A Phase 3 Study With Elranatamab Versus Lenalidomide in Patients With Newly Diagnosed Multiple Myeloma After Transplant

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	473
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	eficacia	NO

Información

Identificador
2023-508897-27-00 (CTIS)

Cod. Protocolo
C1071007

Transicionado 2021-006052-14

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

Enfermedad investigada
Multiple Myeloma

Título Científico
C1071007 - MAGNETISMM-7
A RANDOMIZED, 2-ARM, PHASE 3 STUDY OF ELRANATAMAB (PF-06863135) VERSUS LENALIDOMIDE IN PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA AFTER UNDERGOING AUTOLOGOUS STEM-CELL TRANSPLANTATION

Justificación

No aportado

Objetivo Principal

To compare the efficacy of elranatamab versus lenalidomide

Variables de Evaluación Primaria

Progression-free survival (PFS) by Blinded Independent Central Review (BICR) per International Myeloma Working Group (IMWG)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To compare the efficacy of elranatamab versus lenalidomide To determine the safety and tolerability of elranatamab To evaluate the PK of elranatamab To evaluate the immunogenicity of elranatamab To evaluate the impact of study intervention on participant healthrelated quality of life (HRQoL)

Variables de Evaluación Secundaria

Minimal residual disease (MRD)-negative rate at 12 months after randomization per IMWG as assessed via next-generation sequencing (NGS) PFS by BICR per IMWG in IMWG 2025 high-risk participants PFS by BICR per IMWG in IMWG 2025 standard-risk participants Overall survival (OS)

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) at Visit 1 (Screening), or at the pre-screening visit, as applicable. - Male participants and female participants of childbearing potential must agree to use contraception 10. Adequate post-ASCT recovery of BM function at screening and randomization as characterized by the following: - Absolute neutrophil count (ANC) 1.0 × 109/L (use of granulocyte colonystimulating factor [G-CSF] is permitted if completed at least 7 days prior to planned start of dosing; G-CSF should not be used to

reach this level); - Platelets 75 × 109/L (transfusion support is permitted if completed at least 7 days prior to planned start of dosing); and - Hemoglobin 8 g/dL (transfusion support is permitted if completed at least 14 days prior to planned start of dosing). 11. Corrected serum calcium 14 mg/dL (3.5 mmol/L). 12. Resolved acute effects of any prior therapy to baseline severity or CTCAE Grade 1. 13. Capable of giving signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol. 2. Participants who are willing and able to comply with all scheduled visits, treatment plan, laboratory tests, lifestyle considerations, and other study procedures. 3. Diagnosis of MM as defined according to IMWG criteria1 with measurable disease at diagnosis as defined by serum M-protein 0.5 g/dL (5 g/L), by urine M-protein 200 mg/24 hours, or by serum free light chain (FLC) assay with involved FLC level 10 mg/dL, provided serum FLC ratio is abnormal. 4. PR or better according to IMWG criteria at the time of randomization. 5. Identification of the dominant malignant (index) clone as assessed by central laboratory NGS test (Adaptive Biotechnologies clonoSEQ® assay. 6. ECOG performance status 1. 7. Left ventricular ejection fraction (LVEF) 40% as determined by a multigated acquisition (MUGA) scan or echocardiogram (ECHO). 8. Adequate hepatic function characterized by the following: - Total bilirubin 2 × upper limit of normal (3 × ULN if documented Gilberts syndrome and direct bilirubin ULN); - Aspartate aminotransferase (AST) 2.5 × ULN; and - Alanine aminotransferase (ALT) 2.5 × ULN. 9. Adequate renal function defined according to local institutional standard method: estimated glomerular filtration rate (eGFR) 30 mL/min/1.73 m2 using Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) 2021 equation or estimated creatinine clearance (CrCl) 30 mL/min using Cockcroft Gault formula. If both formulae are calculated, the higher of the 2 values may be used. A 24-hour urine collection for CrCl may also be used in equivocal cases where amyloidosis is suspected.

Criterios de Exclusión

1. Plasma cell leukemia defined as more than 20% circulating plasma cells and an absolute count >2 × 109/L plasma cells in peripheral blood) 10. Other surgical (including major surgery within 14 days prior to enrollment), medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigators judgment, make the participant inappropriate for the study. 2. Amyloidosis, Waldenströms macroglobulinemia, or Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes (POEMS) syndrome. 3. Known active central nervous system (CNS) involvement or clinical signs of myelomatous meningeal involvement 4. Impaired cardiovascular function or clinically significant cardiovascular diseases, defined as any of the following within 6 months prior to enrollment: - Acute myocardial infarction or acute coronary syndromes (eg, unstable angina, coronary artery bypass graft, coronary angioplasty or stenting, symptomatic pericardial effusion); - Clinically significant cardiac arrhythmias (eg, uncontrolled atrial fibrillation or uncontrolled paroxysmal supraventricular tachycardia); - Thromboembolic or cerebrovascular events (eg, transient ischemic attack, cerebrovascular accident, deep vein thrombosis [unless associated with a central venous access complication] or pulmonary embolism); Prolonged time from the beginning of the Q wave to the end of the T wave (QT) syndrome or QT corrected using Fridericas formula (QTcF) >470 msec at screening. 5. Ongoing Grade 3 peripheral sensory or motor neuropathy. 6. History of Guillain-Barré syndrome (GBS) or GBS variants, or history of any Grade 3 peripheral motor polyneuropathy. 7. Live attenuated vaccine within 4 weeks of the first dose. 8. Known or suspected hypersensitivity to the study interventions or any of its excipients. 9. Any other active malignancy within 3 years prior to enrollment, except for adequately treated basal cell or squamous cell skin cancer, or carcinoma in situ, or Stage 0/1 with minimal risk of recurrence per the investigator.

Calendario

(Última actualización: 08/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
19/04/2022	28/06/2022	26/07/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
17/10/2025	No aportado	No aportado	No aportado	No aportado

Promotor

Pfizer Inc. United States

66 Hudson Boulevard East

Contact Person

Clinical Medical Lead

+18007181021

PfizerCTIS@pfizer.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitari Germans Trias i Pujol

Ctra. Canyet, s/n Edificio General - 1a planta / Módulos urgencias - 1a planta 08916 Badalona

ceic.germanstrias@gencat.cat

934978956

Centros

Activo (09/08/2022)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Ed Consultas Externas planta 8. Serv Hematologia

Activo (15/09/2022)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Activo (30/06/2022)

Fundacio Assistencial De Mutua De Terrassa Fpc

Terrassa

BARCELONA

NA

Cerrado (10/02/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Activo (14/07/2022)

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

Salamanca

SALAMANCA

Servicio de Hematología

Activo (20/07/2022)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑON

Madrid

MADRID

Activo (13/07/2022)

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Planta Primera - Institut Josep Carreras

Activo (13/12/2024)

Hospital San Pedro de Alcantara

Cáceres

CÁCERES

Servicio de Hematología. Ensayos Clínicos.

Activo (18/07/2022)

Hospital Universitari De Girona Doctor Josep Trueta

Girona

GERONA

Hematología Clínica

Activo (15/07/2022)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Activo (20/07/2022)

HOSPITAL UNIVERSITARIO DE LA PRINCESA

Madrid

MADRID

Activo (22/07/2022)

HOSPITAL UNIVERSITARIO HM SANCHINARRO

Madrid

MADRID

Centro Integral Oncologico Clara Campal

Activo (09/12/2024)

Hospital Universitario La Paz

Madrid

MADRID

Servicio de Hematología. Ensayos Clínicos.

Activo (18/07/2022)

HOSPITAL UNIVERSITARIO QUIRONSALUD MADRID

Pozuelo de Alarcón

MADRID

Cerrado (10/02/2022)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Activo (30/06/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

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

Institut Catala D'oncologia

Girona

GERONA

Hematologia Clinica

Activo (28/06/2022)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Servicio de Hematología

Medicamentos

Zelvina 5 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Zelvina 10 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Privigen 100 mg/ml solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

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

Experimental

Zelvina 15 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

ELRANATAMAB
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-

Principios Activos: N/A

Huérfano

Experimental

Sin resultados

A Phase 3 Study With Elranatamab Versus Lenalidomide in Patients With Newly Diagnosed Multiple Myeloma After Transplant

State	Type of participants	Age Ranges
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	473
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	effectiveness	NO

Information

Identifier
2023-508897-27-00 (CTIS)

Protocol Code
C1071007

Transitioned 2021-006052-14

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

Investigated Disease
Multiple Myeloma

Scientific Title
C1071007 - MAGNETISMM-7
A RANDOMIZED, 2-ARM, PHASE 3 STUDY OF ELRANATAMAB (PF-06863135) VERSUS LENALIDOMIDE IN PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA AFTER UNDERGOING AUTOLOGOUS STEM-CELL TRANSPLANTATION

Rationale

Not provided

Main Objective

To compare the efficacy of elranatamab versus lenalidomide

Primary Endpoints

Progression-free survival (PFS) by Blinded Independent Central Review (BICR) per International Myeloma Working Group (IMWG)

Temporary moments of secondary assessment

Not provided

Secondary Objective

To compare the efficacy of elranatamab versus lenalidomide To determine the safety and tolerability of elranatamab To evaluate the PK of elranatamab To evaluate the immunogenicity of elranatamab To evaluate the impact of study intervention on participant healthrelated quality of life (HRQoL)

Secondary Endpoints

Minimal residual disease (MRD)-negative rate at 12 months after randomization per IMWG as assessed via next-generation sequencing (NGS) PFS by BICR per IMWG in IMWG 2025 high-risk participants PFS by BICR per IMWG in IMWG 2025 standard-risk participants Overall survival (OS)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Participants age 18 years (or the minimum country specific age of consent if >18) at Visit 1 (Screening), or at the pre-screening visit, as applicable. - Male participants and female participants of childbearing potential must agree to use contraception 10. Adequate post-ASCT recovery of BM function at screening and randomization as characterized by the following: - Absolute neutrophil count (ANC) 1.0 × 109/L (use of granulocyte colonystimulating factor [G-CSF] is permitted if completed at least 7 days prior to planned start of dosing; G-CSF should not be used to

reach this level); - Platelets 75 × 109/L (transfusion support is permitted if completed at least 7 days prior to planned start of dosing); and - Hemoglobin 8 g/dL (transfusion support is permitted if completed at least 14 days prior to planned start of dosing). 11. Corrected serum calcium 14 mg/dL (3.5 mmol/L). 12. Resolved acute effects of any prior therapy to baseline severity or CTCAE Grade 1. 13. Capable of giving signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol. 2. Participants who are willing and able to comply with all scheduled visits, treatment plan, laboratory tests, lifestyle considerations, and other study procedures. 3. Diagnosis of MM as defined according to IMWG criteria1 with measurable disease at diagnosis as defined by serum M-protein 0.5 g/dL (5 g/L), by urine M-protein 200 mg/24 hours, or by serum free light chain (FLC) assay with involved FLC level 10 mg/dL, provided serum FLC ratio is abnormal. 4. PR or better according to IMWG criteria at the time of randomization. 5. Identification of the dominant malignant (index) clone as assessed by central laboratory NGS test (Adaptive Biotechnologies clonoSEQ® assay. 6. ECOG performance status 1. 7. Left ventricular ejection fraction (LVEF) 40% as determined by a multigated acquisition (MUGA) scan or echocardiogram (ECHO). 8. Adequate hepatic function characterized by the following: - Total bilirubin 2 × upper limit of normal (3 × ULN if documented Gilberts syndrome and direct bilirubin ULN); - Aspartate aminotransferase (AST) 2.5 × ULN; and - Alanine aminotransferase (ALT) 2.5 × ULN. 9. Adequate renal function defined according to local institutional standard method: estimated glomerular filtration rate (eGFR) 30 mL/min/1.73 m2 using Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) 2021 equation or estimated creatinine clearance (CrCl) 30 mL/min using Cockcroft Gault formula. If both formulae are calculated, the higher of the 2 values may be used. A 24-hour urine collection for CrCl may also be used in equivocal cases where amyloidosis is suspected.

Exclusion criteria

1. Plasma cell leukemia defined as more than 20% circulating plasma cells and an absolute count >2 × 109/L plasma cells in peripheral blood) 10. Other surgical (including major surgery within 14 days prior to enrollment), medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigators judgment, make the participant inappropriate for the study. 2. Amyloidosis, Waldenströms macroglobulinemia, or Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes (POEMS) syndrome. 3. Known active central nervous system (CNS) involvement or clinical signs of myelomatous meningeal involvement 4. Impaired cardiovascular function or clinically significant cardiovascular diseases, defined as any of the following within 6 months prior to enrollment: - Acute myocardial infarction or acute coronary syndromes (eg, unstable angina, coronary artery bypass graft, coronary angioplasty or stenting, symptomatic pericardial effusion); - Clinically significant cardiac arrhythmias (eg, uncontrolled atrial fibrillation or uncontrolled paroxysmal supraventricular tachycardia); - Thromboembolic or cerebrovascular events (eg, transient ischemic attack, cerebrovascular accident, deep vein thrombosis [unless associated with a central venous access complication] or pulmonary embolism); Prolonged time from the beginning of the Q wave to the end of the T wave (QT) syndrome or QT corrected using Fridericas formula (QTcF) >470 msec at screening. 5. Ongoing Grade 3 peripheral sensory or motor neuropathy. 6. History of Guillain-Barré syndrome (GBS) or GBS variants, or history of any Grade 3 peripheral motor polyneuropathy. 7. Live attenuated vaccine within 4 weeks of the first dose. 8. Known or suspected hypersensitivity to the study interventions or any of its excipients. 9. Any other active malignancy within 3 years prior to enrollment, except for adequately treated basal cell or squamous cell skin cancer, or carcinoma in situ, or Stage 0/1 with minimal risk of recurrence per the investigator.

Calendar

(Last Update: 08/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
19/04/2022	28/06/2022	26/07/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
17/10/2025	Not aported	Not aported	Not aported	Not aported

Sponsor

Pfizer Inc. United States

66 Hudson Boulevard East

Contact Person

Clinical Medical Lead

+18007181021

PfizerCTIS@pfizer.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitari Germans Trias i Pujol

Ctra. Canyet, s/n Edificio General - 1a planta / Módulos urgencias - 1a planta 08916 Badalona

ceic.germanstrias@gencat.cat

934978956

Sites

Active (09/08/2022)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Ed Consultas Externas planta 8. Serv Hematologia

Active (15/09/2022)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Active (30/06/2022)

Fundacio Assistencial De Mutua De Terrassa Fpc

Terrassa

BARCELONA

NA

Closed (10/02/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Active (14/07/2022)

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

Salamanca

SALAMANCA

Servicio de Hematología

Active (20/07/2022)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑON

Madrid

MADRID

Active (13/07/2022)

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Planta Primera - Institut Josep Carreras

Active (13/12/2024)

Hospital San Pedro de Alcantara

Cáceres

CÁCERES

Servicio de Hematología. Ensayos Clínicos.

Active (18/07/2022)

Hospital Universitari De Girona Doctor Josep Trueta

Girona

GERONA

Hematología Clínica

Active (15/07/2022)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Active (20/07/2022)

HOSPITAL UNIVERSITARIO DE LA PRINCESA

Madrid

MADRID

Active (22/07/2022)

HOSPITAL UNIVERSITARIO HM SANCHINARRO

Madrid

MADRID

Centro Integral Oncologico Clara Campal

Active (09/12/2024)

Hospital Universitario La Paz

Madrid

MADRID

Servicio de Hematología. Ensayos Clínicos.

Active (18/07/2022)

HOSPITAL UNIVERSITARIO QUIRONSALUD MADRID

Pozuelo de Alarcón

MADRID

Closed (10/02/2022)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Active (30/06/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

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

Institut Catala D'oncologia

Girona

GERONA

Hematologia Clinica

Active (28/06/2022)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Servicio de Hematología

Medication

Zelvina 5 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Zelvina 10 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Privigen 100 mg/ml solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

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

Experimental

Zelvina 15 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

ELRANATAMAB
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Active Principles: N/A

Orphan

Experimental

No results