# 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

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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

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MADRID

Hematology

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

**Hospital Universitario Puerta De Hierro De Majadahonda**

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# Medication

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IV INFUSION

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Active Principles: N/A

Experimental

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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