

Cevostamab in Combination with Pomalidomide and Dexamethasone Versus Standard of Care in Patients with Previously Treated Multiple Myeloma

Estado

Reclutando

Tipo de Participantes

No aportado

Rangos de Edad

Mayores de 64 , Adultos (18-64 años)

Género

Ambos

Fases

Fase III

Participantes esperados

251

Resultados

Sin resultados

Bajo nivel intervención

No

Enfermedad rara

No

Cobertura geográfica

Sin determinar

Ámbitos del ensayo

seguridad, eficacia

Terapia avanzada

NO

Información

Identificador

2025-524028-23-00 (CTIS)

Cod. Protocolo

CO46096

Área terapéutica

Enfermedades [C] - Cáncer [C04]

Enfermedad investigada

Multiple Myeloma

Título Científico

A Phase III, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy and Safety of Cevostamab in Combination with Pomalidomide and Dexamethasone Versus Standard of Care in Patients with Multiple Myeloma who Have Received One to Three Prior Lines of Therapy

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of cevostamab in combination with pomalidomide and dexamethasone (CevosPd) compared with standard of care (SOC) based on two primary endpoints i.e. Minimal Residual Disease (MRD)-negative Complete Response (CR) rate Progression-Free Survival (PFS)

Variables de Evaluación Primaria

MRD-negative CR rate at 9 months measured in bone marrow aspirate by next-generation sequencing (NGS) PFS, defined as the time from randomization to the earliest date of disease progression, based on IRC assessment by IMWG criteria, or death due to any cause, whichever occurs first. For participants who have not progressed and are alive, PFS will be censored at the last disease evaluation.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the efficacy of CevosPd compared with SOC with respect to very good partial response (VGPR) or better rate and overall survival (OS) endpoints

To evaluate the health-related quality of life of participants treated with CevosPd compared with SOC with respect to time to confirmed deteriorationin Disease Symptoms scale, defined as an increase in 16 points or more from baseline followed by a second deterioration at a subsequent assessment, as assessed by the European Organisation for Research and Treatment of Cancer (EORTC)-Quality of Life Questionnaire Multiple Myeloma Module 20 (QLQ-MY20).

To evaluate the efficacy of CevosPd compared with SOC with respect to overall response Rate (ORR), complete response (CR), time to first response (TTR), time to best response (TTBR), duration of response (DOR), PFS, PFS2, Overall MRD-negative CR rate, Overall MRD-negative rate, Sustained MRD-negative CR rate endpoints.

To evaluate the safety of CevosPd compared with SOC

To evaluate the health-related quality of life of CevosPd compared with SOC

To evaluate the immunogenicity of cevostamab in CevosPd regimen

Variables de Evaluación Secundaria

VGPR or better rate, defined as the proportion of participants with best overall response of VGPR or better, based on the IRC assessment per IMWG criteria

OS, defined as the time from randomization to death due to any cause. If the participant is alive or the vital status is unknown, then OS will be censored at the date the participant was last known to be alive.

Time to confirmed deteriorationin Disease Symptoms scale, defined as an increase in 16 points or more from

baseline followed by a second deterioration at a subsequent assessment, as assessed by the EORTC QLQ-MY20
 ORR, defined as the proportion of participants with a stringent complete response (sCR), CR, VGPR, or partial response (PR)

CR rate, defined as proportion of participants achieving a CR or sCR

TTR (for participants who achieve a response of PR or better), defined as time from randomization to first achieving a PR or better

TTBR (for participants who achieve a response of PR or better), defined as time from randomization to achieving the deepest response

DOR (for participants who achieve a response of PR or better), defined as the time from the date of first documented response of PR or better until the first date of disease progression or death from any cause, whichever occurs first.

PFS by investigator, defined as the time from randomization to the earliest date of disease progression, based on the investigators assessment, or death due to any cause, whichever occurs first.

PFS2, defined as time from randomization to disease progression based on the investigators assessment, or death from any cause after initiation of new antimyeloma therapy, whichever is earlier. If disease progression after initiation of new antimyeloma therapy cannot be measured, a PFS2 event is defined as the date of discontinuation of new antimyeloma therapy or death from any cause, whichever is earlier.

Overall MRD-negative CR rate, defined as proportion of participants who achieve CR or better and MRD negativity (10-5 threshold) at any timepoint

Overall MRD-negative rate, defined as proportion of participants who achieve MRD negativity (10-5 threshold) at any timepoint regardless of clinical response

Sustained MRD-negative CR rate (at 6, 12, and 24 months, for participants who achieve MRD-negative CR), defined as the maintenance of MRD negativity confirmed 6, 12, or 24 months since first MRD-negative CR assessment

Incidence and severity of adverse events, with severity determined according to the National Cancer Institute Common Toxicity Criteria for Adverse Events, Version 5.0(NCI CTCAE v5.0)and American Society for Transplantation and Cellular Therapy(ASTCT)Consensus Grading for cytokine release syndrome(CRS)(Lee et al. 2019), immune effector cell-associated (ICANS)(Lee et al. 2019), and hemophagocytic lymphohistiocytosis (HLH)/immune effector cell-associated HLH-like syndrome(IEC-HS)(Hines et al. 2023)

Change from baseline in selected vital signs

Change from baseline in selected clinical laboratory test results

Tolerability as assessed by the incidence of dose interruptions, dose reductions, dose intensity, and treatment discontinuation

Presence, frequency of occurrence, severity, and/or degree of interference with daily function of shortness of breath, cough, heart palpitations, rash, dizziness, and nausea assessed by the National Cancer Institute Patient Reported Outcomes Common Terminology Criteria for Adverse Events (NCI PRO-CTCAE)

Change from baseline in shortness of breath, cough, heart palpitations, rash, dizziness, and nausea assessed by the NCI PRO-CTCAE

Change from Cycle 1 Day 8 in treatment-related side effect bother as assessed by the Functional Assessment of Cancer Therapy-General, General Population 5 (FACTG GP5)

Change from baseline in disease symptoms scale of the EORTC QLQ-MY20

Change from baseline in global health status/quality of life (GHS/QoL) scale of the EORTC QLQ-C30

Time to confirmed deterioration in GHS/QoL, defined as a decrease in 10 points or more from baseline followed by a second deterioration at a subsequent assessment, as assessed by the EORTC QLQ-C30

Change from baseline in fatigue as assessed by the EORTC QLQ-C30

Time to confirmed deterioration in fatigue, defined as an increase in 10 points or more from baseline followed by a second deterioration at a subsequent assessment as assessed by the EORTC QLQ-C30

Proportion of participants experiencing a clinically meaningful improvement in disease symptoms while on treatment, defined as a decrease in 16 points or more from baseline as assessed by the EORTC QLQ-MY20

Proportion of participants experiencing a clinically meaningful improvement in GHS/QoL while on treatment, defined as an increase in 10 points or more from baseline as assessed by the EORTC QLQ-C30

Proportion of participants experiencing a clinically meaningful improvement in fatigue while on treatment, defined as a decrease in 10 points or more from baseline as assessed by the EORTC QLQ-C30

Prevalence of anti-drug antibody (ADA) against cevostamab at baseline and incidence of ADA against cevostamab during the study

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Willing to undergo scheduled assessments and procedures including bone marrow biopsy and aspirate samples. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 at screening and immediately prior to start of administration of study treatment. Individuals with ECOG Performance Status of 2 solely due to local symptoms of myeloma (e.g., pain) are eligible Life expectancy of at least 12 weeks MM diagnosis according to the IMWG diagnostic criteria Measurable disease defined as at least one of the following by central laboratory assessment Serum M-protein 0.5 g/dL (5 g/L) Urine M-protein 200 mg/24 h Light chain MM without measurable M-protein in serum or urine: serum immunoglobulin free light chain > 10 mg/dL and abnormal serum immunoglobulin kappa-lambda free light chain ratio < 0.26 or > 1.65 Received one to three lines of prior therapy (for guidelines to determine prior lines of therapy, see Section 12.14) that included at least two consecutive cycles of either of the following: A regimen containing an anti-CD38 therapy, and - A regimen containing lenalidomide, and For the United States: a regimen containing a PI For countries outside the United States, a regimen containing a PI is allowed but not mandated

Criterios de Exclusión

Known history of amyloidosis (e.g., positive Congo Red stain or equivalent in tissue biopsy or documented within serum amyloid P component scan)
Lesions in proximity of vital organs that may develop sudden decompensation/deterioration in the setting of a tumor flare
Plasma cell leukemia or circulating plasma cell count exceeding 500 cells/ μ L or 5% of the peripheral blood white cells
Waldenströms macroglobulinemia or POEMS syndrome
Inability to tolerate thromboprophylaxis, or contraindication to thromboprophylaxis
Known history of interstitial lung disease

Calendario

(Última actualización: 29/07/2026)

Autorización 09/07/2026	Inicio de Ensayo 28/07/2026	Inclusión Primer Paciente No aportado	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

F. Hoffmann-La Roche AG Switzerland
Grenzacherstrasse 124

Contact Person

Trial Information System - TISL
41616881111
global.eudract@roche.com

Monetary support: N/A
Tipo de promotor: Comercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

C/ Doctor Esquerdo, 46 28007 Madrid

ceim.hgugm@salud.madrid.org

915867007

Centros

No iniciado (--/--/----)	Clinica Universidad De Navarra Pamplona NAVARRA Hematology	No iniciado (--/--/----)	Hospital Clinic De Barcelona Barcelona BARCELONA Hematology
No iniciado (--/--/----)	Hospital Costa Del Sol Marbella MÁLAGA Hematology	No iniciado (--/--/----)	Hospital General Universitario Gregorio Maranon Madrid MADRID Hematology
No iniciado (--/--/----)	Hospital Universitari Vall D Hebron Barcelona BARCELONA Hematology	No iniciado (--/--/----)	Hospital Universitario De Salamanca Salamanca SALAMANCA Hematology
No iniciado (--/--/----)	Institut Catala D&#39;oncologia Badalona BARCELONA Hematology		

Medicamentos

CARFILZOMIB

LYOPHILIZED POWDER FOR SOLUTION FOR INJECTION
IV INFUSION

–

Principios Activos: N/A

Experimental

DEXAMETHASONE

TABLET
ORAL

–

Principios Activos: N/A

Experimental

Empliciti 400 mg powder for concentrate for solution for infusion.

SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01XC23 - ELOTUZUMAB

Principios Activos: N/A

Experimental

Empliciti 300 mg powder for concentrate for solution for infusion.

SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01XC23 - ELOTUZUMAB

Principios Activos: N/A

Experimental

POMALIDOMIDE

CAPSULE, HARD
ORAL

–

Principios Activos: N/A

Experimental

DEXAMETHASONE

SOLUTION FOR INJECTION
IV INFUSION

–

Principios Activos: N/A

Experimental

DEXAMETHASONE

SOLUTION FOR INJECTION
IV INFUSION

–

Principios Activos: N/A

Experimental

Cevostamab

CONCENTRATE FOR SOLUTION FOR INFUSION
IV INFUSION

–

Principios Activos: N/A

Huérfano

Experimental

POMALIDOMIDE

CAPSULE, HARD
ORAL

Principios Activos: N/A

Experimental

DEXAMETHASONE

TABLET
ORAL

Principios Activos: N/A

Experimental

POMALIDOMIDE

CAPSULE, HARD
ORAL

Principios Activos: N/A

Experimental

DARATUMUMAB

SOLUTION FOR INJECTION
SUBCUTANEOUS

Principios Activos: N/A

Experimental

CARFILZOMIB

SOLUTION FOR INFUSION
IV INFUSION

Principios Activos: N/A

Experimental

POMALIDOMIDE

CAPSULE, HARD
ORAL

Principios Activos: N/A

Experimental

Cevostamab

CONCENTRATE FOR SOLUTION FOR INFUSION
IV INFUSION

Principios Activos: N/A

Huérfano

Experimental

Sin resultados

Cevostamab in Combination with Pomalidomide and Dexamethasone Versus Standard of Care in Patients with Previously Treated Multiple Myeloma

State
Recruiting

Type of participants
Not provided

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

Gender
Both

Phases
Phase III

Expected Participants
251

Results
No results

Low level of intervention
No

Rare disease
No

Geographic coverage
Undetermined

Areas of the study
safety, effectiveness

Advanced therapy
NO

Information

Identifier
2025-524028-23-00 (CTIS)

Protocol Code
CO46096

Therapeutic area
Diseases [C] - Cancer [C04]

Investigated Disease
Multiple Myeloma

Scientific Title
A Phase III, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy and Safety of Cevostamab in Combination with Pomalidomide and Dexamethasone Versus Standard of Care in Patients with Multiple Myeloma who Have Received One to Three Prior Lines of Therapy

Rationale

Not provided

Main Objective

To evaluate the efficacy of cevostamab in combination with pomalidomide and dexamethasone (CevosPd) compared with standard of care (SOC) based on two primary endpoints i.e. Minimal Residual Disease (MRD)-negative Complete Response (CR) rate Progression-Free Survival (PFS)

Primary Endpoints

MRD-negative CR rate at 9 months measured in bone marrow aspirate by next-generation sequencing (NGS) PFS, defined as the time from randomization to the earliest date of disease progression, based on IRC assessment by IMWG criteria, or death due to any cause, whichever occurs first. For participants who have not progressed and are alive, PFS will be censored at the last disease evaluation.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the efficacy of CevosPd compared with SOC with respect to very good partial response (VGPR) or better rate and overall survival (OS) endpoints

To evaluate the health-related quality of life of participants treated with CevosPd compared with SOC with respect to time to confirmed deterioration in Disease Symptoms scale, defined as an increase in 16 points or more from baseline followed by a second deterioration at a subsequent assessment, as assessed by the European Organisation for Research and Treatment of Cancer (EORTC)-Quality of Life Questionnaire Multiple Myeloma Module 20 (QLQ-MY20).

To evaluate the efficacy of CevosPd compared with SOC with respect to overall response Rate (ORR), complete response (CR), time to first response (TTR), time to best response (TTBR), duration of response (DOR), PFS, PFS2, Overall MRD-negative CR rate, Overall MRD-negative rate, Sustained MRD-negative CR rate endpoints.

To evaluate the safety of CevosPd compared with SOC

To evaluate the health-related quality of life of CevosPd compared with SOC

To evaluate the immunogenicity of cevostamab in CevosPd regimen

Secondary Endpoints

VGPR or better rate, defined as the proportion of participants with best overall response of VGPR or better, based on the IRC assessment per IMWG criteria

OS, defined as the time from randomization to death due to any cause. If the participant is alive or the vital status is unknown, then OS will be censored at the date the participant was last known to be alive.

Time to confirmed deterioration in Disease Symptoms scale, defined as an increase in 16 points or more from

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Overall MRD-negative CR rate, defined as proportion of participants who achieve CR or better and MRD negativity (10-5 threshold) at any timepoint

Overall MRD-negative rate, defined as proportion of participants who achieve MRD negativity (10-5 threshold) at any timepoint regardless of clinical response

Sustained MRD-negative CR rate (at 6, 12, and 24 months, for participants who achieve MRD-negative CR), defined as the maintenance of MRD negativity confirmed 6, 12, or 24 months since first MRD-negative CR assessment

Incidence and severity of adverse events, with severity determined according to the National Cancer Institute Common Toxicity Criteria for Adverse Events, Version 5.0 (NCI CTCAE v5.0) and American Society for Transplantation and Cellular Therapy (ASTCT) Consensus Grading for cytokine release syndrome (CRS) (Lee et al. 2019), immune effector cell-associated (ICANS) (Lee et al. 2019), and hemophagocytic lymphohistiocytosis (HLH)/immune effector cell-associated HLH-like syndrome (IEC-HS) (Hines et al. 2023)

Change from baseline in selected vital signs

Change from baseline in selected clinical laboratory test results

Tolerability as assessed by the incidence of dose interruptions, dose reductions, dose intensity, and treatment discontinuation

Presence, frequency of occurrence, severity, and/or degree of interference with daily function of shortness of breath, cough, heart palpitations, rash, dizziness, and nausea assessed by the National Cancer Institute Patient Reported Outcomes Common Terminology Criteria for Adverse Events (NCI PRO-CTCAE)

Change from baseline in shortness of breath, cough, heart palpitations, rash, dizziness, and nausea assessed by the NCI PRO-CTCAE

Change from Cycle 1 Day 8 in treatment-related side effect bother as assessed by the Functional Assessment of Cancer Therapy-General, General Population 5 (FACTG GP5)

Change from baseline in disease symptoms scale of the EORTC QLQ-MY20

Change from baseline in global health status/quality of life (GHS/QoL) scale of the EORTC QLQ-C30

Time to confirmed deterioration in GHS/QoL, defined as a decrease in 10 points or more from baseline followed by a second deterioration at a subsequent assessment, as assessed by the EORTC QLQ-C30

Change from baseline in fatigue as assessed by the EORTC QLQ-C30

Time to confirmed deterioration in fatigue, defined as an increase in 10 points or more from baseline followed by a second deterioration at a subsequent assessment as assessed by the EORTC QLQ-C30

Proportion of participants experiencing a clinically meaningful improvement in disease symptoms while on treatment, defined as a decrease in 16 points or more from baseline as assessed by the EORTC QLQ-MY20

Proportion of participants experiencing a clinically meaningful improvement in GHS/QoL while on treatment, defined as an increase in 10 points or more from baseline as assessed by the EORTC QLQ-C30

Proportion of participants experiencing a clinically meaningful improvement in fatigue while on treatment, defined as a decrease in 10 points or more from baseline as assessed by the EORTC QLQ-C30

Prevalence of anti-drug antibody (ADA) against cevostamab at baseline and incidence of ADA against cevostamab during the study

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Willing to undergo scheduled assessments and procedures including bone marrow biopsy and aspirate samples. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 at screening and immediately prior to start of administration of study treatment. Individuals with ECOG Performance Status of 2 solely due to local symptoms of myeloma (e.g., pain) are eligible Life expectancy of at least 12 weeks MM diagnosis according to the IMWG diagnostic criteria Measurable disease defined as at least one of the following by central laboratory assessment Serum M-protein 0.5 g/dL (5 g/L) Urine M-protein 200 mg/24 h Light chain MM without measurable M-protein in serum or urine: serum immunoglobulin free light chain > 10 mg/dL and abnormal serum immunoglobulin kappa-lambda free light chain ratio < 0.26 or > 1.65 Received one to three lines of prior therapy (for guidelines to determine prior lines of therapy, see Section 12.14) that included at least two consecutive cycles of either of the following: A regimen containing an anti-CD38 therapy, and - A regimen containing lenalidomide, and For the United States: a regimen containing a PI For countries outside the United States, a regimen containing a PI is allowed but not mandated

Exclusion criteria

Known history of amyloidosis (e.g., positive Congo Red stain or equivalent in tissue biopsy or documented within serum amyloid P component scan)
Lesions in proximity of vital organs that may develop sudden decompensation/deterioration in the setting of a tumor flare
Plasma cell leukemia or circulating plasma cell count exceeding 500 cells/ μ L or 5% of the peripheral blood white cells
Waldenströms macroglobulinemia or POEMS syndrome
Inability to tolerate thromboprophylaxis, or contraindication to thromboprophylaxis
Known history of interstitial lung disease

Calendar

(Last Update: 29/07/2026)

Authorization 09/07/2026	Start of Trial 28/07/2026	First patient inclusion Not aported	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

F. Hoffmann-La Roche AG Switzerland
Grenzacherstrasse 124

Contact Person

Trial Information System - TISL
41616881111
global.eudract@roche.com

Monetary support: N/A
Sponsor type: Commercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón
C/ Doctor Esquerdo, 46 28007 Madrid

ceim.hgugm@salud.madrid.org
915867007

Sites

not initialized (---/---/----)	Clinica Universidad De Navarra Pamplona NAVARRA Hematology
not initialized (---/---/----)	Hospital Clinic De Barcelona Barcelona BARCELONA Hematology
not initialized (---/---/----)	Hospital Costa Del Sol Marbella MÁLAGA Hematology
not initialized (---/---/----)	Hospital General Universitario Gregorio Maranon Madrid MADRID Hematology
not initialized (---/---/----)	Hospital Universitari Vall D Hebron Barcelona BARCELONA Hematology
not initialized (---/---/----)	Hospital Universitario De Salamanca Salamanca SALAMANCA Hematology
not initialized (---/---/----)	Institut Catala D&#39;oncologia Badalona BARCELONA Hematology

Medication

CARFILZOMIB

LYOPHILIZED POWDER FOR SOLUTION FOR INJECTION
IV INFUSION

–

Active Principles: N/A

Experimental

DEXAMETHASONE

TABLET
ORAL

–

Active Principles: N/A

Experimental

Empliciti 400 mg powder for concentrate for solution for infusion.

SOLUTION FOR INFUSION
IV INFUSION

ATC code: L01XC23 - ELOTUZUMAB

Active Principles: N/A

Experimental

Empliciti 300 mg powder for concentrate for solution for infusion.

SOLUTION FOR INFUSION
IV INFUSION

ATC code: L01XC23 - ELOTUZUMAB

Active Principles: N/A

Experimental

POMALIDOMIDE

CAPSULE, HARD
ORAL

–

Active Principles: N/A

Experimental

DEXAMETHASONE

SOLUTION FOR INJECTION
IV INFUSION

–

Active Principles: N/A

Experimental

DEXAMETHASONE

SOLUTION FOR INJECTION
IV INFUSION

–

Active Principles: N/A

Experimental

Cevostamab

CONCENTRATE FOR SOLUTION FOR INFUSION
IV INFUSION

–

Active Principles: N/A

Orphan

Experimental

POMALIDOMIDE

CAPSULE, HARD
ORAL

Active Principles: N/A

Experimental

DEXAMETHASONE

TABLET
ORAL

Active Principles: N/A

Experimental

POMALIDOMIDE

CAPSULE, HARD
ORAL

Active Principles: N/A

Experimental

DARATUMUMAB

SOLUTION FOR INJECTION
SUBCUTANEOUS

Active Principles: N/A

Experimental

CARFILZOMIB

SOLUTION FOR INFUSION
IV INFUSION

Active Principles: N/A

Experimental

POMALIDOMIDE

CAPSULE, HARD
ORAL

Active Principles: N/A

Experimental

Cevostamab

CONCENTRATE FOR SOLUTION FOR INFUSION
IV INFUSION

Active Principles: N/A

Orphan

Experimental

No results