A proof-of-concept study to learn whether linvoseltamab can eliminate abnormal plasma cells that may lead to multiple myeloma in adult patients with High-Risk Monoclonal Gammopathy of Undetermined Significance or Non-High-Risk Smoldering 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 II	30
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, dosis	NO

Información

Identificador
2023-505242-25-00 (CTIS)

Cod. Protocolo
R5458-ONC-2257

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

Enfermedad investigada
High-Risk Monoclonal Gammopathy of Undetermined Significance; Non-High-Risk Smoldering Multiple Myeloma

Título Científico
PHASE 2 DOSE-RANGING AND INTERCEPTION STUDY OF LINVOSELTAMAB IN PATIENTS WITH HIGH-RISK MONOCLONAL GAMMOPATHY OF UNDETERMINED SIGNIFICANCE OR NON-HIGH-RISK SMOLDERING MULTIPLE MYELOMA

Justificación

No aportado

Objetivo Principal

Safety Run-In (Part 1): To evaluate the safety and tolerability of linvoseltamab in ascending dose-level cohorts and select the highest dose level for investigation in the expansion part. Expansion (Part 2): To evaluate the ability of linvoseltamab to induce complete responses (CR) by dosing regimen.

Variables de Evaluación Primaria

Part 1: Frequency of adverse events of special interest (AESI) during the safety observation period
Part 1: Frequency of treatment-emergent adverse events (TEAEs) during the safety observation period
Part 1: Severity of TEAEs during the safety observation period
Part 2: Achievement of complete response (CR) as determined by the investigator

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To characterize the safety of linvoseltamab
To evaluate the proportion of participants that achieve minimal residual disease (MRD) negativity
To evaluate the proportion of participants with sustained MRD negativity
To evaluate the overall response rate (ORR)
To evaluate the duration of response (DOR)
To evaluate biochemical progression-free survival (PFS)
To characterize the pharmacokinetic (PK) properties of linvoseltamab
To assess the immunogenicity of linvoseltamab

Variables de Evaluación Secundaria

Frequency of TEAEs
Severity of TEAEs
Frequency of serious adverse events (SAEs)
Severity of SAEs
Frequency of laboratory abnormalities
Severity of laboratory abnormalities
Minimal residual disease (MRD) negativity among participants that achieve a response of CR
Sustained MRD negativity on an annual basis
Overall response of partial response (PR) or better as determined by the investigator
Duration of response (DOR) as determined by the investigator

Biochemical progression-free survival (PFS) as determined by the investigator
Concentration of linvoseltamab in serum over time
Incidence of anti-drug antibodies (ADAs) to linvoseltamab over the study duration
Magnitude of ADAs to linvoseltamab over the study duration

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

HR-MGUS or NHR-SMM as defined in the protocol
Eastern Cooperative Oncology Group (ECOG) performance status 1
Adequate hematologic and hepatic function, as described in the protocol
Estimated glomerular filtration rate (GFR) 30 mL/min/1.73 m2 by the modification of diet in renal disease (MDRD) equation.
NOTE: Other protocol defined inclusion criteria apply

Criterios de Exclusión

High-risk SMM according to risk stratification models as defined in the protocol.
Evidence of any of myeloma-defining events, as described in the protocol
Diagnosis of systemic light-chain amyloidosis, Waldenström macroglobulinemia (lymphoplasmacytic lymphoma), solitary plasmacytoma, or symptomatic MM
Clinically significant cardiac or vascular disease within 3 months of study enrollment, as described in the protocol
Any infection requiring hospitalization or treatment with IV anti-infectives within 28 days of the first dose of linvoseltamab
Uncontrolled human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) infection; or other uncontrolled infection or unexplained signs of infection.
NOTE: Other protocol defined exclusion criteria apply

Calendario

(Última actualización: 12/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
20/05/2024	05/11/2024	05/11/2024	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 Parc Tauli

Plaça de la Torre de lAigua, s/n 08208 Sabadell

ceic@tauli.cat

937458454-937458451

Centros

Activo (22/11/2024)

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Hematology

Activo (07/11/2024)

Hospital General Universitario Morales Meseguer

Murcia

MURCIA

Hematology

Activo (07/02/2025)

Hospital Universitari Mútua Terrassa

Terrassa

BARCELONA

Hematology

Activo (18/10/2024)

Hospital Universitario De Cabuenes

Gijon

ASTURIAS

Hematology

Activo (28/03/2025)

Hospital Universitario De La Princesa

Madrid

MADRID

Hematology

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

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Activo (10/10/2024)

Hospital Universitario Virgen De Las Nieves

Granada

GRANADA

Hematology

Activo (05/06/2025)

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Activo (11/12/2024)

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Medicamentos

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

Código ATC: L04AC07 - TOCILIZUMAB
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

Dexamethasone 4 mg tablets
TABLET
ORAL

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

Experimental

Diphenhydramine Hydrochloride 25 mg Tablets
TABLET
ORAL

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

Experimental

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

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

Experimental

Linvoseltamab
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

-
Principios Activos: N/A

Experimental

Sin resultados

A proof-of-concept study to learn whether linvoseltamab can eliminate abnormal plasma cells that may lead to multiple myeloma in adult patients with High-Risk Monoclonal Gammopathy of Undetermined Significance or Non-High-Risk Smoldering Multiple Myeloma

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	30
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, dose	NO

Information

Identifier
2023-505242-25-00 (CTIS)

Protocol Code
R5458-ONC-2257

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

Investigated Disease
High-Risk Monoclonal Gammopathy of Undetermined Significance; Non-High-Risk Smoldering Multiple Myeloma

Scientific Title
PHASE 2 DOSE-RANGING AND INTERCEPTION STUDY OF LINVOSELTAMAB IN PATIENTS WITH HIGH-RISK MONOCLONAL GAMMOPATHY OF UNDETERMINED SIGNIFICANCE OR NON-HIGH-RISK SMOLDERING MULTIPLE MYELOMA

Rationale

Not provided

Main Objective

Safety Run-In (Part 1): To evaluate the safety and tolerability of linvoseltamab in ascending dose-level cohorts and select the highest dose level for investigation in the expansion part. Expansion (Part 2): To evaluate the ability of linvoseltamab to induce complete responses (CR) by dosing regimen.

Primary Endpoints

Part 1: Frequency of adverse events of special interest (AESI) during the safety observation period
Part 1: Frequency of treatment-emergent adverse events (TEAEs) during the safety observation period
Part 1: Severity of TEAEs during the safety observation period
Part 2: Achievement of complete response (CR) as determined by the investigator

Temporary moments of secondary assessment

Not provided

Secondary Objective

To characterize the safety of linvoseltamab
To evaluate the proportion of participants that achieve minimal residual disease (MRD) negativity
To evaluate the proportion of participants with sustained MRD negativity
To evaluate the overall response rate (ORR)
To evaluate the duration of response (DOR)
To evaluate biochemical progression-free survival (PFS)
To characterize the pharmacokinetic (PK) properties of linvoseltamab
To assess the immunogenicity of linvoseltamab

Secondary Endpoints

Frequency of TEAEs
Severity of TEAEs
Frequency of serious adverse events (SAEs)
Severity of SAEs
Frequency of laboratory abnormalities
Severity of laboratory abnormalities
Minimal residual disease (MRD) negativity among participants that achieve a response of CR
Sustained MRD negativity on an annual basis
Overall response of partial response (PR) or better as determined by the investigator
Duration of response (DOR) as determined by the investigator

Biochemical progression-free survival (PFS) as determined by the investigator
Concentration of linvoseltamab in serum over time
Incidence of anti-drug antibodies (ADAs) to linvoseltamab over the study duration
Magnitude of ADAs to linvoseltamab over the study duration

Temporary moments of secondary assessment

Not provided

Inclusion criteria

HR-MGUS or NHR-SMM as defined in the protocol
Eastern Cooperative Oncology Group (ECOG) performance status 1
Adequate hematologic and hepatic function, as described in the protocol
Estimated glomerular filtration rate (GFR) 30 mL/min/1.73 m2 by the modification of diet in renal disease (MDRD) equation.
NOTE: Other protocol defined inclusion criteria apply

Exclusion criteria

High-risk SMM according to risk stratification models as defined in the protocol.
Evidence of any of myeloma-defining events, as described in the protocol
Diagnosis of systemic light-chain amyloidosis, Waldenström macroglobulinemia (lymphoplasmacytic lymphoma), solitary plasmacytoma, or symptomatic MM
Clinically significant cardiac or vascular disease within 3 months of study enrollment, as described in the protocol
Any infection requiring hospitalization or treatment with IV anti-infectives within 28 days of the first dose of linvoseltamab
Uncontrolled human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) infection; or other uncontrolled infection or unexplained signs of infection.
NOTE: Other protocol defined exclusion criteria apply

Calendar

(Last Update: 12/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
20/05/2024	05/11/2024	05/11/2024	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 Parc Tauli

Plaça de la Torre de lAigua, s/n 08208 Sabadell

ceic@tauli.cat

937458454-937458451

Sites

Active (22/11/2024)

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Hematology

Active (07/11/2024)

Hospital General Universitario Morales Meseguer

Murcia

MURCIA

Hematology

Active (07/02/2025)

Hospital Universitari Mútua Terrassa

Terrassa

BARCELONA

Hematology

Active (18/10/2024)

Hospital Universitario De Cabuenes

Gijon

ASTURIAS

Hematology

Active (28/03/2025)

Hospital Universitario De La Princesa

Madrid

MADRID

Hematology

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

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Active (10/10/2024)

Hospital Universitario Virgen De Las Nieves

Granada

GRANADA

Hematology

Active (05/06/2025)

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Active (11/12/2024)

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Medication

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

ATC code: L04AC07 - TOCILIZUMAB
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

Dexamethasone 4 mg tablets
TABLET
ORAL

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

Experimental

Diphenhydramine Hydrochloride 25 mg Tablets
TABLET
ORAL

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

Experimental

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

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

Experimental

Linvoseltamab
SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

-
Active Principles: N/A

Experimental

No results