Phase 1/2 Study of Linvoseltamab in Adult 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	270
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, dosis	NO

Información

Identificador
2024-511454-45-00 (CTIS)

Cod. Protocolo
R5458-ONC-1826

Transicionado 2018-003188-78

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

Enfermedad investigada
Relapsed or Refractory Multiple Myeloma

Título Científico
PHASE 1/2 FIH STUDY OF REGN5458 (ANTI-BCMA X ANTI-CD3 BISPECIFIC ANTIBODY) IN PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA

Justificación

No aportado

Objetivo Principal

PHASE 1
Part 1 (Intravenous Dose Escalation): To assess the safety, tolerability, and dose-limiting toxicities (DLTs) and to determine one or more recommended phase 2 dose regimens (RP2DRs) of linvoseltamab as intravenous (IV) monotherapy in patients with relapsed or refractory multiple myeloma (RRMM)
Part 2 (Subcutaneous Administration): To assess the safety, tolerability, and dose-limiting toxicities (DLTs), and pharmacokinetic (PK) properties, and to determine a dosing regimen of subcutaneous linvoseltamab monotherapy in patients with RRMM.
PHASE 2
Cohorts 1 and 2: To assess the anti-tumor activity of IV linvoseltamab separately in cohorts 1 and 2, as measured by objective response rate (ORR) and as determined by an Independent Review Committee (IRC), in patients who have progressed on or after 3 prior lines of therapy or who are triple-refractory (defined as refractory to a(n) proteasome inhibitor (PI), immunomodulatory imide drug (IMiD), and anti-CD38 monoclonal antibody).
Cohort 3: To assess the safety and efficacy of anti-IL-6R pre-treatment in preventing CRS in patients treated with IV linvoseltamab, and to assess anti-tumor activity in patients who receive anti-IL-6R pre-treatment as measured by investigator assessed ORR in patients who had previously progressed on or after 3 prior lines of therapy or who are triple-refractory (defined as refractory to a(n) PI, IMiD, and anti-CD38 monoclonal antibody), and in patients who had previously relapsed after receiving BCMA directed chimeric antigen receptor (CAR)-T cellular therapy.

Variables de Evaluación Primaria

Phase 1: Incidence of dose-limiting toxicities (DLTs) from the first dose through the end of the DLT observation period
Phase 1: Incidence and severity of treatment-emergent adverse events (TEAEs)
Phase 1: Incidence and severity of adverse events of special interest (AESI)
Phase 1, Part 2: Assessment of the pharmacokinetics (PK) of linvoseltamab
Phase 2, cohorts 1 and 2: Objective response rate (ORR) as determined by an Independent Review Committee (IRC)
Phase 2, cohort 3: Incidence and severity of cytokine release syndrome (CRS) with linvoseltamab
Phase 2, cohort 3: ORR of IV linvoseltamab as assessed by investigator

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Phase 1- Part 1: To assess the preliminary anti-tumor activity of IV linvoseltamab as determined by the investigator and measured by ORR, duration of response (DOR), progression-free survival (PFS), rate of minimal residual disease (MRD) negative status, and overall survival (OS)
Phase 1- Part 1: To evaluate the PK properties of IV linvoseltamab
Phase 1- Part 1: To characterize the immunogenicity of IV linvoseltamab

Phase 1- Part 1: To assess the anti-tumor activity of IV linvoseltamab in patients treated in phase 1 dose level 7 (full dose) as measured by ORR and as determined by an Independent Review Committee (IRC)
Phase 1- Part 2: To assess the preliminary anti-tumor activity of SC linvoseltamab as determined by the investigator and measured by ORR, DOR, PFS, rate of MRD negative status, and OS
Phase 1- Part 2: To characterize the immunogenicity of SC linvoseltamab
Phase 2- cohorts 1 and 2: To assess the anti-tumor activity of IV linvoseltamab as measured by: ORR, as determined by the investigator; DOR and PFS, as determined by an IRC and the investigator; Rate of MRD negative status; OS
Phase 2- cohorts 1 and 2: To evaluate the effects of IV linvoseltamab on health-related quality of life (HRQoL) and patient-reported functions and symptoms
Phase 2- cohorts 1 and 2: To evaluate the safety and tolerability of IV linvoseltamab
Phase 2- cohorts 1 and 2: To evaluate the PK properties of IV linvoseltamab
Phase 2- cohorts 1 and 2: To characterize the immunogenicity of IV linvoseltamab
Phase 2- cohorts 3: To assess the anti-tumor activity of IV linvoseltamab as measured by: DOR and PFS, as determined by the investigator; Rate of MRD negative status; OS
Phase 2- cohorts 3: To evaluate the effects of IV linvoseltamab on health-related quality of life (HRQoL) and patient-reported functions and symptoms
Phase 2- cohorts 3: To evaluate the safety and tolerability of IV linvoseltamab
Phase 2- cohorts 3: To evaluate the PK properties of IV linvoseltamab
Phase 2- cohorts 3: To characterize the immunogenicity of IV linvoseltamab

Variables de Evaluación Secundaria

Phase 1 part 1 and Phase 2: Concentrations of linvoseltamab in the serum over time
Phase 1 and Phase 2: Incidence over time of anti-drug antibodies (ADAs) to linvoseltamab
Phase 1 and Phase 2: Titer of anti-drug antibodies (ADAs) to linvoseltamab over time
Phase 1 and Phase 2: Incidence of neutralizing antibodies (Nab) to linvoseltamab over time
Phase 2, cohorts 1 and 2: Duration of response (DOR) as determined by an IRC, measured using the IMWG criteria
Phase 1 and Phase 2: DOR as determined by an investigator, measured using the International Myeloma Working Group (IMWG) criteria
Phase 2: Progression-free survival (PFS) as determined by an IRC, measured using the IMWG criteria
Phase 1 and Phase 2: PFS as determined by an investigator, measured using the IMWG criteria
Phase 1: Rate of minimal residual disease (MRD) negative status, as determined by the investigator using the IMWG criteria
Phase 2: Rate of MRD negative status
Phase 1 and Phase 2: Overall survival (OS)
Phase 1, part 1 dose level 7 (DL7): ORR as measured as determined by blinded IRC, as measured using the IMWG criteria
Phase 1 and Phase 2: ORR as determined by the investigator, measured using the IMWG criteria
Phase 2: Effects of linvoseltamab on health-related quality of life (HRQoL) and patient-reported symptoms and functioning per European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)
Phase 2: Effects of linvoseltamab on HRQOL and patient-reported symptoms and functioning per Quality of Life Questionnaire-Multiple Myeloma module 20 [QLQ-MY20])
Phase 2: Effects of linvoseltamab on HRQOL and patient-reported symptoms and functioning per EuroQoL-5 Dimension-3 Level Scale [EQ-5D-3L])
Phase 2: Change in patient-reported global health status/QoL per EORTC QLQ-C30
Phase 2: Time to definitive deterioration in patient-reported global health status/QoL per EORTC QLQ-C30
Phase 2: Effects of linvoseltamab on patient-reported functions and symptoms per EORTC QLQ-C30
Phase 2: Effects of linvoseltamab on patient-reported functions and symptoms per QLQ-MY20
Phase 2: Incidence and severity of TEAEs with linvoseltamab
Phase 2: Incidence and severity of AESIs with linvoseltamab

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Eastern Cooperative Oncology Group (ECOG) performance status 1 Confirmed diagnosis of active Multiple Myeloma (MM) by International Myeloma Working Group (IMWG) diagnostic criteria Patients must have myeloma that is response-evaluable according to the 2016 IMWG response criteria as defined in the protocol. Phase 1, Part 1 (Dose Escalation): Patients with MM who have exhausted all therapeutic options that are expected to provide meaningful clinical benefit, either through disease relapse, treatment refractory disease or intolerance of the therapy and including either: a. Progression on or after at least 3 lines of therapy, or intolerance of therapy, including a PI, an IMiD, and an anti-CD38 antibody, OR b. Progression on or after an anti-CD38 antibody and have disease that is "double refractory" to a proteasome inhibitor and an IMiD, or intolerance of therapy. The anti-CD38 antibody may have been administered alone or in combination with another agent such as a proteasome inhibitor (PI). Refractory disease is defined as lack of response or relapse within 60 days of last treatment. Phase 1, Part 2 (SC Administration): Patients with MM whose disease meets the following criteria: a. Progression on or after at least 3 prior lines of therapy including a(n) PI, IMiD, and anti-CD38 antibody, OR b. Patients must be triple-refractory, defined as being refractory to prior treatment with at least 1 anti-CD38 antibody, a PI, and an IMiD. Phase 2 (Cohorts 1 and 2): Patients with MM whose disease meets the following criteria: a. Progression on or after at least 3 prior lines of therapy including a(n) PI, IMiD, and anti-CD38 antibody, OR b. Patients must be triple- refractory, defined as being refractory* to prior treatment with at least 1 PI, 1 IMiD, and an anti-CD38 antibody. *Refractory disease is defined as progression during treatment or within 60 days after completion of therapy, or <25% response to therapy. Phase 2 (Cohort 3): Patients with MM whose disease meets the following criteria: Progression on or after at least 3 prior lines of therapy including a(n) PI, IMiD, and anti-CD38 antibody, OR Patients must be triple- refractory, defined as being refractory* to prior treatment with at least 1 PI, 1 IMiD, and an anti-CD38 antibody. * Refractory disease is defined as progression during treatment or within 60 days after completion of therapy, or <25% response to therapy. AND, if patients have relapsed after a BCMA-directed CAR-T cellular therapy then: Treatment with a CAR-T must have been associated with a response of PR or better, and If CAR-T cellular therapy was the most recent prior therapy, excluding corticosteroids, then treatment must have been a minimum of 60 days prior to treatment with linvoseltamab Other protocol defined inclusion criteria apply

Criterios de Exclusión

Diagnosis of plasma cell leukemia, primary systemic light-chain amyloidosis, (excluding myeloma-associated amyloidosis), Waldenström macroglobulinemia (lymphoplasmacytic lymphoma), or POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes) Patients with known MM brain lesions or meningeal involvement Cardiac ejection fraction <40% by echocardiogram or multi-gated acquisition scan (MUGA) Prior treatment with BCMA-directed immunotherapies, including BCMA bispecific antibodies and BiTEs. Note: BCMA antibody-drug conjugates are not excludedand BCMA-directed CAR-T treatment is not excluded in Phase 2 Cohort 3. History of allogeneic stem cell transplantation at any time, or autologous stem cell transplantation within 12 weeks of the start of study treatment Other protocol defined exclusion criteria apply

Calendario

(Última actualización: 22/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
18/03/2022	03/06/2022	28/06/2022	No aportado	No aportado

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

Regeneron Pharmaceuticals Inc. United States

777 Old Saw Mill River Road

Contact Person

Medical Affairs

+353818882469

medical.information_EU@regeneron.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 (30/09/2022)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Activo (22/07/2022)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA)

Salamanca

SALAMANCA

Hematology

Cerrado (30/09/2022)

HOSPITAL CLINICO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Activo (18/07/2022)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Hematology

Cerrado (30/09/2022)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

Hematology

Cerrado (30/09/2022)

HOSPITAL UNIVERSITARIO DE CABUEÑES

Gijón

ASTURIAS

Activo (19/09/2022)

HOSPITAL UNIVERSITARIO DE LA PRINCESA

Madrid

MADRID

Activo (03/06/2022)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Hematology

Activo (23/06/2022)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Hematology

Medicamentos

Linvoseltamab
SOLUTION FOR INJECTION
SOLUTION FOR INJECTION

-

Principios Activos: N/A

Experimental

Dermodrin 30 mg/2 ml soluie injectabil
SOLUTION FOR INJECTION
IV INFUSION

Código ATC: R06AA02 - DIFENHIDRAMINA
Principios Activos: N/A

Experimental

Dexamethasone phosphate 4 mg/ml solution for injection/infusion
SOLUTION FOR INJECTION/INFUSION
IV INFUSION

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

Experimental

Paracetamol 500 mg Film-Coated Tablets
FILM-COATED TABLET
ORAL

Código ATC: N02BE01 - PARACETAMOL
Principios Activos: N/A

Experimental

Diphenhydramine Hydrochloride 25 mg Tablets
TABLET
ORAL

Código ATC: R06AA02 - DIFENHIDRAMINA
Principios Activos: N/A

Experimental

Linvoseltamab
SOLUTION FOR INFUSION
SOLUTION FOR INFUSION

-

Principios Activos: N/A

Experimental

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

Código ATC: L04AC07 - TOCILIZUMAB
Principios Activos: N/A

Experimental

Dexamethasone 4 mg tablets
TABLET
ORAL

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

Experimental

Sin resultados

Phase 1/2 Study of Linvoseltamab in Adult 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	270
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, dose	NO

Information

Identifier
2024-511454-45-00 (CTIS)

Protocol Code
R5458-ONC-1826

Transitioned 2018-003188-78

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

Investigated Disease
Relapsed or Refractory Multiple Myeloma

Scientific Title
PHASE 1/2 FIH STUDY OF REGN5458 (ANTI-BCMA X ANTI-CD3 BISPECIFIC ANTIBODY) IN PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA

Rationale

Not provided

Main Objective

PHASE 1
Part 1 (Intravenous Dose Escalation): To assess the safety, tolerability, and dose-limiting toxicities (DLTs) and to determine one or more recommended phase 2 dose regimens (RP2DRs) of linvoseltamab as intravenous (IV) monotherapy in patients with relapsed or refractory multiple myeloma (RRMM)
Part 2 (Subcutaneous Administration): To assess the safety, tolerability, and dose-limiting toxicities (DLTs), and pharmacokinetic (PK) properties, and to determine a dosing regimen of subcutaneous linvoseltamab monotherapy in patients with RRMM.
PHASE 2
Cohorts 1 and 2: To assess the anti-tumor activity of IV linvoseltamab separately in cohorts 1 and 2, as measured by objective response rate (ORR) and as determined by an Independent Review Committee (IRC), in patients who have progressed on or after 3 prior lines of therapy or who are triple-refractory (defined as refractory to a(n) proteasome inhibitor (PI), immunomodulatory imide drug (IMiD), and anti-CD38 monoclonal antibody).
Cohort 3: To assess the safety and efficacy of anti-IL-6R pre-treatment in preventing CRS in patients treated with IV linvoseltamab, and to assess anti-tumor activity in patients who receive anti-IL-6R pre-treatment as measured by investigator assessed ORR in patients who had previously progressed on or after 3 prior lines of therapy or who are triple-refractory (defined as refractory to a(n) PI, IMiD, and anti-CD38 monoclonal antibody), and in patients who had previously relapsed after receiving BCMA directed chimeric antigen receptor (CAR)-T cellular therapy.

Primary Endpoints

Phase 1: Incidence of dose-limiting toxicities (DLTs) from the first dose through the end of the DLT observation period
Phase 1: Incidence and severity of treatment-emergent adverse events (TEAEs)
Phase 1: Incidence and severity of adverse events of special interest (AESI)
Phase 1, Part 2: Assessment of the pharmacokinetics (PK) of linvoseltamab
Phase 2, cohorts 1 and 2: Objective response rate (ORR) as determined by an Independent Review Committee (IRC)
Phase 2, cohort 3: Incidence and severity of cytokine release syndrome (CRS) with linvoseltamab
Phase 2, cohort 3: ORR of IV linvoseltamab as assessed by investigator

Temporary moments of secondary assessment

Not provided

Secondary Objective

Phase 1- Part 1: To assess the preliminary anti-tumor activity of IV linvoseltamab as determined by the investigator and measured by ORR, duration of response (DOR), progression-free survival (PFS), rate of minimal residual disease (MRD) negative status, and overall survival (OS)
Phase 1- Part 1: To evaluate the PK properties of IV linvoseltamab
Phase 1- Part 1: To characterize the immunogenicity of IV linvoseltamab

Phase 1- Part 1: To assess the anti-tumor activity of IV linvoseltamab in patients treated in phase 1 dose level 7 (full dose) as measured by ORR and as determined by an Independent Review Committee (IRC)
Phase 1- Part 2: To assess the preliminary anti-tumor activity of SC linvoseltamab as determined by the investigator and measured by ORR, DOR, PFS, rate of MRD negative status, and OS
Phase 1- Part 2: To characterize the immunogenicity of SC linvoseltamab
Phase 2- cohorts 1 and 2: To assess the anti-tumor activity of IV linvoseltamab as measured by: ORR, as determined by the investigator; DOR and PFS, as determined by an IRC and the investigator; Rate of MRD negative status; OS
Phase 2- cohorts 1 and 2: To evaluate the effects of IV linvoseltamab on health-related quality of life (HRQoL) and patient-reported functions and symptoms
Phase 2- cohorts 1 and 2: To evaluate the safety and tolerability of IV linvoseltamab
Phase 2- cohorts 1 and 2: To evaluate the PK properties of IV linvoseltamab
Phase 2- cohorts 1 and 2: To characterize the immunogenicity of IV linvoseltamab
Phase 2- cohorts 3: To assess the anti-tumor activity of IV linvoseltamab as measured by: DOR and PFS, as determined by the investigator; Rate of MRD negative status; OS
Phase 2- cohorts 3: To evaluate the effects of IV linvoseltamab on health-related quality of life (HRQoL) and patient-reported functions and symptoms
Phase 2- cohorts 3: To evaluate the safety and tolerability of IV linvoseltamab
Phase 2- cohorts 3: To evaluate the PK properties of IV linvoseltamab
Phase 2- cohorts 3: To characterize the immunogenicity of IV linvoseltamab

Secondary Endpoints

Phase 1 part 1 and Phase 2: Concentrations of linvoseltamab in the serum over time
Phase 1 and Phase 2: Incidence over time of anti-drug antibodies (ADAs) to linvoseltamab
Phase 1 and Phase 2: Titer of anti-drug antibodies (ADAs) to linvoseltamab over time
Phase 1 and Phase 2: Incidence of neutralizing antibodies (Nab) to linvoseltamab over time
Phase 2, cohorts 1 and 2: Duration of response (DOR) as determined by an IRC, measured using the IMWG criteria
Phase 1 and Phase 2: DOR as determined by an investigator, measured using the International Myeloma Working Group (IMWG) criteria
Phase 2: Progression-free survival (PFS) as determined by an IRC, measured using the IMWG criteria
Phase 1 and Phase 2: PFS as determined by an investigator, measured using the IMWG criteria
Phase 1: Rate of minimal residual disease (MRD) negative status, as determined by the investigator using the IMWG criteria
Phase 2: Rate of MRD negative status
Phase 1 and Phase 2: Overall survival (OS)
Phase 1, part 1 dose level 7 (DL7): ORR as measured as determined by blinded IRC, as measured using the IMWG criteria
Phase 1 and Phase 2: ORR as determined by the investigator, measured using the IMWG criteria
Phase 2: Effects of linvoseltamab on health-related quality of life (HRQoL) and patient-reported symptoms and functioning per European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)
Phase 2: Effects of linvoseltamab on HRQOL and patient-reported symptoms and functioning per Quality of Life Questionnaire-Multiple Myeloma module 20 [QLQ-MY20])
Phase 2: Effects of linvoseltamab on HRQOL and patient-reported symptoms and functioning per EuroQoL-5 Dimension-3 Level Scale [EQ-5D-3L])
Phase 2: Change in patient-reported global health status/QoL per EORTC QLQ-C30
Phase 2: Time to definitive deterioration in patient-reported global health status/QoL per EORTC QLQ-C30
Phase 2: Effects of linvoseltamab on patient-reported functions and symptoms per EORTC QLQ-C30
Phase 2: Effects of linvoseltamab on patient-reported functions and symptoms per QLQ-MY20
Phase 2: Incidence and severity of TEAEs with linvoseltamab
Phase 2: Incidence and severity of AESIs with linvoseltamab

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Eastern Cooperative Oncology Group (ECOG) performance status 1 Confirmed diagnosis of active Multiple Myeloma (MM) by International Myeloma Working Group (IMWG) diagnostic criteria Patients must have myeloma that is response-evaluable according to the 2016 IMWG response criteria as defined in the protocol. Phase 1, Part 1 (Dose Escalation): Patients with MM who have exhausted all therapeutic options that are expected to provide meaningful clinical benefit, either through disease relapse, treatment refractory disease or intolerance of the therapy and including either: a. Progression on or after at least 3 lines of therapy, or intolerance of therapy, including a PI, an IMiD, and an anti-CD38 antibody, OR b. Progression on or after an anti-CD38 antibody and have disease that is "double refractory" to a proteasome inhibitor and an IMiD, or intolerance of therapy. The anti-CD38 antibody may have been administered alone or in combination with another agent such as a proteasome inhibitor (PI). Refractory disease is defined as lack of response or relapse within 60 days of last treatment. Phase 1, Part 2 (SC Administration): Patients with MM whose disease meets the following criteria: a. Progression on or after at least 3 prior lines of therapy including a(n) PI, IMiD, and anti-CD38 antibody, OR b. Patients must be triple-refractory, defined as being refractory to prior treatment with at least 1 anti-CD38 antibody, a PI, and an IMiD. Phase 2 (Cohorts 1 and 2): Patients with MM whose disease meets the following criteria: a. Progression on or after at least 3 prior lines of therapy including a(n) PI, IMiD, and anti-CD38 antibody, OR b. Patients must be triple- refractory, defined as being refractory* to prior treatment with at least 1 PI, 1 IMiD, and an anti-CD38 antibody. *Refractory disease is defined as progression during treatment or within 60 days after completion of therapy, or <25% response to therapy. Phase 2 (Cohort 3): Patients with MM whose disease meets the following criteria: Progression on or after at least 3 prior lines of therapy including a(n) PI, IMiD, and anti-CD38 antibody, OR Patients must be triple- refractory, defined as being refractory* to prior treatment with at least 1 PI, 1 IMiD, and an anti-CD38 antibody. * Refractory disease is defined as progression during treatment or within 60 days after completion of therapy, or <25% response to therapy. AND, if patients have relapsed after a BCMA-directed CAR-T cellular therapy then: Treatment with a CAR-T must have been associated with a response of PR or better, and If CAR-T cellular therapy was the most recent prior therapy, excluding corticosteroids, then treatment must have been a minimum of 60 days prior to treatment with linvoseltamab Other protocol defined inclusion criteria apply

Exclusion criteria

Diagnosis of plasma cell leukemia, primary systemic light-chain amyloidosis, (excluding myeloma-associated amyloidosis), Waldenström macroglobulinemia (lymphoplasmacytic lymphoma), or POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes) Patients with known MM brain lesions or meningeal involvement Cardiac ejection fraction <40% by echocardiogram or multi-gated acquisition scan (MUGA) Prior treatment with BCMA-directed immunotherapies, including BCMA bispecific antibodies and BiTEs. Note: BCMA antibody-drug conjugates are not excludedand BCMA-directed CAR-T treatment is not excluded in Phase 2 Cohort 3. History of allogeneic stem cell transplantation at any time, or autologous stem cell transplantation within 12 weeks of the start of study treatment Other protocol defined exclusion criteria apply

Calendar

(Last Update: 22/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
18/03/2022	03/06/2022	28/06/2022	Not aported	Not aported

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

Regeneron Pharmaceuticals Inc. United States

777 Old Saw Mill River Road

Contact Person

Medical Affairs

+353818882469

medical.information_EU@regeneron.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 (30/09/2022)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Active (22/07/2022)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA)

Salamanca

SALAMANCA

Hematology

Closed (30/09/2022)

HOSPITAL CLINICO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Active (18/07/2022)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Hematology

Closed (30/09/2022)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

Hematology

Closed (30/09/2022)

HOSPITAL UNIVERSITARIO DE CABUEÑES

Gijón

ASTURIAS

Active (19/09/2022)

HOSPITAL UNIVERSITARIO DE LA PRINCESA

Madrid

MADRID

Active (03/06/2022)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Hematology

Active (23/06/2022)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Hematology

Medication

Linvoseltamab
SOLUTION FOR INJECTION
SOLUTION FOR INJECTION

-

Active Principles: N/A

Experimental

Dermodrin 30 mg/2 ml soluie injectabil
SOLUTION FOR INJECTION
IV INFUSION

ATC code: R06AA02 - DIFENHIDRAMINA
Active Principles: N/A

Experimental

Dexamethasone phosphate 4 mg/ml solution for injection/infusion
SOLUTION FOR INJECTION/INFUSION
IV INFUSION

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

Experimental

Paracetamol 500 mg Film-Coated Tablets
FILM-COATED TABLET
ORAL

ATC code: N02BE01 - PARACETAMOL
Active Principles: N/A

Experimental

Diphenhydramine Hydrochloride 25 mg Tablets
TABLET
ORAL

ATC code: R06AA02 - DIFENHIDRAMINA
Active Principles: N/A

Experimental

Linvoseltamab
SOLUTION FOR INFUSION
SOLUTION FOR INFUSION

-

Active Principles: N/A

Experimental

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

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

Experimental

Dexamethasone 4 mg tablets
TABLET
ORAL

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

Experimental

No results