A Study to Assess A Change in Disease Activity and Adverse Events of Intravenous Etentamig and Daratumumab (Etentamig+D) Compared to Daratumumab, Lenalidomide, and Dexamethasone (DRd) in Adult Participants with Newly Diagnosed Multiple Myeloma Not Eligible for Transplant

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II , Fase III	36
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador
2025-520897-21-00 (CTIS)

Cod. Protocolo
M25-586

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

Enfermedad investigada
Multiple Myeloma

Título Científico
A Phase 2/3, Multicenter, Randomized, Open-Label Study Evaluating the Efficacy and Safety of Etentamig and Daratumumab (Etentamig+D) Compared to Daratumumab, Lenalidomide, and Dexamethasone (DRd) in Subjects

with Newly Diagnosed Multiple Myeloma Not Eligible for Transplant

Justificación

No aportado

Objetivo Principal

Phase 2: To determine the RP3D of etentamig in combination with daratumumab in partcipants with Newly Diagnosed Multiple Myeloma (NDMM) that are not eligible for transplant
Phase 3: To evaluate the efficacy of etentamig administered with daratumumab in participants with NDMM that are not eligible for transplant
To evaluate the efficacy of etentamig administered with daratumumab in participants with NDMM that are not eligible for transplant

Variables de Evaluación Primaria

Phase 2: Clinical activity as determined by International Myeloma Working Group (IMWG (2016) response rates [Overall Response Rate (ORR), Complete Response (CR) or better, Very Good Partial Response (VGPR), Partial Response (PR)]
Phase 3: Minimal Residual Disease (MRD) negative CR rate
Phase 3: Progression-Free Survival (PFS)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Phase 2: To determine safety and tolerability of etentamig in combination with daratumumab in participants with NDMM that are not eligible for transplant
Phase 2: To determine the clinical activity of etentamig in combination with daratumumab in participants with NDMM that are not eligible for transplant
Phase 2: To determine the pharmacokinetics and immunogenicity of etentamig when given in combination with daratumumab in participants with NDMM that are not eligible for transplant
Phase 3: To further evaluate the efficacy of etentamig administered with daratumumab in participants with NDMM that are not eligible for transplant
Phase 3: To further evaluate the safety and tolerability of etentamig administered with daratumumab in participants with NDMM that are not eligible for transplant

Variables de Evaluación Secundaria

Phase 2: MRD negative CR rate

Phase 2: PFS
Phase 2: Sustained MRD negativity rate (12 months)
Phase 2: Overall Survival (OS)
Phase 2: Safety and Tolerability
Phase 2: Maximum Observed Serum Concentration (Cmax)
Phase 2: Time to Cmax (time to maximum observed concentration, Tmax)
Phase 2: Area Under the Serum Concentration-Time Curve (AUC)
Phase 2: Positive or negative anti-drug antibodies (ADAs) and neutralizing anti-drug antibodies (NAbs)
Phase 3: OS
Phase 3: Sustained MRD negativity rate (12 months)
Phase 3: Rate of CR
Phase 3: Rate of VGPR or better
Phase 3: ORR
Phase 3: Time to Response (TTR)
Phase 3: Duration of Response (DOR)
Phase 3: Time-to-progression (TTP)
Phase 3: Duration of Response (DOR)
Phase 3: Time-to-progression (TTP)
Phase 3: Event Free Survival (EFS)
Phase 3: Progression-Free Survival on Subsequent Therapy (PFS2)
Phase 3: Safety and tolerability
Phase 3: Change from baseline in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) Physical Functioning score
Phase 3: Change from baseline in EORTC QLQ-C30 Global Health Status/QoL score
Phase 3: Change from baseline and time to deterioration in the remaining scales and items of EORTC QLQ-C30
Phase 3: Symptomatic AEs as assessed by the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)
Phase 3: Overall bother due to treatment side effects as assessed by the Functional Assessment of Cancer Therapy-General (FACT-G) GP5
Phase 3: Change from baseline in Patient Global Impression of Severity (PGIS) scores
Phase 3: Change from baseline in European Quality of Life 5 Dimensions (EQ-5D-5L) scores

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Participants must have confirmed NDMM according to the IMWG diagnostic criteria, and per investigator's judgement, participant is not suitable to receive high-dose chemotherapy and stem cell transplantation due to factors likely to have a negative impact on tolerability of high dose chemotherapy and ASCT.
International Myeloma Working Group (IMWG) Myeloma Frailty Index Score of 1
Eastern Cooperative Oncology Group (ECOG) performance of 1
All participants must have measurable disease per central laboratory with at least 1 of the following assessed within 28 days prior to enrollment: Serum M-protein 0.5 g/dL (5 g/L). Urine M-protein 200 mg/24 hours. Serum free light chain (FLC) 100 mg/L (10 mg/dL) (involved light chain) and an abnormal serum kappa lambda ratio only for participants without measurable serum or urine M-protein.

Criterios de Exclusión

Prior or current systemic therapy or SCT for multiple myeloma or any plasma cell dyscrasia other than short course of corticosteroids Participants received treatment with anti-cancer therapy (including chemotherapy, radiotherapy, biologics, immunotherapy, cellular therapies and/or steroids at doses > 20 mg dexamethasone or equivalent) or undergone a major surgical procedure within 21 days or within 5 half-lives of an anticancer therapy, prior to the first dose of study treatment, whichever is shorter Participant treated with any investigational treatment within 30 days or 5 half-lives of the treatment (whichever is longer) prior to the first dose of study treatment or is currently enrolled in another clinical study Participant who has known active central nervous system involvement of Multiple Myeloma (MM) Participant who has history of clinically significant renal, neurologic, psychiatric, endocrine, metabolic, immunologic, pulmonary, or hepatic disease within the last 6 months that, in the investigator's opinion, would adversely affect the participant's participation in the study

Calendario

(Última actualización: 02/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
18/02/2026	25/02/2026	17/03/2026	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
No aportado	No aportado	No aportado	No aportado	No aportado

Promotor

AbbVie Deutschland GmbH & Co. KG Germany

Knollstrasse

Contact Person

Global Clinical Trials Helpdesk

4961117201520

global-clinical-trials@abbvie.com

Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Activo (27/02/2026)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Activo (27/02/2026)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Activo (11/05/2026)

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Hematology

Activo (12/03/2026)

El Hospital Universitario De Gran Canaria Dr. Negrin

Las Palmas De Gran Canaria

LAS PALMAS

Hematology

Activo (03/03/2026)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Activo (10/04/2026)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology and Hemotherapy

Activo (04/03/2026)

Hospital Universitario De Leon

Leon

LEÓN

Hematology

Activo (25/02/2026)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (08/04/2026)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Activo (12/03/2026)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Activo (09/03/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology and Hemotherapy

Activo (17/03/2026)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Activo (29/05/2026)

Institut Catala D'oncologia

Badalona

BARCELONA

Hematology

Medicamentos

LENALIDOMIDE
CAPSULE
ORAL USE

-
Principios Activos: N/A

Experimental

DARATUMUMAB
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-
Principios Activos: N/A

Experimental

DEXAMETHASONE
SOLUTION FOR INJECTION
INTRAVENOUS ADMINISTRATION

-
Principios Activos: N/A

Experimental

LENALIDOMIDE
CAPSULE
ORAL USE

-
Principios Activos: N/A

Experimental

LENALIDOMIDE
CAPSULES
ORAL USE

-
Principios Activos: N/A

Experimental

DEXAMETHASONE
TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

LENALIDOMIDE
CAPSULE
ORAL USE

-
Principios Activos: N/A

Experimental

LENALIDOMIDE
CAPSULE
ORAL USE

-
Principios Activos: N/A

Experimental

LENALIDOMIDE
CAPSULE
ORAL USE

-

Principios Activos: N/A

Experimental

Etentamig
SOLUTION FOR INFUSION
INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

Sin resultados

A Study to Assess A Change in Disease Activity and Adverse Events of Intravenous Etentamig and Daratumumab (Etentamig+D) Compared to Daratumumab, Lenalidomide, and Dexamethasone (DRd) in Adult Participants with Newly Diagnosed Multiple Myeloma Not Eligible for Transplant

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II , Phase III	36
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	NO

Information

Identifier
2025-520897-21-00 (CTIS)

Protocol Code
M25-586

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

Investigated Disease
Multiple Myeloma

Scientific Title
A Phase 2/3, Multicenter, Randomized, Open-Label Study Evaluating the Efficacy and Safety of Etentamig and Daratumumab (Etentamig+D) Compared to Daratumumab, Lenalidomide, and Dexamethasone (DRd) in Subjects

with Newly Diagnosed Multiple Myeloma Not Eligible for Transplant

Rationale

Not provided

Main Objective

Phase 2: To determine the RP3D of etentamig in combination with daratumumab in partcipants with Newly Diagnosed Multiple Myeloma (NDMM) that are not eligible for transplant
Phase 3: To evaluate the efficacy of etentamig administered with daratumumab in participants with NDMM that are not eligible for transplant
To evaluate the efficacy of etentamig administered with daratumumab in participants with NDMM that are not eligible for transplant

Primary Endpoints

Phase 2: Clinical activity as determined by International Myeloma Working Group (IMWG (2016) response rates [Overall Response Rate (ORR), Complete Response (CR) or better, Very Good Partial Response (VGPR), Partial Response (PR)]
Phase 3: Minimal Residual Disease (MRD) negative CR rate
Phase 3: Progression-Free Survival (PFS)

Temporary moments of secondary assessment

Not provided

Secondary Objective

Phase 2: To determine safety and tolerability of etentamig in combination with daratumumab in participants with NDMM that are not eligible for transplant
Phase 2: To determine the clinical activity of etentamig in combination with daratumumab in participants with NDMM that are not eligible for transplant
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Phase 3: To further evaluate the safety and tolerability of etentamig administered with daratumumab in participants with NDMM that are not eligible for transplant

Secondary Endpoints

Phase 2: MRD negative CR rate

Phase 2: PFS
Phase 2: Sustained MRD negativity rate (12 months)
Phase 2: Overall Survival (OS)
Phase 2: Safety and Tolerability
Phase 2: Maximum Observed Serum Concentration (Cmax)
Phase 2: Time to Cmax (time to maximum observed concentration, Tmax)
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Phase 3: Progression-Free Survival on Subsequent Therapy (PFS2)
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Phase 3: Change from baseline in Patient Global Impression of Severity (PGIS) scores
Phase 3: Change from baseline in European Quality of Life 5 Dimensions (EQ-5D-5L) scores

Temporary moments of secondary assessment

Not provided

Inclusion criteria

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Calendar

(Last Update: 02/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
18/02/2026	25/02/2026	17/03/2026	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
Not aported	Not aported	Not aported	Not aported	Not aported

Sponsor

AbbVie Deutschland GmbH & Co. KG Germany

Knollstrasse

Contact Person

Global Clinical Trials Helpdesk

4961117201520

global-clinical-trials@abbvie.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Regional de la Comunidad de Madrid

C/ Aduana 29 3ª planta 28013 Madrid

comite.regional@salud.madrid.org

913702824

Sites

Active (27/02/2026)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Active (27/02/2026)

Clinica Universidad De Navarra

Madrid

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Active (03/03/2026)

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MADRID

Hematology and Hemotherapy

Active (04/03/2026)

Hospital Universitario De Leon

Leon

LEÓN

Hematology

Active (25/02/2026)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Active (08/04/2026)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Active (12/03/2026)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Active (09/03/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology and Hemotherapy

Active (17/03/2026)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Active (29/05/2026)

Institut Catala D'oncologia

Badalona

BARCELONA

Hematology

Medication

LENALIDOMIDE
CAPSULE
ORAL USE

-
Active Principles: N/A

Experimental

DARATUMUMAB
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-
Active Principles: N/A

Experimental

DEXAMETHASONE
SOLUTION FOR INJECTION
INTRAVENOUS ADMINISTRATION

-
Active Principles: N/A

Experimental

LENALIDOMIDE
CAPSULE
ORAL USE

-
Active Principles: N/A

Experimental

LENALIDOMIDE
CAPSULES
ORAL USE

-
Active Principles: N/A

Experimental

DEXAMETHASONE
TABLET
ORAL USE

-
Active Principles: N/A

Experimental

LENALIDOMIDE
CAPSULE
ORAL USE

-
Active Principles: N/A

Experimental

LENALIDOMIDE
CAPSULE
ORAL USE

-
Active Principles: N/A

Experimental

LENALIDOMIDE
CAPSULE
ORAL USE

-

Active Principles: N/A

Experimental

Etentamig
SOLUTION FOR INFUSION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

No results