A trial to determine the safety and effectiveness of CC-92480 in combination with bortezomib and dexamethasone as compared to pomalidomide in combination with bortezomib and dexamethasone in people who have Multiple Myeloma that is not responsive after treatment or has returned after a period of treatment.

Estado
Fin Reclutamiento

Tipo de Participantes
No aportado

Rangos de Edad
Mayores de 64 , Adultos (18-64 años)

Género
Ambos

Fases
Fase III

Participantes esperados
576

Resultados
Sin resultados

Bajo nivel intervención
No

Enfermedad rara
Si

Cobertura geográfica
Sin determinar

Ámbitos del ensayo
tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, farmacogenómica

Terapia avanzada
NO

Información

Identificador
2023-509859-13-00 (CTIS)

Cod. Protocolo
CA057-001

Transicionado 2021-001957-30

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

Enfermedad investigada
Relapsed or Refractory Multiple Myeloma (RRMM)

Título Científico

A Phase 3, Two-Stage, Randomized, Multicenter, Open-Label Study Comparing Mezigdomide (CC-92480), Bortezomib And Dexamethasone (MeziVd) Versus Pomalidomide, Bortezomib And Dexamethasone (PVd) In Subjects With Relapsed Or Refractory Multiple Myeloma (RRMM): Successor-1

Justificación

No aportado

Objetivo Principal

To compare the progression-free survival (PFS) of mezigdomide, bortezomib and dexamethasone (MeziVd) to that of pomalidomide, bortezomib and dexamethasone (PVd) in subjects with relapsed or refractory multiple myeloma (RRMM)

Variables de Evaluación Primaria

Progression free Survival (PFS)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

In Stage 1, to determine the dose of mezigdomide in combination with bortezomib and dexamethasone to continue in Stage 2 of the study
In Stage 1, to determine the plasma concentrations of mezigdomide in combination with bortezomib and dexamethasone
To compare overall survival (OS) between MeziVd and PVd in subjects with RRMM
To evaluate additional efficacy parameters in subjects with RRMM treated with MeziVd compared to PVd
To evaluate minimal residual disease (MRD) negativity rate in subjects treated with MeziVd compared to those treated with PVd
To evaluate safety of MeziVd compared to PVd in subjects with RRMM
In subjects randomized to Stage 2, to evaluate cancer-related symptoms and health related quality of life (HRQoL) using the European Organization for Research and Treatment of Cancer - Quality of Life C30 questionnaire (EORTC QLQC30) and the European Quality of Life Multiple Myeloma Module (EORTC QLQ-MY20) in subjects treated with MeziVd compared to PVd

Variables de Evaluación Secundaria

Recommended mezigdomide dose
Pharmacokinetics
Overall Survival (OS)

Overall Response Rate (OR)
Complete Response Rate (CR) or better
Very Good Partial Response Rate (VGPR) or better
Time to Response (TTR)
Duration of Response (DOR)
Time to Progression (TTP)
Time to Next Treatment (TTNT)
Progression-free survival 2 (PFS-2)
Minimal residual disease (MRD) negativity
Safety
Health Related Quality of Life (HRQoL) Evaluation

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Subject has documented diagnosis of MM and measurable disease, defined as: M-protein 0.5 g/dL by serum protein electrophoresis (sPEP), or 200 mg/24-hour urine collection by urine protein electrophoresis (uPEP) or For subjects without measurable disease in sPEP or uPEP: serum free light chain (sFLC) levels > 100 mg/L (10 mg/dL) involved light chain and an abnormal kappa/lambda FLC ratio Subject has received 1 to 3 prior anti-myeloma lines of therapy Subject must have received prior treatment with a lenalidomide containing regimen. For country-specific requirements, see APPENDIX I Subject achieved a minimal response [MR] or better to at least 1 prior antimyeloma therapy Subject must have documented disease progression during or after their last antimyeloma regimen Subject has an Eastern Cooperative Oncology Group (ECOG) performance status score of 0, 1 or 2.

Criterios de Exclusión

Subject has had prior treatment with mezigdomide or pomalidomide
Subject has had progression during treatment or within 60 days of the last dose of a proteasome inhibitor, except as noted below: a. Subjects who progressed while being treated with, or within 60 days of last dose of bortezomib maintenance given once every 2 weeks or less are not excluded.
For participants with prior treatment of a bortezomib containing regimen, the best response achieved was not a minimal response (MR) or better, or participant discontinued bortezomib due to toxicity.

Calendario

(Última actualización: 21/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
22/09/2022	25/11/2022	20/03/2023	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
11/04/2024	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

CEIm Hospital Universitario 12 de Octubre

Glorieta de Málaga, S/N 28041 Madrid

ceic@h12o.es

917792613

Centros

Activo (30/11/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Activo (30/11/2022)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Activo (21/02/2022)

HOSPITAL COSTA DEL SOL

Marbella

MÁLAGA

Activo (21/02/2022)

Hospital Costa Del Sol

Marbella

MÁLAGA

Hematology

Cerrado (16/06/2026)

HOSPITAL DE LEON (COMPLEJO ASISTENCIAL UNIVERSITARIO DE LEON)

León

LEÓN

Activo (25/11/2022)

HOSPITAL G. UNIVERSITARIO J.M. MORALES MESEGUER

Murcia

MURCIA

Activo (25/11/2022)

Hospital General Universitario Morales Meseguer

Murcia

MURCIA

Hematology and Medical Oncology

Activo (03/01/2024)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology

Activo (03/01/2024)

Hospital San Pedro De Alcántara

Cáceres

CÁCERES

Hematologia

Activo (10/11/2022)

HOSPITAL UNIVERSITARI SON ESPASES

Palma

BALEARES

Cerrado (16/06/2026)

Hospital Universitario De Leon

Leon

LEÓN

Hematology

Activo (31/01/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Activo (31/01/2023)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Activo (10/11/2022)

University Hospital Son Espases

Palma

BALEARES

Hematology

Medicamentos

Imnovid 4 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

CC-92480
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

CC-92480
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

Dexamethason 4 mg GALEN®
TABLET
ORAL

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

Experimental

CC-92480
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

Imnovid 3 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Imnovid 2 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

VELCADE 1 mg powder for solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS

Código ATC: L01XG01 - BORTEZOMIB
Principios Activos: N/A

Experimental

CC-92480
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

CC-92480
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Dexamethason-ratiopharm® 4 mg Tabletten
TABLET
ORAL

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

Experimental

Dexamethason CF 20 mg/ml, injectievloeistof
SOLUTION FOR INJECTION
INTRAVENOUS USE

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

Experimental

CC-92480
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

DEXAMETHASONE
TABLET
ORAL

Dexamethason 4 mg JENAPHARM®
TABLET
ORAL

-

Principios Activos: N/A

Experimental

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

Experimental

Sin resultados

A trial to determine the safety and effectiveness of CC-92480 in combination with bortezomib and dexamethasone as compared to pomalidomide in combination with bortezomib and dexamethasone in people who have Multiple Myeloma that is not responsive after treatment or has returned after a period of treatment.

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	576
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics, pharmacogenomics	NO

Information

Identifier
2023-509859-13-00 (CTIS)

Protocol Code
CA057-001

Transitioned 2021-001957-30

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

Investigated Disease
Relapsed or Refractory Multiple Myeloma (RRMM)

Scientific Title

A Phase 3, Two-Stage, Randomized, Multicenter, Open-Label Study Comparing Mezigdomide (CC-92480), Bortezomib And Dexamethasone (MeziVd) Versus Pomalidomide, Bortezomib And Dexamethasone (PVd) In Subjects With Relapsed Or Refractory Multiple Myeloma (RRMM): Successor-1

Rationale

Not provided

Main Objective

To compare the progression-free survival (PFS) of mezigdomide, bortezomib and dexamethasone (MeziVd) to that of pomalidomide, bortezomib and dexamethasone (PVd) in subjects with relapsed or refractory multiple myeloma (RRMM)

Primary Endpoints

Progression free Survival (PFS)

Temporary moments of secondary assessment

Not provided

Secondary Objective

In Stage 1, to determine the dose of mezigdomide in combination with bortezomib and dexamethasone to continue in Stage 2 of the study
In Stage 1, to determine the plasma concentrations of mezigdomide in combination with bortezomib and dexamethasone
To compare overall survival (OS) between MeziVd and PVd in subjects with RRMM
To evaluate additional efficacy parameters in subjects with RRMM treated with MeziVd compared to PVd
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To evaluate safety of MeziVd compared to PVd in subjects with RRMM
In subjects randomized to Stage 2, to evaluate cancer-related symptoms and health related quality of life (HRQoL) using the European Organization for Research and Treatment of Cancer - Quality of Life C30 questionnaire (EORTC QLQC30) and the European Quality of Life Multiple Myeloma Module (EORTC QLQ-MY20) in subjects treated with MeziVd compared to PVd

Secondary Endpoints

Recommended mezigdomide dose
Pharmacokinetics
Overall Survival (OS)

Overall Response Rate (OR)
Complete Response Rate (CR) or better
Very Good Partial Response Rate (VGPR) or better
Time to Response (TTR)
Duration of Response (DOR)
Time to Progression (TTP)
Time to Next Treatment (TTNT)
Progression-free survival 2 (PFS-2)
Minimal residual disease (MRD) negativity
Safety
Health Related Quality of Life (HRQoL) Evaluation

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Subject has documented diagnosis of MM and measurable disease, defined as: M-protein 0.5 g/dL by serum protein electrophoresis (sPEP), or 200 mg/24-hour urine collection by urine protein electrophoresis (uPEP) or For subjects without measurable disease in sPEP or uPEP: serum free light chain (sFLC) levels > 100 mg/L (10 mg/dL) involved light chain and an abnormal kappa/lambda FLC ratio Subject has received 1 to 3 prior anti-myeloma lines of therapy Subject must have received prior treatment with a lenalidomide containing regimen. For country-specific requirements, see APPENDIX I Subject achieved a minimal response [MR] or better to at least 1 prior antimyeloma therapy Subject must have documented disease progression during or after their last antimyeloma regimen Subject has an Eastern Cooperative Oncology Group (ECOG) performance status score of 0, 1 or 2.

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Subject has had prior treatment with mezigdomide or pomalidomide
Subject has had progression during treatment or within 60 days of the last dose of a proteasome inhibitor, except as noted below: a. Subjects who progressed while being treated with, or within 60 days of last dose of bortezomib maintenance given once every 2 weeks or less are not excluded.
For participants with prior treatment of a bortezomib containing regimen, the best response achieved was not a minimal response (MR) or better, or participant discontinued bortezomib due to toxicity.

Calendar

(Last Update: 21/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
22/09/2022	25/11/2022	20/03/2023	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
11/04/2024	Not aported	Not aported	Not aported	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

Ceim

CEIm Hospital Universitario 12 de Octubre

Glorieta de Málaga, S/N 28041 Madrid

ceic@h12o.es

917792613

Sites

Active (30/11/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Active (30/11/2022)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Active (21/02/2022)

HOSPITAL COSTA DEL SOL

Marbella

MÁLAGA

Active (21/02/2022)

Hospital Costa Del Sol

Marbella

MÁLAGA

Hematology

Closed (16/06/2026)

HOSPITAL DE LEON (COMPLEJO ASISTENCIAL UNIVERSITARIO DE LEON)

León

LEÓN

Active (25/11/2022)

HOSPITAL G. UNIVERSITARIO J.M. MORALES MESEGUER

Murcia

MURCIA

Active (25/11/2022)

Hospital General Universitario Morales Meseguer

Murcia

MURCIA

Hematology and Medical Oncology

Active (03/01/2024)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology

Active (03/01/2024)

Hospital San Pedro De Alcántara

Cáceres

CÁCERES

Hematologia

Active (10/11/2022)

HOSPITAL UNIVERSITARI SON ESPASES

Palma

BALEARES

Closed (16/06/2026)

Hospital Universitario De Leon

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LEÓN

Hematology

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HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Active (31/01/2023)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Active (10/11/2022)

University Hospital Son Espases

Palma

BALEARES

Hematology

Medication

Imnovid 4 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

CC-92480
CAPSULE
ORAL

-
Active Principles: N/A

Experimental

CC-92480
CAPSULE
ORAL

-
Active Principles: N/A

Experimental

Dexamethason 4 mg GALEN®
TABLET
ORAL

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

Experimental

CC-92480
CAPSULE
ORAL

-
Active Principles: N/A

Experimental

Imnovid 3 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Imnovid 2 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

VELCADE 1 mg powder for solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS

ATC code: L01XG01 - BORTEZOMIB
Active Principles: N/A

Experimental

CC-92480
CAPSULE
ORAL

-
Active Principles: N/A
Experimental

CC-92480
CAPSULE
ORAL

-
Active Principles: N/A
Experimental

Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL

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

Dexamethason-ratiopharm® 4 mg Tabletten
TABLET
ORAL

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

Dexamethason CF 20 mg/ml, injectievloeistof
SOLUTION FOR INJECTION
INTRAVENOUS USE

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

CC-92480
CAPSULE
ORAL

-
Active Principles: N/A
Experimental

DEXAMETHASONE
TABLET
ORAL

Dexamethason 4 mg JENAPHARM®
TABLET
ORAL

-

Active Principles: N/A

Experimental

ATC code: H02AB02 - DEXAMETASONA

Active Principles: N/A

Experimental

No results