

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

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

138

Resultados

Sin resultados

Bajo nivel intervención

No

Enfermedad rara

No

Cobertura geográfica

Sin determinar

Ámbitos del ensayo

seguridad, eficacia, farmacocinética, farmacodinámica

Terapia avanzada

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

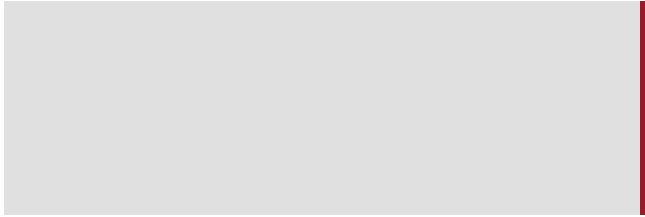
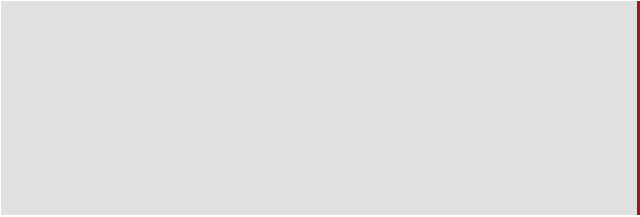
Experimental

RoActemra 20 mg/mL concentrate for solution for infusion

SOLUTION FOR INFUSION
INTRAVENOUS 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 Recruiting	Type of participants Not provided	Age Ranges Older than 64 , Adults (18-64 years)
Gender Both	Phases Phase I , Phase II	Expected Participants 138
Results No results	Low level of intervention No	Rare disease No
Geographic coverage Undetermined	Areas of the study safety, effectiveness, pharmacokinetics, pharmacodynamics	Advanced therapy NO

Information

Identifier 2023-504484-16-00 (CTIS)	Protocol Code CO43923
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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
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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)
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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 14/07/2022	Start of Trial 18/11/2022	First patient inclusion 13/12/2022	Halted 03/01/2023	Restarted 21/07/2023
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 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

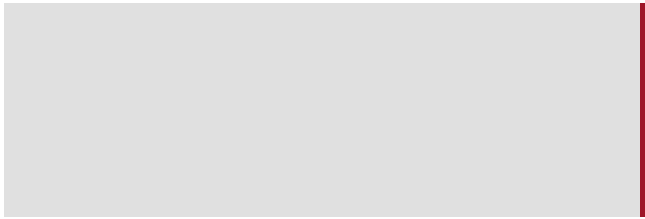
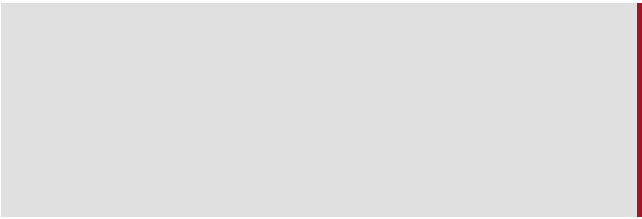
Experimental

RoActemra 20 mg/mL concentrate for solution for infusion

SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

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

Experimental



No results