

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

Estado

Reclutando

Tipo de Participantes

No aportado

Rangos de Edad

Mayores de 64 , Adultos (18-64 años)

Género

Ambos

Fases

Fase I , Fase II

Participantes esperados

38

Resultados

Sin resultados

Bajo nivel intervención

No

Enfermedad rara

Si

Cobertura geográfica

Sin determinar

Ámbitos del ensayo

seguridad, eficacia, farmacocinética,
farmacodinámica, dosis

Terapia avanzada

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 23/10/2025	Inicio de Ensayo 22/01/2026	Inclusión Primer Paciente 13/04/2026	Interrumpido No aportado	Reiniciado No aportado
Fin de reclutamiento No aportado	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global No aportado

Promotor

Celgene Corp. United States

Route 206 And Province Line Road

Contact Person

GSM-CT

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mg-gsm-ct@bms.com

Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematología

Activo (22/01/2026)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematología

Activo (22/01/2026)

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

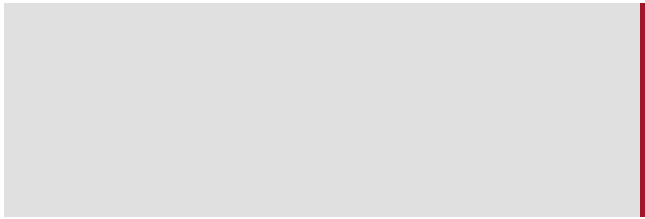
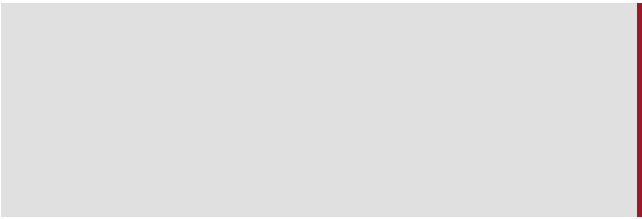
ELRANATAMAB

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
Recruiting

Type of participants
Not provided

Age Ranges
Older than 64 , Adults (18-64 years)

Gender
Both

Phases
Phase I , Phase II

Expected Participants
38

Results
No results

Low level of intervention
No

Rare disease
Yes

Geographic coverage
Undetermined

Areas of the study
safety, effectiveness, pharmacokinetics,
pharmacodynamics, dose

Advanced therapy
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

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

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Temporary moments of secondary assessment

Not provided

Inclusion criteria

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Calendar

(Last Update: 28/04/2026)

Authorization 23/10/2025	Start of Trial 22/01/2026	First patient inclusion 13/04/2026	Halted Not aported	Restarted Not aported
End of recruitment Not aported	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) Not aported	Trial end (Global) Not aported

Sponsor

Celgene Corp. United States

Route 206 And Province Line Road

Contact Person

GSM-CT

003223527611

mg-gsm-ct@bms.com

Monetary support: N/A

Sponsor type: Commercial

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Sites

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SALAMANCA

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Active (22/01/2026)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematologia

Active (22/01/2026)

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

CC-92480
CAPSULE
ORAL

Active Principles: N/A

Experimental

DEXAMETHASONE
TABLET
ORAL

Active Principles: N/A

Experimental

CC-92480
CAPSULE
ORAL

Active Principles: N/A

Experimental

CC-92480
CAPSULE
ORAL

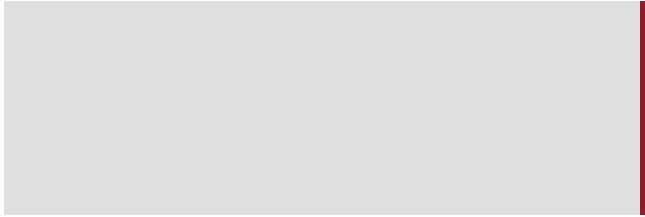
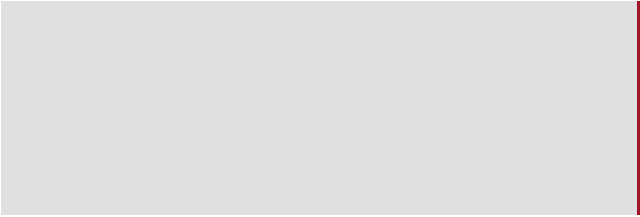
Active Principles: N/A

Experimental

ELRANATAMAB
SOLUTION FOR INJECTION
INTRAVENIOUS INFUSION

Active Principles: N/A

Experimental



No results