CO43923 Master Protocol: A Study Evaluating the Safety and Efficacy of Multiple Treatments in Patients with Multiple Myeloma CO43923 Substudy 1: A Study to Collect Patient-Level Data in Patients with Multiple Myeloma CO43923 Substudy 2 Cevos + Len Treatment: A Study Evaluating the Safety and Efficacy of Cevostamab in Combination with Lenalidomide in Patients with Cytogenetic High-Risk Features Receiving Maintenance Treatment After First Response from Multiple Myeloma Post-Stem Cell Transplant CO43923 Substudy 4 Cevostamab+ Iberdomide Treatment: A Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Cevostamab in Combination with Iberdomide in Patients with Relapsed 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	138
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica	NO

Información

Identificador
2023-504484-16-00 (CTIS)

Cod. Protocolo
CO43923

Transicionado 2021-005918-34

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

Enfermedad investigada
Multiple Myeloma (MM)

Título Científico

CO43923 Master Protocol: A Platform Study Evaluating the Safety and Efficacy of Multiple Treatments in Patients with Multiple Myeloma CO43923 Substudy 1: A Non-Interventional Study to Collect Patient-Level Data in Patients with Multiple Myeloma CO43923 Substudy 2 Cevos + Len Treatment: A Phase Ib, Single Arm, Open-Label Study Evaluating the Safety and Efficacy of Cevostamab in Combination with Lenalidomide in Patients with Cytogenetic High-Risk Features Receiving Maintenance Treatment After First Response from Multiple Myeloma Post-Stem Cell Transplant CO43923 Substudy 4 Cevostamab+ Iberdomide Treatment: A Phase Ib, Single Arm, Open-Label Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Cevostamab in Combination with Iberdomide in Patients with Relapsed or Refractory Multiple Myeloma

Justificación

No aportado

Objetivo Principal

CO43923 Master Protocol: - Stage 1: To evaluate the safety of the study treatment, including evaluation of the tolerability of the dosing schedules and doses - Stage 1: To characterize maximum tolerated dose (MTD) and/or recommended Phase II dose (RP2D) when a dose-finding phase is used - Stage 2: To evaluate the efficacy of the study treatment based on objective response rate (ORR), rate of complete response (CR) or stringent complete response (sCR), rate of very good partial response (VGPR), progression-free survival (PFS) and overall survival (OS) CO43923 Substudy 1: To describe patient and disease characteristics and treatment patterns from initial diagnosis of patients with first-line and later lines of therapy in relapsed or refractory multiple myeloma (R/R MM) CO43923 Substudy 2 Cevos + Len Treatment: To evaluate the safety of cevostamab in combination with lenalidomide (Cevos + Len) as a maintenance treatment in patients with MM after autologous stem cell transplant (SCT) following first-line treatment
CO43923 Substudy 4 Cevostamab+ Iberdomide Treatment: To evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of cevostamab in combination with iberdomide (Cevostamab + Iberdomide) in patients with R/R MM.

Variables de Evaluación Primaria

1. Stage 1: Incidence and severity of adverse events, including dose-limiting toxicities (DLTs), with severity determined according to National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5.0 (NCI CTCAE v5.0); for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome(ICANS), severity is determined according to respective American Society for Transplantation and Cellular Therapy (ASTCT) Consensus Grading Scales
2. Stage 2: ORR, defined as the proportion of patients with a stringent complete response (sCR), CR, very good partial response (VGPR), or partial response (PR)
3. Stage 2: Rate of CR or sCR, defined as proportion of patients achieving a CR or sCR
4. Stage 2: Rate of VGPR or better, defined as the proportion of patients achieving a VGPR or better
5. Stage 2: PFS, defined as the time from initiation of study treatment to the first occurrence of progressive disease or death from any cause (whichever occurs first)
6. Stage 2: OS, defined as the time from initiation of study treatment to death from any cause

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

CO43923 Stage 1 (for maintenance substudies): To evaluate the preliminary efficacy of the study treatment
CO43923 Stage 1 (for all other substudies): To evaluate the preliminary efficacy of the study treatment
CO43923 Stage 2: To evaluate the efficacy of the study treatment based on duration of response (DOR), time to first response, time to best response, minimal residual disease (MRD) negativity rate
CO43923 Stage 2: To evaluate the safety of the study treatment
CO43923 Substudy 1: To describe treatment effectiveness and clinical outcomes in patients with first-line and later lines of therapy in R/R MM
CO43923 Substudy 1: To collect biological samples obtained as part of standard of care for use in preclinical, exploratory biomarker research, and translational studies
CO43923 Substudy 1: To collect safety (adverse event) information from patients with R/R MM who are treated with first-line and later lines of therapy in routine clinical practice

Variables de Evaluación Secundaria

1. Stage 1 (maintenance substudies): Conversion to a better response (e.g., from PR to VGPR or better; or from VGPR to CR/sCR or from CR to sCR)
2. Stage 1 (maintenance substudies): PFS, defined as the time from initiation of study treatment to the first occurrence of progressive disease or death from any cause (whichever occurs first)
3. Stage 1 (maintenance substudies): OS, defined as the time from initiation of study treatment to death from any cause
4. Stage 1 (maintenance substudies): MRD negativity rate, defined as proportion of patients who are MRD negative at any time by next-generation sequencing (NGS) on bone marrow aspirate
5. Stage 1 (all other substudies): ORR, defined as the proportion of patients with a sCR, CR, VGPR, or PR
6. Stage 1 (all other substudies): Rate of CR or sCR, defined as proportion of patients achieving a CR or sCR
7. Stage 1 (all other substudies): Rate of VGPR or better, defined as the proportion of patients achieving a VGPR or better
8. Stage 1 (all other substudies): PFS, defined as the time from initiation of study treatment to the first occurrence of progressive disease or death from any cause (whichever occurs first)
9. CO43271 Stage 1 (all other substudies): DOR, defined as the time from the first documented objective response until disease progression or death from any cause, (whichever occurs first)
10. Stage 1 (all other substudies): OS, defined as the time from initiation of study treatment to death from any cause
11. Stage 1 (all other substudies): MRD negativity rate, defined as proportion of patients who are MRD negative at any time by NGS on bone marrow aspirate
12. Stage 1 (all other substudies): Time to first response (for patients who achieve a response of PR or better), defined as time from initiation of study treatment to first achieving a PR or better
13. Stage 1 (all other substudies): Time to best response (for patients who achieve a response of PR or better), defined as time from initiation of study treatment to achieving the deepest response
14. Stage 2: DOR, defined as the time from the first documented objective response until disease progression or death from any cause (whichever occurs first)
15. Stage 2: Time to first response (for patients who achieve a response of PR or better), defined as time from initiation of study treatment to achieving a PR or better
16. Stage 2: Time to best response (for patients who achieve a response of PR or better), defined as time from initiation of study treatment to achieving the deepest response
17. Stage 2: MRD negativity rate, defined as proportion of patients who are MRD negative by NGS on bone marrow aspirate

18. Stage 2: Incidence and severity of adverse events, including DLTs, with severity determined according to NCI CTCAE v5.0; for CRS and ICANS, severity is determined according to ASTCT Consensus Grading Scales

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

CO43923 Master Protocol: Diagnosed with multiple myeloma (MM) per International Myeloma Working Group (IMWG) criteria
CO43923 Master Protocol: Eastern Cooperative Oncology Group Performance Status of 0, 1, or 2
CO43923 Substudy 1: A current or past diagnosis of MM in the first line or later setting, including maintenance therapy
CO43923 Substudy 2 Cevos + Len Treatment: Completion of planned induction therapy and achievement of at least a partial response (PR)
CO43923 Substudy 4 Cevostamab+ Iberdomide Treatment: Previously exposed to at least a PI, an IMiD, and an anti-CD38 antibody for the treatment of R/R MM for whom no suitable SOC therapy options are available

Criterios de Exclusión

CO43923 Master Protocol: History of other malignancy within 2 years prior to screening, except those with negligible risk of metastasis or death
CO43923 Master Protocol: History of confirmed progressive multifocal leukoencephalopathy
CO43923 Master Protocol: Known history of HIV seropositivity
CO43923 Substudy 2 Cevos + Len Treatment: Hypersensitivity reactions to lenalidomide or other immunomodulatory drugs
CO43923 Substudy 4 Cevostamab+ Iberdomide Treatment: Treatment with systemic immunosuppressive medications including, but not limited to, prednisone, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-TNF agents within 2 weeks prior to starting pre-phase

Calendario

(Última actualización: 12/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
14/07/2022	18/11/2022	13/12/2022	03/01/2023	21/07/2023

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

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 del Hospital Clínico Universitario de Valencia

Avda. Vicente Blasco Ibáñez, 17 46010 Valencia

ceic_hcv@gva.es

Centros

Activo (20/09/2023)

HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA

València

VALENCIA

Hematología

Activo (18/09/2023)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Hematología

No iniciado (--/--/----)

Institut Catala D´oncologia

Badalona

BARCELONA

Servicio de Hematología

Activo (02/08/2024)

Institut Catala D'oncologia

Badalona

BARCELONA

Servicio de Hematología Clínica

Medicamentos

Iberdomide

CAPSULE

ORAL USE

-

Principios Activos: N/A

Experimental

Revlimid 10 mg hard capsules

CAPSULE, HARD

ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA

Principios Activos: N/A

Experimental

Iberdomide

CAPSULE

ORAL USE

-

Principios Activos: N/A

Experimental

Revlimid 5 mg hard capsules

CAPSULE, HARD

ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA

Principios Activos: N/A

Experimental

Iberdomide

CAPSULE

ORAL USE

-

Principios Activos: N/A

Experimental

Cevostamab

SOLUTION FOR INFUSION

INTRAVENOUS INFUSION

-

Principios Activos: N/A

Huérfano

Experimental

Iberdomide

CAPSULE

ORAL USE

-

Principios Activos: N/A

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion

SOLUTION FOR INFUSION

INTRAVENIOUS INFUSION

Código ATC: L04AC07 - TOCILIZUMAB

Principios Activos: N/A

Experimental

Sin resultados

CO43923 Master Protocol: A Study Evaluating the Safety and Efficacy of Multiple Treatments in Patients with Multiple Myeloma CO43923 Substudy 1: A Study to Collect Patient-Level Data in Patients with Multiple Myeloma CO43923 Substudy 2 Cevos + Len Treatment: A Study Evaluating the Safety and Efficacy of Cevostamab in Combination with Lenalidomide in Patients with Cytogenetic High-Risk Features Receiving Maintenance Treatment After First Response from Multiple Myeloma Post-Stem Cell Transplant CO43923 Substudy 4 Cevostamab+ Iberdomide Treatment: A Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Cevostamab in Combination with Iberdomide in Patients with Relapsed 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	138
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics	NO

Information

Identifier
2023-504484-16-00 (CTIS)

Protocol Code
CO43923

Transitioned 2021-005918-34

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

Investigated Disease
Multiple Myeloma (MM)

Scientific Title

CO43923 Master Protocol: A Platform Study Evaluating the Safety and Efficacy of Multiple Treatments in Patients with Multiple Myeloma CO43923 Substudy 1: A Non-Interventional Study to Collect Patient-Level Data in Patients with Multiple Myeloma CO43923 Substudy 2 Cevos + Len Treatment: A Phase Ib, Single Arm, Open-Label Study Evaluating the Safety and Efficacy of Cevostamab in Combination with Lenalidomide in Patients with Cytogenetic High-Risk Features Receiving Maintenance Treatment After First Response from Multiple Myeloma Post-Stem Cell Transplant CO43923 Substudy 4 Cevostamab+ Iberdomide Treatment: A Phase Ib, Single Arm, Open-Label Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Cevostamab in Combination with Iberdomide in Patients with Relapsed or Refractory Multiple Myeloma

Rationale

Not provided

Main Objective

CO43923 Master Protocol: - Stage 1: To evaluate the safety of the study treatment, including evaluation of the tolerability of the dosing schedules and doses - Stage 1: To characterize maximum tolerated dose (MTD) and/or recommended Phase II dose (RP2D) when a dose-finding phase is used - Stage 2: To evaluate the efficacy of the study treatment based on objective response rate (ORR), rate of complete response (CR) or stringent complete response (sCR), rate of very good partial response (VGPR), progression-free survival (PFS) and overall survival (OS) CO43923 Substudy 1: To describe patient and disease characteristics and treatment patterns from initial diagnosis of patients with first-line and later lines of therapy in relapsed or refractory multiple myeloma (R/R MM) CO43923 Substudy 2 Cevos + Len Treatment: To evaluate the safety of cevostamab in combination with lenalidomide (Cevos + Len) as a maintenance treatment in patients with MM after autologous stem cell transplant (SCT) following first-line treatment
CO43923 Substudy 4 Cevostamab+ Iberdomide Treatment: To evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of cevostamab in combination with iberdomide (Cevostamab + Iberdomide) in patients with R/R MM.

Primary Endpoints

1. Stage 1: Incidence and severity of adverse events, including dose-limiting toxicities (DLTs), with severity determined according to National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5.0 (NCI CTCAE v5.0); for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome(ICANS), severity is determined according to respective American Society for Transplantation and Cellular Therapy (ASTCT) Consensus Grading Scales
2. Stage 2: ORR, defined as the proportion of patients with a stringent complete response (sCR), CR, very good partial response (VGPR), or partial response (PR)
3. Stage 2: Rate of CR or sCR, defined as proportion of patients achieving a CR or sCR
4. Stage 2: Rate of VGPR or better, defined as the proportion of patients achieving a VGPR or better
5. Stage 2: PFS, defined as the time from initiation of study treatment to the first occurrence of progressive disease or death from any cause (whichever occurs first)
6. Stage 2: OS, defined as the time from initiation of study treatment to death from any cause

Temporary moments of secondary assessment

Not provided

Secondary Objective

CO43923 Stage 1 (for maintenance substudies): To evaluate the preliminary efficacy of the study treatment
CO43923 Stage 1 (for all other substudies): To evaluate the preliminary efficacy of the study treatment
CO43923 Stage 2: To evaluate the efficacy of the study treatment based on duration of response (DOR), time to first response, time to best response, minimal residual disease (MRD) negativity rate
CO43923 Stage 2: To evaluate the safety of the study treatment
CO43923 Substudy 1: To describe treatment effectiveness and clinical outcomes in patients with first-line and later lines of therapy in R/R MM
CO43923 Substudy 1: To collect biological samples obtained as part of standard of care for use in preclinical, exploratory biomarker research, and translational studies
CO43923 Substudy 1: To collect safety (adverse event) information from patients with R/R MM who are treated with first-line and later lines of therapy in routine clinical practice

Secondary Endpoints

1. Stage 1 (maintenance substudies): Conversion to a better response (e.g., from PR to VGPR or better; or from VGPR to CR/sCR or from CR to sCR)
2. Stage 1 (maintenance substudies): PFS, defined as the time from initiation of study treatment to the first occurrence of progressive disease or death from any cause (whichever occurs first)
3. Stage 1 (maintenance substudies): OS, defined as the time from initiation of study treatment to death from any cause
4. Stage 1 (maintenance substudies): MRD negativity rate, defined as proportion of patients who are MRD negative at any time by next-generation sequencing (NGS) on bone marrow aspirate
5. Stage 1 (all other substudies): ORR, defined as the proportion of patients with a sCR, CR, VGPR, or PR
6. Stage 1 (all other substudies): Rate of CR or sCR, defined as proportion of patients achieving a CR or sCR
7. Stage 1 (all other substudies): Rate of VGPR or better, defined as the proportion of patients achieving a VGPR or better
8. Stage 1 (all other substudies): PFS, defined as the time from initiation of study treatment to the first occurrence of progressive disease or death from any cause (whichever occurs first)
9. CO43271 Stage 1 (all other substudies): DOR, defined as the time from the first documented objective response until disease progression or death from any cause, (whichever occurs first)
10. Stage 1 (all other substudies): OS, defined as the time from initiation of study treatment to death from any cause
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16. Stage 2: Time to best response (for patients who achieve a response of PR or better), defined as time from initiation of study treatment to achieving the deepest response
17. Stage 2: MRD negativity rate, defined as proportion of patients who are MRD negative by NGS on bone marrow aspirate

18. Stage 2: Incidence and severity of adverse events, including DLTs, with severity determined according to NCI CTCAE v5.0; for CRS and ICANS, severity is determined according to ASTCT Consensus Grading Scales

Temporary moments of secondary assessment

Not provided

Inclusion criteria

CO43923 Master Protocol: Diagnosed with multiple myeloma (MM) per International Myeloma Working Group (IMWG) criteria
CO43923 Master Protocol: Eastern Cooperative Oncology Group Performance Status of 0, 1, or 2
CO43923 Substudy 1: A current or past diagnosis of MM in the first line or later setting, including maintenance therapy
CO43923 Substudy 2 Cevos + Len Treatment: Completion of planned induction therapy and achievement of at least a partial response (PR)
CO43923 Substudy 4 Cevostamab+ Iberdomide Treatment: Previously exposed to at least a PI, an IMiD, and an anti-CD38 antibody for the treatment of R/R MM for whom no suitable SOC therapy options are available

Exclusion criteria

CO43923 Master Protocol: History of other malignancy within 2 years prior to screening, except those with negligible risk of metastasis or death
CO43923 Master Protocol: History of confirmed progressive multifocal leukoencephalopathy
CO43923 Master Protocol: Known history of HIV seropositivity
CO43923 Substudy 2 Cevos + Len Treatment: Hypersensitivity reactions to lenalidomide or other immunomodulatory drugs
CO43923 Substudy 4 Cevostamab+ Iberdomide Treatment: Treatment with systemic immunosuppressive medications including, but not limited to, prednisone, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-TNF agents within 2 weeks prior to starting pre-phase

Calendar

(Last Update: 12/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
14/07/2022	18/11/2022	13/12/2022	03/01/2023	21/07/2023

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

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 del Hospital Clínico Universitario de Valencia

Avda. Vicente Blasco Ibáñez, 17 46010 Valencia

ceic_hcv@gva.es

Sites

Active (20/09/2023)

HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA

València

VALENCIA

Hematología

Active (18/09/2023)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Hematología

not initialized (--/--/----)

Institut Catala D´oncologia

Badalona

BARCELONA

Servicio de Hematología

Active (02/08/2024)

Institut Catala D'oncologia

Badalona

BARCELONA

Servicio de Hematología Clínica

Medication

Iberdomide
CAPSULE
ORAL USE

-

Active Principles: N/A

Experimental

Revlimid 10 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

Iberdomide
CAPSULE
ORAL USE

-

Active Principles: N/A

Experimental

Revlimid 5 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

Iberdomide
CAPSULE
ORAL USE

-

Active Principles: N/A

Experimental

Cevostamab
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-

Active Principles: N/A

Orphan

Experimental

Iberdomide
CAPSULE
ORAL USE

-

Active Principles: N/A

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

ATC code: L04AC07 - TOCILIZUMAB
Active Principles: N/A

Experimental

No results