Phase 1b/2a Study to Evaluate Mezigdomide in Combination with Elranatamab in Relapsed and/or Refractory 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 I , Fase II	38
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica, dosis	NO

Información

Identificador
2025-522090-11-00 (CTIS)

Cod. Protocolo
CA057-1040

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

Enfermedad investigada
Relapsed or Refractory Multiple Myeloma (RRMM)

Título Científico
A Phase 1b/2a, Multicenter, Open-label Study to Determine the Recommended Dose and Schedule, and Evaluate the Safety and Preliminary Efficacy of Mezigdomide in Combination with Elranatamab in Participants with Relapsed and/or Refractory Multiple Myeloma

Justificación

No aportado

Objetivo Principal

The main goal is to determine the safety and tolerability of Mezigdomide in combination with Elranatamab in participants with RRMM and to determine the recommended Phase 2 dose (RP2D; the dose to be used in subsequent, larger studies) and schedule of Mezigdomide when given in combination in participants with RRMM.

Variables de Evaluación Primaria

The main endpoints include the type, frequency, seriousness, and severity of all aAEs.
Establish the RP2D and dosing schedule of mezigdomide in combination with elranatamab.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

The secondary goal is to see how well mezigdomide works in combination with elranatamab and to see if there is any small amount of detectable disease (minimum residual disease; MRD) after study treatment among participants who achieve a complete response or better (CR; a type of overall response for myeloma after treatment).

Variables de Evaluación Secundaria

The secondary endpoints relate to the effectiveness of the treatment. Specific metrics to be examined include the percentage of participants who respond to treatment (overall response rate; ORR), the percentage of participants who have a very good partial response or better
The percentage of participants who have a very good partial response or better (VGPRR) or complete response or better (CRR) as well as additional measures of response including the time to response (TTR; how long it takes for the treatment to start working), duration of response (DOR; how long the response lasts), progression free survival (PFS; how long it takes for the disease to get worse), and overall survival (OS; how long participants stay alive after receiving the treatment
Number of participants who do not have detectable disease in the body with a sensitive laboratory test. This is called minimum residual disease negativity rate.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Signed Written Informed Consent
Participant with a history of RRMM who received 2 to 4 prior lines of anti-myeloma therapy.
Participants must have measurable disease as determined by local laboratory.
Participant consents to hospitalization requirements.
Participant consents to serial BMAs and/or BMBs during screening, study treatment, and at EOT.
Participant has an ECOG PS of 0 to 1

Criterios de Exclusión

Participant with known current or history of CNS involvement of MM
Participant cannot tolerate oral medications and/or has gastrointestinal disease (within 3 months of screening) or any gastrointestinal surgery that may significantly alter the absorption of oral study treatment
Ongoing Grade 2 peripheral sensory or motor neuropathy.
History of GBS or GBS variants, or history of any Grade 3 peripheral motor polyneuropathy.
HIV positive patients.
Participant has known chronic, active HBV/HCV infection
Participant has a prior history of malignancies other than MM, except if the participant has been free of the disease for 3 years.
Participant has a history or presence of clinically relevant CNS pathology such as epilepsy, seizure, paresis, aphasia, stroke, subarachnoid hemorrhage or CNS bleed, severe brain injuries, dementia, Parkinsons disease, cerebellar disease, organic brain syndrome, or psychosis

Calendario

(Última actualización: 28/04/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
23/10/2025	22/01/2026	13/04/2026	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

Celgene Corp. United States

Route 206 And Province Line Road

Contact Person

GSM-CT

003223527611

mg-gsm-ct@bms.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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923291100

Centros

Activo (22/01/2026)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematologia

Activo (22/01/2026)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematologia

Medicamentos

CC-92480
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

CC-92480
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

CC-92480
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

CC-92480
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

DEXAMETHASONE
TABLET
ORAL

-
Principios Activos: N/A

Experimental

CC-92480
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

CC-92480
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

ELRANATAMAB
SOLUTION FOR INJECTION
INTRAVENIOUS INFUSION

-
Principios Activos: N/A

Experimental

Sin resultados

Phase 1b/2a Study to Evaluate Mezigdomide in Combination with Elranatamab in Relapsed and/or Refractory Multiple Myeloma

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	38
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics, dose	NO

Information

Identifier
2025-522090-11-00 (CTIS)

Protocol Code
CA057-1040

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

Investigated Disease
Relapsed or Refractory Multiple Myeloma (RRMM)

Scientific Title
A Phase 1b/2a, Multicenter, Open-label Study to Determine the Recommended Dose and Schedule, and Evaluate the Safety and Preliminary Efficacy of Mezigdomide in Combination with Elranatamab in Participants with Relapsed and/or Refractory Multiple Myeloma

Rationale

Not provided

Main Objective

The main goal is to determine the safety and tolerability of Mezigdomide in combination with Elranatamab in participants with RRMM and to determine the recommended Phase 2 dose (RP2D; the dose to be used in subsequent, larger studies) and schedule of Mezigdomide when given in combination in participants with RRMM.

Primary Endpoints

The main endpoints include the type, frequency, seriousness, and severity of all aAEs.
Establish the RP2D and dosing schedule of mezigdomide in combination with elranatamab.

Temporary moments of secondary assessment

Not provided

Secondary Objective

The secondary goal is to see how well mezigdomide works in combination with elranatamab and to see if there is any small amount of detectable disease (minimum residual disease; MRD) after study treatment among participants who achieve a complete response or better (CR; a type of overall response for myeloma after treatment).

Secondary Endpoints

The secondary endpoints relate to the effectiveness of the treatment. Specific metrics to be examined include the percentage of participants who respond to treatment (overall response rate; ORR), the percentage of participants who have a very good partial response or better
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Temporary moments of secondary assessment

Not provided

Inclusion criteria

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Calendar

(Last Update: 28/04/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
23/10/2025	22/01/2026	13/04/2026	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

Celgene Corp. United States

Route 206 And Province Line Road

Contact Person

GSM-CT

003223527611

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Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Active (22/01/2026)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematologia

Active (22/01/2026)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematologia

Medication

CC-92480
CAPSULE
ORAL

-
Active Principles: N/A
Experimental

CC-92480
CAPSULE
ORAL

-
Active Principles: N/A
Experimental

CC-92480
CAPSULE
ORAL

-
Active Principles: N/A
Experimental

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CAPSULE
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Active Principles: N/A
Experimental

DEXAMETHASONE
TABLET
ORAL

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Active Principles: N/A
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Active Principles: N/A
Experimental

CC-92480
CAPSULE
ORAL

-
Active Principles: N/A
Experimental

ELRANATAMAB
SOLUTION FOR INJECTION
INTRAVENIOUS INFUSION

-
Active Principles: N/A
Experimental

No results