Study to evaluate the effects of CLR 131 in patients with B-Cell malignancies (CLOVER-1) and expansion study to evaluate the effects of CLR 131 specifically in patients with Waldenstrom Macroglobulinemia (CLOVER-WaM)

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	65
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	seguridad, eficacia	NO

Información

Identificador
2023-508671-37-00 (CTIS)

Cod. Protocolo
DCL-16-001

Transicionado 2020-005297-10

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

Enfermedad investigada
Waldenstrom Macroglobulinemia

Título Científico
An Open-Label, Multicenter, Phase 2 Study of CLR 131 in Patients with Relapsed or Refractory (R/R) Select B-Cell Malignancies (CLOVER-1) and Expansion Cohort in Patients with Waldenstrom Macroglobulinemia (CLOVER-WaM)

Justificación

No aportado

Objetivo Principal

The primary objective of the study is to determine the major response rate (MRR) of CLR 131 in patients with WM who have received at least two prior lines of therapy.

Variables de Evaluación Primaria

The primary endpoint is the MRR, which is defined as the proportion of patients following the infusion of CLR 131 with complete response (CR), very good partial response (VGPR), or partial response (PR) determined from criteria modified from the VIth Waldenstroms Macroglobulinemia Criteria for Response Assessment up to 12 months post first CLR 131 infusion in WM patients who have received at least two prior lines of therapy.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

1. To determine the overall response rate (ORR), treatment free survival (TFS), duration of response (DOR), and clinical benefit rate (CBR) in the population under study
2. To further describe the safety and tolerability (AE) profile of CLR 131 in the population under study, and in sub-populations

Variables de Evaluación Secundaria

1. Overall response rate (ORR), defined as the proportion of patients with a MR, PR, VGPR, or CR determined from criteria modified from the VIth Waldenstroms Macroglobulinemia Criteria for Response Assessment.
2. Treatment free survival (TFS), defined as the time from last CLR 131 dose to time to initiation of subsequent therapy or death.
3. Duration of response (DOR) is defined as the time from the first documentation of response (including CR, VGPR, PR) to PD or death. For DOR, patients who are alive and progression free during this study will have their event time censored on the last disease assessment.
4. Clinical benefit rate (CBR) is defined as the proportion of patients with CR, VGPR, PR, MR, and SD determined from criteria modified from the VIth Waldenstroms Macroglobulinemia Criteria for Response Assessment.
5. Safety. Adverse events (AEs), serious AE (SAEs), AEs with Grade 3, laboratory results, vital signs, electrocardiogram (ECG), and Eastern Cooperative Oncology Group (ECOG) performance status (PS).

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Histologically or cytologically confirmed WM. Patients with a diagnosis of LPL may be enrolled with prior Sponsor approval.
2. Patient has an Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 to 2.
3. Patient is 18 years of age or older.
4. Life expectancy of at least 6 months.
5. Received at least two prior lines of therapy for WM.

Criterios de Exclusión

1. Ongoing Grade 2 or greater toxicities due to previous therapies, excluding alopecia.
10. Pregnancy or breast-feeding.
2. Prior external-beam RT resulting in greater than 20% of total bone marrow receiving greater than 20 Gy.
3. Prior total body or hemi-body irradiation. Patients who have received prior low-dose total body or hemi-body irradiation may be allowed on a case-by-case basis after discussion with Sponsor (considerations may include factors such as time since irradiation, total lifetime accumulated dose, etc.).
4. Patients with second malignancies in addition to WM, if the second malignancy has required systemic therapy in the last 2 years. Exceptions to this criterion include secondary malignancies in remission, successfully treated skin malignancies, skin malignancies only requiring topic treatment or surgical excision, or other cancer that do not require therapy.
5. Anti-cancer therapy within two weeks of initial CLR 131 infusion.
6. Major surgery within 6 weeks of enrollment.
7. History of hypersensitivity to thyroid protection medication (e.g., potassium iodide, Lugols solution, etc.)
8. Known history of human immunodeficiency virus, active or chronic hepatitis C, or hepatitis B infection.
9. Presence of active infection within 72 hours prior to dosing; patients with ongoing use of prophylactic antibiotics, antifungals, or antivirals are eligible as long as there is no evidence of active infection and the antibiotics, antifungals, or antivirals are not included on the list of prohibited medications.

Calendario

(Última actualización: 26/03/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
28/04/2022	10/06/2022	11/08/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
12/01/2024	No aportado	No aportado	29/02/2024	No aportado

Promotor

Cellectar Biosciences Inc. United States

100 Campus Drive

Contact Person

Clinical Trial Team

16083278125

clinical@cellectar.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

C/ Doctor Esquerdo, 46 28007 Madrid

ceim.hgugm@salud.madrid.org

915867007

Centros

Activo (10/06/2022)

CLINICA UNIVERSIDAD DE NAVARRA

Madrid

MADRID

Hematología

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

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Activo (14/10/2022)

Complejo Asistencial Universitario De Salamanca

Salamanca

SALAMANCA

Hematología

Activo (29/07/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Hematología

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (21/10/2022)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Hematología

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

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

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

Hospital Unviersitario Miguel Servet

Zaragoza

ZARAGOZA

Hematology

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

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medicamentos

-

-

ORAL

Código ATC: V03AB21 - IODURO DE POTASIO

Principios Activos: N/A

Experimental

PRD8597279

STERILE SOLUTION

INTRAVENIOUS INFUSION

-

Principios Activos: N/A

Huérfano

Experimental

Sin resultados

Study to evaluate the effects of CLR 131 in patients with B-Cell malignancies (CLOVER-1) and expansion study to evaluate the effects of CLR 131 specifically in patients with Waldenstrom Macroglobulinemia (CLOVER-WaM)

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	65
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	safety, effectiveness	NO

Information

Identifier
2023-508671-37-00 (CTIS)

Protocol Code
DCL-16-001

Transitioned 2020-005297-10

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

Investigated Disease
Waldenstrom Macroglobulinemia

Scientific Title
An Open-Label, Multicenter, Phase 2 Study of CLR 131 in Patients with Relapsed or Refractory (R/R) Select B-Cell Malignancies (CLOVER-1) and Expansion Cohort in Patients with Waldenstrom Macroglobulinemia (CLOVER-WaM)

Rationale

Not provided

Main Objective

The primary objective of the study is to determine the major response rate (MRR) of CLR 131 in patients with WM who have received at least two prior lines of therapy.

Primary Endpoints

The primary endpoint is the MRR, which is defined as the proportion of patients following the infusion of CLR 131 with complete response (CR), very good partial response (VGPR), or partial response (PR) determined from criteria modified from the VIth Waldenstroms Macroglobulinemia Criteria for Response Assessment up to 12 months post first CLR 131 infusion in WM patients who have received at least two prior lines of therapy.

Temporary moments of secondary assessment

Not provided

Secondary Objective

1. To determine the overall response rate (ORR), treatment free survival (TFS), duration of response (DOR), and clinical benefit rate (CBR) in the population under study
2. To further describe the safety and tolerability (AE) profile of CLR 131 in the population under study, and in sub-populations

Secondary Endpoints

1. Overall response rate (ORR), defined as the proportion of patients with a MR, PR, VGPR, or CR determined from criteria modified from the VIth Waldenstroms Macroglobulinemia Criteria for Response Assessment.
2. Treatment free survival (TFS), defined as the time from last CLR 131 dose to time to initiation of subsequent therapy or death.
3. Duration of response (DOR) is defined as the time from the first documentation of response (including CR, VGPR, PR) to PD or death. For DOR, patients who are alive and progression free during this study will have their event time censored on the last disease assessment.
4. Clinical benefit rate (CBR) is defined as the proportion of patients with CR, VGPR, PR, MR, and SD determined from criteria modified from the VIth Waldenstroms Macroglobulinemia Criteria for Response Assessment.
5. Safety. Adverse events (AEs), serious AE (SAEs), AEs with Grade 3, laboratory results, vital signs, electrocardiogram (ECG), and Eastern Cooperative Oncology Group (ECOG) performance status (PS).

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Histologically or cytologically confirmed WM. Patients with a diagnosis of LPL may be enrolled with prior Sponsor approval.
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1. Ongoing Grade 2 or greater toxicities due to previous therapies, excluding alopecia.
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Calendar

(Last Update: 26/03/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
28/04/2022	10/06/2022	11/08/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
12/01/2024	Not aported	Not aported	29/02/2024	Not aported

Sponsor

Cellectar Biosciences Inc. United States

100 Campus Drive

Contact Person

Clinical Trial Team

16083278125

clinical@cellectar.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

C/ Doctor Esquerdo, 46 28007 Madrid

ceim.hgugm@salud.madrid.org

915867007

Sites

Active (10/06/2022)

CLINICA UNIVERSIDAD DE NAVARRA

Madrid

MADRID

Hematología

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

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Active (14/10/2022)

Complejo Asistencial Universitario De Salamanca

Salamanca

SALAMANCA

Hematología

Active (29/07/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Hematología

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Active (21/10/2022)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Hematología

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

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

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

Hospital Unviersitario Miguel Servet

Zaragoza

ZARAGOZA

Hematology

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

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medication

-

-

ORAL

ATC code: V03AB21 - IODURO DE POTASIO

Active Principles: N/A

Experimental

PRD8597279

STERILE SOLUTION

INTRAVENIOUS INFUSION

-

Active Principles: N/A

Orphan

Experimental

No results