objetivo Principal

PART 1: To assess DLTs, safety and tolerability of elranatamab + daratumumab in order to select a RP3D for the combination to be used in Part 2 of this study.
PART 2: To compare the efficacy of elranatamab (Arm A) vs daratumumab + pomalidomide + dexamethasone (Arm C) as measured by PFS
PART 3:
To assess the safety of elranatamab (Arm D) and elranatamab + daratumumab (Arm E) with increased risk minimization for serious infection, including required infection prophylaxis

Variables de Evaluación Primaria

Part 1: DLTs during the DLT observation period (14 days from first elranatamab dose + first 28 days following first dose of elranatamab + daratumumab).
Part 2: PFS by blinded independent central review (BICR) per IMWG
Part 3: AEs as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), timing, and seriousness, and relationship to study treatment during the first 84 days following first elranatamab dose. Severity of CRS and ICANS will be assessed according to ASTCT criteria

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Part 1: To assess the rate of Grade 2 cytokine release syndrome (CRS) when elranatamab is administered with a 2 step-up priming regimen along with premedication.
Part 1: To evaluate the overall safety profile of elranatamab using 2 stepup priming doses and in combination with daratumumab.
Part 1: To evaluate the efficacy of elranatamab + daratumumab as measured by PFS, ORR, DOR, CRR, DOCR, TTR, OS, and % MRD negative.
Part 1: To evaluate the PK of elranatamab.
Part 1: To evaluate the immunogenicity of elranatamab.
Part 1: To evaluate the PK of daratumumab.
Part 2 Key secondary: To compare the efficacy of Arm A vs Arm C as measured by OS.
Part 2: To compare the efficacy of Arm A vs Arm C as measured by PFS, PFS2, ORR, DOR, CRR, DOCR, TTR, % MRD negative, and % Sustained MRD negative.

Part 2: To determine the safety and tolerability of elranatamab monotherapy.
Part 2: To evaluate the PK of elranatamab in Arm A
Part 2: To evaluate the immunogenicity of elranatamab in Arm A
Part 2: To evaluate the impact of treatment on participant HRQoL in Arm A and Arm C.
Part 3: To evaluate the overall safety profile of elranatamab (Arm D) and elranatamab plus daratumumab (Arm E) with increased risk minimization for serious infection, including required infection prophylaxis
Part 3: To evaluate the efficacy of elranatamab (Arm D) and elranatamab plus daratumumab (Arm E) as measured by PFS, ORR, DOR, CRR, DOCR, TTR, OS, % MRD negative, and % Sustained MRD negative.
Part 3: To evaluate the PK of elranatamab in Arm D and Arm E
Part 3: To evaluate the immunogenicity of elranatamab in Arm D and Arm E
Part 3: To evaluate the PK of daratumumab

Variables de Evaluación Secundaria

Part 1: Grade 2 CRS rate during the 28 days following the first dose of elranatamab.
Part 1: Adverse events (AEs) as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), timing, seriousness, and relationship to elranatamab in combination with daratumumab. Severity of CRS and immune effector cell-associated neurotoxicity syndrome (ICANS) will be assessed according to ASTCT criteria; Laboratory abnormalities as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), and timing.
Part1: ORR and CRR, per IMWG (International Myeloma Working Group) response criteria as determined by investigator; Time to event endpoints: TTR, DOR, DOCR and PFS per IMWG response criteria as determined by investigator, and OS; MRD negativity rate (central lab) per IMWG sequencing criteria.
Part 1: Predose and postdose concentrations of elranatamab
Part 1: Anti-drug antibodies (ADAs) and neutralizing antibodies (NAbs) against elranatamab.
Part 1: Predose concentrations of daratumumab.
Part 2 Key secondary: OS.
Part 2: PFS and PFS2 by Investigator per IMWG ORR by BICR per IMWG DOR by BICR per IMWG CRR by BICR per IMWG DOCR by BICR per IMWG TTR by BICR per IMWG MRD negativity rate (central lab) per IMWG Sustained MRD negativity rate (central lab) per IMWG
Part 2: AEs as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), timing, seriousness, and relationship to study treatment. The severity of CRS and ICANS will be assessed according to ASTCT criteria. Laboratory abnormalities as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), and timing.
Part 2: Predose and postdose concentrations of elranatamab.
Part 2: ADAs and NAbs against elranatamab.
Part 2: of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) and myeloma quality of life questionnaire (MY20).
Part 3: AEs as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), timing, seriousness, and relationship to study treatment. Severity of CRS and ICANS will be assessed according to ASTCT criteria Laboratory abnormalities as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), and timing
Part 3: ORR and CRR per IMWG Time to event endpoints: TTR, DOR, DOCR and PFS per IMWG response criteria, and OS MRD negativity rate (central lab) per IMWG Sustained MRD negativity rate (central lab) per IMWG
Part 3: Predose and postdose concentrations of elranatamab
Part 3: ADAs and NAbs against elranatamab
Part 3: Predose concentrations of daratumumab

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Participants age 18 years (or the minimum country-specific age of consent if >18). 2. Prior diagnosis of multiple myeloma (MM) as defined according to IMWG criteria (Rajkumar et al, 2014). 3. Measurable disease based on IMWG criteria as defined by at least 1 of the following: Serum M-protein 0.5 g/dL; Urinary M-protein excretion 200 mg/24 hours; Serum immunoglobulin free light chain (FLC) 10 mg/dL (100 mg/L) AND abnormal serum immunoglobulin kappa to lambda FLC ratio (<0.26 or >1.65). 4. Prior anti-MM therapy: Part 1: At least 3 prior lines of anti-MM therapy including treatment with lenalidomide and a PI. Part 2: At least 1, but not more than 3, prior lines of anti-MM therapy including treatment with lenalidomide and a PI. Part 3 Arm D: At least 1, but not more than 3, prior lines of anti-MM therapy including treatment with lenalidomide and an anti-CD38-directed therapy. Part 3 Arm E: At least 1, but not more than 3, prior lines of anti-MM therapy including treatment with lenalidomide. 5. Eastern Cooperative Oncology Group (ECOG) performance status <2. 6. Left ventricular ejection fraction (LVEF) 40% as determined by a multiple gated acquisition (MUGA) scan or echocardiogram (ECHO). 7. Adequate hepatic, renal and bone marrow (BM) function. 8. Corrected serum calcium 14 mg/dL (3.5 mmol/L), or free ionized calcium 6.5 mg/dL (1.6 mmol/L). 9. Resolved acute effects of any prior therapy to baseline severity or CTCAE Grade 1.

Criterios de Exclusión

1. Smoldering MM.
7. Ongoing Grade 3 or higher peripheral sensory or motor neuropathy.
10. Any other active malignancy within 3 years prior to enrollment, except for adequately treated basal cell or squamous cell skin cancer, carcinoma in situ, or Stage 0/1 malignancy with minimal risk of recurrence per investigator.
8. History of Guillain-Barr syndrome (GBS) or GBS variants, or history of any Grade 3 peripheral motor polyneuropathy.
9. Active hepatitis B virus (HBV), hepatitis C virus (HCV), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), human immunodeficiency virus (HIV), or any active, uncontrolled bacterial, fungal, or viral infection.
15. Part 3 Arm E: Refractory to prior anti-CD38-directed therapy (disease progression while on or within 60 days of the last dose of any anti-CD38-directed therapy).
11. Participants with known or suspected hypersensitivity to the study interventions or any of their excipients.
12. Previous treatment with a BCMA-directed therapy or a CD3-redirecting therapy.
13. Parts 1 and 2: Anti-CD38-directed therapy within 6 months preceding the first dose of treatment in this study.
14. Part 2: Refractory to prior anti-CD38-directed therapy (disease progression while on or within 60 days of the last dose of any anti-CD38-directed therapy or failure to achieve at least MR).
16. Part 2: Previous pomalidomide therapy.
19. Administration with an investigational product (eg, drug or vaccine) concurrent with study intervention or within 30 days (or as determined by the local requirement) preceding the first dose of study intervention used in this study. A participant may be eligible if they are in the follow-up phase of an investigational study if they meet the criterion for time elapsed from previous administration of investigational product. Cases must be discussed with sponsors medical monitor to judge eligibility.
17. Part 3: Any anti-myeloma drug therapy within 14 days of the first dose of study intervention (includes dexamethasone).
18. Live attenuated vaccine must not be administered within 4 weeks of the first dose of study intervention. Refer to Section 6.8 Concomitant Therapy.
2. Plasma cell leukemia.
20. For women of childbearing potential: Pregnancy test positive at screening.
21. Part 2: Active inflammatory gastrointestinal disease, chronic diarrhea, known diverticular disease or previous gastric resection or lap band surgery. Gastroesophageal reflux disease under treatment with proton pump inhibitors is allowed (assuming no drug interaction potential).
3. Amyloidosis, Waldenströms macroglobulinemia, or POEMS Syndrome.
4. Known active CNS involvement or clinical signs of myelomatous meningeal involvement.
5. Stem cell transplant within 12 weeks prior to enrollment, active GVHD (other than Grade 1 skin involvement), or GVHD requiring treatment.

6. Impaired cardiovascular function or clinically significant cardiovascular diseases within 6 months prior to enrollment.

Calendario

(Última actualización: 18/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
19/10/2021	11/11/2021	03/02/2022	20/10/2023	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
25/10/2023	No aportado	No aportado	No aportado	No aportado

Promotor

Pfizer Inc. United States

66 Hudson Boulevard East

Contact Person

Clinical Medical Lead

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ClinicalTrials.gov_Inquiries@pfizer.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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Centros

Activo (13/06/2022)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Serv Hematologia

Activo (07/06/2022)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Activo (07/06/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

NA

Activo (21/06/2022)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA)

Salamanca

SALAMANCA

Servicio de Hematologia

Activo (02/06/2022)

Hospital Universitari Mutua Terrassa

Terrassa

BARCELONA

NA

Activo (21/12/2021)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Activo (20/01/2022)

HOSPITAL UNIVERSITARIO DE LA PRINCESA

Madrid

MADRID

NA

Cerrado (08/06/2026)

Hospital Universitario de Toledo

Toledo

TOLEDO

Activo (21/12/2021)

HOSPITAL UNIVERSITARIO HM SANCHINARRO

Madrid

MADRID

Servicio Hematología y Hemoterapia / Oncología, Ensayos Clínicos Fases I START-Madrid-CIOCC

Activo (02/06/2022)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

NA

Cerrado (14/12/2023)

HOSPITAL UNIVERSITARIO REINA SOFIA

Córdoba

CÓRDOBA

Activo (11/11/2021)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

NA

Activo (29/11/2021)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

NA

Activo (02/06/2022)

Institut Catala D´oncologia

Girona

GERONA

Haematology Department

Activo (22/12/2021)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Haematology Department

Medicamentos

Neofordex 40 mg tablets
TABLET
ORAL

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

Experimental

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

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

Experimental

Imnovid 2 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A

Huérfano
Experimental

ELRANATAMAB
SOLUTION FOR INJECTION
SUBCUTANEOUS

-

Principios Activos: N/A

Huérfano
Experimental

DARZALEX 1800 mg solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS

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

Huérfano
Experimental

Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A

Huérfano
Experimental

Imnovid 4 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A

Huérfano
Experimental

Imnovid 3 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A

Huérfano
Experimental

Sin resultados

MagnetisMM-5: A Phase 3 Study of Elranatamab (PF-06863135) Monotherapy and Elranatamab + Daratumumab Versus Daratumumab + Pomalidomide + Dexamethasone in Participants With Relapsed/Refractory Multiple Myeloma

State	Type of participants	Age Ranges
Halted	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	500
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics, dose	NO

Information

Identifier
2023-509208-14-00 (CTIS)

Protocol Code
C1071005

Transitioned 2021-000044-22

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

Investigated Disease
MULTIPLE MYELOMA

Scientific Title
C1071005 - MAGNETISMM-5: AN OPEN-LABEL, 3-ARM, MULTICENTER, RANDOMIZED PHASE 3 STUDY TO EVALUATE THE EFFICACY AND SAFETY OF ELRANATAMAB (PF-06863135) MONOTHERAPY AND

ELRANATAMAB + DARATUMUMAB VERSUS DARATUMUMAB + POMALIDOMIDE + DEXAMETHASONE IN PARTICIPANTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST 1 PRIOR LINE OF THERAPY INCLUDING LENALIDOMIDE AND A PROTEASOME INHIBITOR

Rationale

Not provided

Main Objective

PART 1: To assess DLTs, safety and tolerability of elranatamab + daratumumab in order to select a RP3D for the combination to be used in Part 2 of this study.
PART 2: To compare the efficacy of elranatamab (Arm A) vs daratumumab + pomalidomide + dexamethasone (Arm C) as measured by PFS
PART 3:
To assess the safety of elranatamab (Arm D) and elranatamab + daratumumab (Arm E) with increased risk minimization for serious infection, including required infection prophylaxis

Primary Endpoints

Part 1: DLTs during the DLT observation period (14 days from first elranatamab dose + first 28 days following first dose of elranatamab + daratumumab).
Part 2: PFS by blinded independent central review (BICR) per IMWG
Part 3: AEs as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), timing, and seriousness, and relationship to study treatment during the first 84 days following first elranatamab dose. Severity of CRS and ICANS will be assessed according to ASTCT criteria

Temporary moments of secondary assessment

Not provided

Secondary Objective

Part 1: To assess the rate of Grade 2 cytokine release syndrome (CRS) when elranatamab is administered with a 2 step-up priming regimen along with premedication.
Part 1: To evaluate the overall safety profile of elranatamab using 2 stepup priming doses and in combination with daratumumab.
Part 1: To evaluate the efficacy of elranatamab + daratumumab as measured by PFS, ORR, DOR, CRR, DOCR, TTR, OS, and % MRD negative.
Part 1: To evaluate the PK of elranatamab.
Part 1: To evaluate the immunogenicity of elranatamab.
Part 1: To evaluate the PK of daratumumab.
Part 2 Key secondary: To compare the efficacy of Arm A vs Arm C as measured by OS.
Part 2: To compare the efficacy of Arm A vs Arm C as measured by PFS, PFS2, ORR, DOR, CRR, DOCR, TTR, % MRD negative, and % Sustained MRD negative.

Part 2: To determine the safety and tolerability of elranatamab monotherapy.
Part 2: To evaluate the PK of elranatamab in Arm A
Part 2: To evaluate the immunogenicity of elranatamab in Arm A
Part 2: To evaluate the impact of treatment on participant HRQoL in Arm A and Arm C.
Part 3: To evaluate the overall safety profile of elranatamab (Arm D) and elranatamab plus daratumumab (Arm E) with increased risk minimization for serious infection, including required infection prophylaxis
Part 3: To evaluate the efficacy of elranatamab (Arm D) and elranatamab plus daratumumab (Arm E) as measured by PFS, ORR, DOR, CRR, DOCR, TTR, OS, % MRD negative, and % Sustained MRD negative.
Part 3: To evaluate the PK of elranatamab in Arm D and Arm E
Part 3: To evaluate the immunogenicity of elranatamab in Arm D and Arm E
Part 3: To evaluate the PK of daratumumab

Secondary Endpoints

Part 1: Grade 2 CRS rate during the 28 days following the first dose of elranatamab.
Part 1: Adverse events (AEs) as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), timing, seriousness, and relationship to elranatamab in combination with daratumumab. Severity of CRS and immune effector cell-associated neurotoxicity syndrome (ICANS) will be assessed according to ASTCT criteria; Laboratory abnormalities as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), and timing.
Part1: ORR and CRR, per IMWG (International Myeloma Working Group) response criteria as determined by investigator; Time to event endpoints: TTR, DOR, DOCR and PFS per IMWG response criteria as determined by investigator, and OS; MRD negativity rate (central lab) per IMWG sequencing criteria.
Part 1: Predose and postdose concentrations of elranatamab
Part 1: Anti-drug antibodies (ADAs) and neutralizing antibodies (NAbs) against elranatamab.
Part 1: Predose concentrations of daratumumab.
Part 2 Key secondary: OS.
Part 2: PFS and PFS2 by Investigator per IMWG ORR by BICR per IMWG DOR by BICR per IMWG CRR by BICR per IMWG DOCR by BICR per IMWG TTR by BICR per IMWG MRD negativity rate (central lab) per IMWG Sustained MRD negativity rate (central lab) per IMWG
Part 2: AEs as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), timing, seriousness, and relationship to study treatment. The severity of CRS and ICANS will be assessed according to ASTCT criteria. Laboratory abnormalities as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), and timing.
Part 2: Predose and postdose concentrations of elranatamab.
Part 2: ADAs and NAbs against elranatamab.
Part 2: of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) and myeloma quality of life questionnaire (MY20).
Part 3: AEs as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), timing, seriousness, and relationship to study treatment. Severity of CRS and ICANS will be assessed according to ASTCT criteria Laboratory abnormalities as characterized by type, frequency, severity (as graded by NCI CTCAE v5.0), and timing
Part 3: ORR and CRR per IMWG Time to event endpoints: TTR, DOR, DOCR and PFS per IMWG response criteria, and OS MRD negativity rate (central lab) per IMWG Sustained MRD negativity rate (central lab) per IMWG
Part 3: Predose and postdose concentrations of elranatamab
Part 3: ADAs and NAbs against elranatamab
Part 3: Predose concentrations of daratumumab

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Participants age 18 years (or the minimum country-specific age of consent if >18). 2. Prior diagnosis of multiple myeloma (MM) as defined according to IMWG criteria (Rajkumar et al, 2014). 3. Measurable disease based on IMWG criteria as defined by at least 1 of the following: Serum M-protein 0.5 g/dL; Urinary M-protein excretion 200 mg/24 hours; Serum immunoglobulin free light chain (FLC) 10 mg/dL (100 mg/L) AND abnormal serum immunoglobulin kappa to lambda FLC ratio (<0.26 or >1.65). 4. Prior anti-MM therapy: Part 1: At least 3 prior lines of anti-MM therapy including treatment with lenalidomide and a PI. Part 2: At least 1, but not more than 3, prior lines of anti-MM therapy including treatment with lenalidomide and a PI. Part 3 Arm D: At least 1, but not more than 3, prior lines of anti-MM therapy including treatment with lenalidomide and an anti-CD38-directed therapy. Part 3 Arm E: At least 1, but not more than 3, prior lines of anti-MM therapy including treatment with lenalidomide. 5. Eastern Cooperative Oncology Group (ECOG) performance status <2. 6. Left ventricular ejection fraction (LVEF) 40% as determined by a multiple gated acquisition (MUGA) scan or echocardiogram (ECHO). 7. Adequate hepatic, renal and bone marrow (BM) function. 8. Corrected serum calcium 14 mg/dL (3.5 mmol/L), or free ionized calcium 6.5 mg/dL (1.6 mmol/L). 9. Resolved acute effects of any prior therapy to baseline severity or CTCAE Grade 1.

Exclusion criteria

1. Smoldering MM.
7. Ongoing Grade 3 or higher peripheral sensory or motor neuropathy.
10. Any other active malignancy within 3 years prior to enrollment, except for adequately treated basal cell or squamous cell skin cancer, carcinoma in situ, or Stage 0/1 malignancy with minimal risk of recurrence per investigator.
8. History of Guillain-Barr syndrome (GBS) or GBS variants, or history of any Grade 3 peripheral motor polyneuropathy.
9. Active hepatitis B virus (HBV), hepatitis C virus (HCV), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), human immunodeficiency virus (HIV), or any active, uncontrolled bacterial, fungal, or viral infection.
15. Part 3 Arm E: Refractory to prior anti-CD38-directed therapy (disease progression while on or within 60 days of the last dose of any anti-CD38-directed therapy).
11. Participants with known or suspected hypersensitivity to the study interventions or any of their excipients.
12. Previous treatment with a BCMA-directed therapy or a CD3-redirecting therapy.
13. Parts 1 and 2: Anti-CD38-directed therapy within 6 months preceding the first dose of treatment in this study.
14. Part 2: Refractory to prior anti-CD38-directed therapy (disease progression while on or within 60 days of the last dose of any anti-CD38-directed therapy or failure to achieve at least MR).
16. Part 2: Previous pomalidomide therapy.
19. Administration with an investigational product (eg, drug or vaccine) concurrent with study intervention or within 30 days (or as determined by the local requirement) preceding the first dose of study intervention used in this study. A participant may be eligible if they are in the follow-up phase of an investigational study if they meet the criterion for time elapsed from previous administration of investigational product. Cases must be discussed with sponsors medical monitor to judge eligibility.
17. Part 3: Any anti-myeloma drug therapy within 14 days of the first dose of study intervention (includes dexamethasone).
18. Live attenuated vaccine must not be administered within 4 weeks of the first dose of study intervention. Refer to Section 6.8 Concomitant Therapy.
2. Plasma cell leukemia.
20. For women of childbearing potential: Pregnancy test positive at screening.
21. Part 2: Active inflammatory gastrointestinal disease, chronic diarrhea, known diverticular disease or previous gastric resection or lap band surgery. Gastroesophageal reflux disease under treatment with proton pump inhibitors is allowed (assuming no drug interaction potential).
3. Amyloidosis, Waldenströms macroglobulinemia, or POEMS Syndrome.
4. Known active CNS involvement or clinical signs of myelomatous meningeal involvement.
5. Stem cell transplant within 12 weeks prior to enrollment, active GVHD (other than Grade 1 skin involvement), or GVHD requiring treatment.

6. Impaired cardiovascular function or clinically significant cardiovascular diseases within 6 months prior to enrollment.

Calendar

(Last Update: 18/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
19/10/2021	11/11/2021	03/02/2022	20/10/2023	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
25/10/2023	Not aported	Not aported	Not aported	Not aported

Sponsor

Pfizer Inc. United States

66 Hudson Boulevard East

Contact Person

Clinical Medical Lead

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ClinicalTrials.gov_Inquiries@pfizer.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitari Germans Trias i Pujol

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Sites

Active (13/06/2022)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Serv Hematologia

Active (07/06/2022)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Active (07/06/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

NA

Active (21/06/2022)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA)

Salamanca

SALAMANCA

Servicio de Hematologia

Active (02/06/2022)

Hospital Universitari Mutua Terrassa

Terrassa

BARCELONA

NA

Active (21/12/2021)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Active (20/01/2022)

HOSPITAL UNIVERSITARIO DE LA PRINCESA

Madrid

MADRID

NA

Closed (08/06/2026)

Hospital Universitario de Toledo

Toledo

TOLEDO

Active (21/12/2021)

HOSPITAL UNIVERSITARIO HM SANCHINARRO

Madrid

MADRID

Servicio Hematología y Hemoterapia / Oncología, Ensayos Clínicos Fases I START-Madrid-CIOCC

Active (02/06/2022)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

NA

Closed (14/12/2023)

HOSPITAL UNIVERSITARIO REINA SOFIA

Córdoba

CÓRDOBA

Active (11/11/2021)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

NA

Active (29/11/2021)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

NA

Active (02/06/2022)

Institut Catala D´oncologia

Girona

GERONA

Haematology Department

Active (22/12/2021)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Haematology Department

Medication

Neofordex 40 mg tablets
TABLET
ORAL

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

Experimental

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

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

Experimental

Imnovid 2 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX06 - POMALIDOMIDA
Active Principles: N/A

Orphan
Experimental

ELRANATAMAB
SOLUTION FOR INJECTION
SUBCUTANEOUS

-

Active Principles: N/A

Orphan
Experimental

DARZALEX 1800 mg solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS

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

Orphan
Experimental

Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX06 - POMALIDOMIDA
Active Principles: N/A

Orphan
Experimental

Imnovid 4 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX06 - POMALIDOMIDA
Active Principles: N/A

Orphan
Experimental

Imnovid 3 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX06 - POMALIDOMIDA
Active Principles: N/A

Orphan
Experimental

No results